## **PRIOR AUTHORIZATION PROTOCOLS**

# How do I request an exception to the Ultimate Health Plans' CSNP Formulary?

You can ask Ultimate Health Plans to make an exception to our coverage rules. There are several types of exceptions that you can ask us to make.

- You can ask us to cover your drug even if it is not on our formulary. If approved, this drug will be covered at a pre-determined cost-sharing level, and you would not be able to ask us to provide the drug at a lower cost-sharing level.
- You can ask us to cover a formulary drug at a lower cost-sharing level if this drug is not on the specialty tier. If approved this would lower the amount you must pay for your drug.
- You can ask us to waive coverage restrictions or limits on your drug. For example, for certain drugs, Ultimate Health Plans limits the amount of the drug that we will cover. If your drug has a quantity limit, you can ask us to waive the limit and cover a greater amount.

Generally, Ultimate Health Plans will only approve your request for an exception if the alternative drugs included on the plan's formulary, the lower cost-sharing drug or additional utilization restrictions would not be as effective in treating your condition and/or would cause you to have adverse medical effects.

You should contact us to ask us for an initial coverage decision for a formulary, or utilization restriction exception. When you request a formulary or utilization restriction exception you should submit a statement from your prescriber or physician supporting your request. Generally, we must make our decision within 72 hours of getting your prescriber's supporting statement. You can request an expedited (fast) exception if you or your doctor believe that your health could be seriously harmed by waiting up to 72 hours for a decision. If your request to expedite is granted, we must give you a decision no later than 24 hours after we get a supporting statement from your doctor or other prescriber.

Your prescriber must submit a statement supporting your coverage determination or exception request. In order to help us make a decision more quickly, you should include supporting medical information from your prescriber when you submit your exception request.

#### What if I have additional questions?

You can call us at: 1-800-311-7517 (seven days a week, 24 hours a day) if you have any additional questions. If you have a hearing or speech impairment, please call us at TTY 1-866-706-4757.

### **ACTIMMUNE (S)**

#### **Products Affected**

• Actimmune

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

### ADCIRCA (S)

#### **Products Affected**

• Tadalafil TABS 20MG

• Alyq

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH<br>is symptomatic. One of the following: A) Diagnosis of PAH was<br>confirmed by right heart catheterization or B) Patient is currently on any<br>therapy for the diagnosis of PAH. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.  |
| Coverage<br>Duration               | PAH: Initial: 6 months. Reauth: 12 months.   |
| Other Criteria                     | PAH (Reauth): Documentation of 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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH AND<br>PAH is symptomatic AND One of the following: A) Diagnosis of PAH<br>was confirmed by right heart catheterization or B) Patient is currently on<br>any therapy for the diagnosis of PAH. Chronic thromboembolic<br>pulmonary hypertension (CTEPH) (Initial): One of the following: A) Both<br>of the following: 1) Diagnosis of inoperable or persistent/recurrent<br>CTEPH and 2) CTEPH is symptomatic OR B) Patient is currently on any<br>therapy for the diagnosis of CTEPH. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | PAH, CTEPH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.   |
| Coverage<br>Duration               | PAH, CTEPH: Initial: 6 months. Reauth: 12 months.  |
| Other Criteria                     | PAH, CTEPH (Reauth): Documentation of 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous<br>sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that<br>requires therapeutic intervention. Renal cell carcinoma: Diagnosis of<br>advanced renal cell carcinoma AND trial and failure, contraindication, or<br>intolerance to SUTENT (sunitinib) or NEXAVAR (sorafenib).<br>Neuroendocrine tumors of pancreatic origin (pNET): Diagnosis of<br>progressive pNET that are unresectable, locally advanced, or metastatic.<br>Renal angiomyolipoma: Diagnosis of renal angiomyolipoma and TSC.<br>Breast Cancer: Diagnosis of advanced hormone receptor-positive, HER2-<br>negative breast cancer AND trial and failure, contraindication, or<br>intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole).<br>Neuroendocrine tumors of gastrointestinal (GI) or lung origin: Diagnosis<br>of progressive, well-differentiated, non-functional NET of GI or lung<br>origin AND patient has unresectable, locally advanced or metastatic<br>disease. |
| Age Restrictions                   | SEGA associated with TSC: Patient is 1 year of age or older.  |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>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-<br>associated partial-onset seizures: Patient is 2 years of age or older.   |
| Prescriber<br>Restrictions         | TSC-associated partial-onset seizures: Prescribed by or in consultation with a neurologist.   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

### ALECENSA (S)

#### **Products Affected**

• Alecensa

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

### **ALPHA-1 PROTEINASE INHIBITOR, NON-PREFERRED (S)**

#### **Products Affected**

• Aralast Np INJ 1000MG

- Prolastin-c INJ 1000MG
- Zemaira

• Glassia

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Alpha-1 antitrypsin (AAT) deficiency (initial): Diagnosis of congenital<br>AAT deficiency. Diagnosis of emphysema. Continued conventional<br>treatment for emphysema (e.g., bronchodilators). One of the following: 1)<br>PiZZ, PiZ(null), or Pi(null)(null) protein phenotypes (homozygous) OR 2)<br>other rare AAT disease genotypes associated with pre-treatment serum<br>AAT level less than 11 $\mu$ M/L [e.g., Pi(Malton, Malton), Pi(SZ)]. One of<br>the following: Circulating pre-treatment serum AAT level less than 11<br>$\mu$ M/L (which corresponds to less than 80 mg/dL if measured by radial<br>immunodiffusion or less than 57 mg/dL if measured by nephelometry)<br>OR the patient has a concomitant diagnosis of necrotizing panniculitis.<br>Trial and failure, or intolerance to Prolastin. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | AAT deficiency (initial, reauth): 12 months  |
| Other Criteria                     | AAT deficiency (reauth): Documentation of 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Multiple Sclerosis (MS) (initial): Diagnosis of MS. Physician<br>confirmation that patient has difficulty walking (eg, timed 25 foot walk<br>test). One of the following: expanded disability status scale (EDSS) score<br>less than or equal to 7, or not restricted to using a wheelchair (if EDSS is<br>not measured). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | MS (initial): Prescribed by or in consultation with a neurologist.  |
| Coverage<br>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).  |

### APOKYN (S)

#### **Products Affected**

• Apomorphine Hydrochloride INJ

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

#### **Products Affected**

 Aranesp Albumin Free INJ 100MCG/0.5ML, 100MCG/ML, 10MCG/0.4ML, 150MCG/0.3ML, 200MCG/0.4ML, 200MCG/ML, 25MCG/0.42ML, 25MCG/ML, 300MCG/0.6ML, 40MCG/0.4ML, 40MCG/ML, 500MCG/ML, 60MCG/0.3ML, 60MCG/ML

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>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. CKD (init, reauth), Chemo (init), MDS (init): Verify iron evaluation for adequate iron stores. 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<br>Restrictions         | N/A   |
| Coverage<br>Duration               | CKD (Init): 6 mo. CKD (reauth): 12 mo. Chemo(init, reauth): 3 mo.<br>MDS: (init) 3 mo,(reauth) 12 mo.   |

| Other Criteria | Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 mo is 33% or less (Hgb 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. Documentation of a 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. Documentation of a positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. 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. Documentation of 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%. |
|----------------|---|
|                |   |

### ARCALYST (S)

#### **Products Affected**

• Arcalyst

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Cryopyrin-Associated Periodic Syndromes (CAPS) (Initial): Diagnosis of<br>CAPS, including Familial Cold Auto-inflammatory Syndrome (FCAS)<br>and/or Muckle-Wells Syndrome (MWS). The medication will not be used<br>in combination with another biologic. Deficiency of Interleukin-1<br>Receptor Antagonist (DIRA): Diagnosis of DIRA. Patient weighs at least<br>10 kg. Patient is currently in remission (e.g., no fever, skin rash, and bone<br>pain/no radiological evidence of active bone lesions/C-reactive protein<br>[CRP] less than 5 mg/L). Recurrent Pericarditis (Initial): Diagnosis of<br>recurrent pericarditis as evidenced by at least 2 episodes that occur a<br>minimum of 4 to 6 weeks apart. Trial and failure, contraindication, or<br>intolerance (TF/C/I) to at least one of the following: nonsteroidal anti-<br>inflammatory drugs (e.g., ibuprofen, naproxen), colchicine, or<br>corticosteroids (e.g., prednisone). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | CAPS (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist, or specialist with expertise in the management of CAPS. Recurrent Pericarditis (initial): Prescribed by or in consultation with a cardiologist.   |
| Coverage<br>Duration               | CAPS, Recurrent Pericarditis (initial, reauth): 12 months. DIRA: 12 months.   |

| Other Criteria | CAPS (Reauth): Patient has experienced disease stability or improvement<br>in clinical symptoms while on therapy as evidence by one of the |
|----------------|--|
|                | following: A) improvement in rash, fever, joint pain, headache,  |
|                | conjunctivitis, B) decreased number of disease flare days, C)  |
|                | normalization of inflammatory markers (CRP, ESR, SAA), D)  |
|                | corticosteroid dose reduction, OR E) improvement in MD global score or   |
|                | active joint count. Recurrent Pericarditis (Reauth): Documentation of  |
|                | positive clinical response to therapy.   |

### AUBAGIO (S)

#### **Products Affected**

• Aubagio

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

Teriflunomide

•

### AUSTEDO (S)

#### **Products Affected**

• Austedo

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Chorea associated with Huntington's disease (initial): Diagnosis of Chorea<br>associated with Huntington's disease. Tardive dyskinesia (initial):<br>Diagnosis of moderate to severe tardive dyskinesia. One of the following:<br>1) Patient has persistent symptoms of tardive dyskinesia despite a trial of<br>dose reduction, tapering, or discontinuation of the offending medication<br>or 2) Patient is not a candidate for a trial of dose reduction, tapering, or<br>discontinuation of the offending medication. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | Huntington's disease chorea (initial): Prescribed by a neurologist. Tardive dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist.  |
| Coverage<br>Duration               | Initial: 3 months. Reauth: 12 months  |
| Other Criteria                     | All indications (Reauth): Documentation of 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. Disease is one<br>of the following: unresectable or metastatic. Presence of platelet-derived<br>growth factor receptor alpha (PDGFRA) exon 18 mutation, including<br>PDGFRA D842V mutations. Advanced Systemic Mastocytosis (AdvSM):<br>Diagnosis of AdvSM. Patient has one of the following: a) aggressive<br>systemic mastocytosis (ASM), b) systemic mastocytosis with an<br>associated hematological neoplasm (SM-AHN), or c) mast cell leukemia<br>(MCL). Ayvakit 25 mg - Indolent Systemic Mastocytosis (ISM):<br>Diagnosis of ISM. Platelet count is greater than 50 x 10^9/L. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

### **BALVERSA** (S)

#### **Products Affected**

• Balversa

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Urothelial Carcinoma: Diagnosis of urothelial carcinoma (UC). One of<br>the following: Locally advanced or Metastatic AND Patient has fibroblast<br>growth factor receptor (FGFR) 3 or FGFR2 genetic alterations as detected<br>by an U.S. Food and Drug Administration (FDA)-approved test<br>(therascreen FGFR RGQ RT-PCR Kit) or a test performed at a facility<br>approved by Clinical Laboratory Improvement Amendments (CLIA). One<br>of the following: 1) Patient has progressed during or following at least<br>one line of prior platinum-containing chemotherapy (e.g., gemcitabine<br>with cisplatin or carboplatin, dose dense methotrexate vinblastine<br>doxorubicin cisplatin [DDMVAC] with growth factor support, etc.) OR 2)<br>Patient has progressed within 12 months of neoadjuvant or adjuvant<br>platinum-containing chemotherapy (e.g., [DDMVAC] with growth factor<br>support, gemcitabine with cisplatin, etc.). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Systemic lupus erythematosus (SLE) (init): Diagnosis of active SLE.<br>Autoantibody positive (ie, anti-nuclear antibody [ANA] titer greater than<br>or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL).<br>Currently receiving at least one standard of care treatment for active SLE<br>(eg, antimalarials [eg, Plaquenil (hydroxychloroquine)], corticosteroids<br>[eg, prednisone], or immunosuppressants [eg, methotrexate, Imuran<br>(azathioprine)]). Lupus Nephritis (init): Diagnosis of active lupus<br>nephritis. Currently receiving standard of care treatment for active lupus<br>nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or<br>cyclophosphamide). |
| Age Restrictions                   | N/A   |
| Prescriber<br>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<br>Duration               | SLE, Lupus Nephritis (init, reauth): 6 months   |
| Other Criteria                     | SLE, Lupus Nephritis (reauth): Documentation of 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Diagnosis of polycythemia vera as confirmed by all of the following: 1)<br>One of the following: a) Hemoglobin greater than 16.5 g/dL for men or<br>hemoglobin greater than 16.0 g/dL for women, b) Hematocrit greater than<br>49% for men or hematocrit greater than 48% for women, or c) Increased<br>red cell mass, AND 2) Bone marrow biopsy showing hypercellularity for<br>age with trilineage growth (panmyelosis) including prominent erythroid,<br>granulocytic and megakaryocytic proliferation with pleomorphic, mature<br>megakaryocytes, AND 3) One of the following: a) Presence of JAK2 or<br>JAK2 exon 12 mutation or b) Subnormal serum erythropoietin level. Both<br>of the following: 1) Trial and failure, contraindication or intolerance<br>(TF/C/I) to hydroxyurea, AND 2) TF/C/I to one interferon therapy (e.g.,<br>Intron A, Pegasys, etc). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Chronic myelogenous/myeloid leukemia (CML): Diagnosis of<br>Philadelphia chromosome-positive (Ph+) CML. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma.<br>Cancer is BRAF V600E or V600K mutant type (MT) as detected by a<br>U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF<br>Kit) or a test performed at a facility approved by Clinical Laboratory<br>Improvement Amendments (CLIA). Used in combination with Mektovi<br>(binimetinib). Colorectal Cancer: One of the following diagnoses: Colon<br>Cancer or Rectal Cancer. One of the following: 1) Unresectable or<br>advanced disease or 2) Metastatic disease. Patient has received prior<br>therapy. Cancer is BRAF V600E mutant type as detected by a U.S. Food<br>and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a<br>test performed at a facility approved by Clinical Laboratory Improvement<br>Amendments (CLIA). Used in combination with Erbitux (cetuximab). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy   |

### **BRIVIACT (S)**

#### **Products Affected**

• Briviact TABS

• Briviact SOLN

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

### **BRUKINSA (S)**

#### **Products Affected**

• Brukinsa

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Mantle Cell Lymphoma (MCL): Diagnosis of relapsed or refractory<br>MCL. Trial and failure, contraindication, or intolerance to at least ONE<br>combination treatment of rituximab and chemotherapy (e.g., BR, R-<br>CHOP, R-CVP, R-FCM). Waldenstrom's Macroglobulinemia<br>(WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL.<br>Marginal Zone Lymphoma (MZL): Diagnosis of MZL. Disease is<br>relapsed or refractory. Patient has received at least one prior anti-CD20-<br>based regimen for MZL (e.g., rituximab, obinutuzumab). Chronic<br>Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL):<br>Diagnosis of ONE of the following: CLL or SLL. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months.  |
| Other Criteria                     | Approve for continuation of prior therapy.  |

### CABOMETYX (S)

#### **Products Affected**

• Cabometyx

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Renal cell carcinoma (RCC): Diagnosis of RCC. Hepatocellular<br>Carcinoma (HCC): Diagnosis of HCC. One of the following: a) Trial and<br>failure, contraindication, or intolerance to Nexavar (sorafenib tosylate), or<br>b) Patient has metastatic disease, or c) Patient has extensive liver tumor<br>burden, or d) Patient is inoperable by performance status or comorbidity<br>(local disease or local disease with minimal extrahepatic disease only), or<br>e) Disease is unresectable. Differentiated Thyroid Cancer (DTC):<br>Diagnosis of DTC. Disease has progressed following prior VEGFR-<br>targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib]).<br>Disease or patient is refractory to radioactive iodine treatment or<br>ineligible. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Mantle Cell Lymphoma: Diagnosis of mantle cell lymphoma (MCL)<br>AND patient has received at least one prior therapy for MCL. Chronic<br>Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL):<br>Diagnosis of CLL or SLL. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Schizophrenia: Diagnosis of schizophrenia. Trial and failure,<br>contraindication, or intolerance to two of the following oral generic<br>formulary atypical antipsychotic agents: asenapine, aripiprazole,<br>olanzapine, paliperidone, quetiapine (IR or ER), risperidone, ziprasidone.<br>Bipolar disorder: Diagnosis of bipolar I or II disorder (bipolar<br>depression). Patient has depressive episodes associated with bipolar<br>disorder. Used as monotherapy or as adjunctive therapy with lithium or<br>valproate. Trial and failure, contraindication, or intolerance to quetiapine<br>(IR or ER) or olanzapine. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Thyroid Cancer: Diagnosis of medullary thyroid cancer (MTC). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | Approve for continuation of prior therapy.                   |

### **CARISOPRODOL (S)**

#### **Products Affected**

• Carisoprodol TABS 350MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | The drug is being prescribed for an FDA-approved indication. If the patient is 65 years of age or older, 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                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | N/A  |

### **CAYSTON (S)**

#### **Products Affected**

• Cayston

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Cystic fibrosis (CF) (Initial, Reauth): Diagnosis of CF AND Patient has<br>evidence of Pseudomonas aeruginosa in the lungs.   |
| Age Restrictions                   | CF (Initial): 7 years of age or older   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>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<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Gaucher disease: 12 months  |
| Other Criteria                     | N/A   |

### CHENODAL (S)

#### **Products Affected**

• Chenodal

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Initial: Diagnosis of radiolucent gallstones. Patient has a well-opacifying gallbladder visualized by oral cholecystography. Trial and failure, contraindication or intolerance to ursodiol. Patient is not a candidate for surgery. Stones are not calcified (radiopaque) or radiolucent bile pigment stones. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | Initial, Reauth: Prescribed by or in consultation with a gastroenterologist<br>or provider who has specialized expertise in the management of gallstones   |
| Coverage<br>Duration               | Initial, reauth: 12 months.  |
| Other Criteria                     | Reauth: Patient's disease status has been re-evaluated since the last<br>authorization to confirm the patient's condition warrants continued<br>treatment as evidenced by oral cholecystograms or ultrasonograms.  |

### CHOLBAM (S)

#### **Products Affected**

• Cholbam

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

### CIALIS (S)

#### **Products Affected**

#### • Tadalafil TABS 2.5MG, 5MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | Concurrent use of nitrates.  |
| Required<br>Medical<br>Information | Diagnosis of benign prostatic hyperplasia (BPH). Trial and failure,<br>contraindication, or intolerance to an alpha-blocker (e.g., doxazosin,<br>prazosin, tamsulosin) or a 5-alpha reductase inhibitor (e.g., dutasteride,<br>finasteride). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | N/A  |

### CICLOPIROX (S)

#### **Products Affected**

• Ciclopirox Nail Lacquer

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | All of the following: 1) Patient does not have lunula (matrix)<br>involvement, 2) one of the following: a) Diagnosis of onychomycosis of<br>the toenails, OR b) Diagnosis of onychomycosis of the fingernails, 3)<br>Diagnosis of onychomycosis has been confirmed by one of the following:<br>a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c)<br>histology, 4) If toenail onychomycosis, patient has mild to moderate<br>disease involving at least 1 target toenail, AND 5) Trial and failure (of a<br>minimum 12-week supply), contraindication, or intolerance to oral<br>terbinafine. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE.<br>Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or<br>dysfunction (Type I or II HAE) as documented by one of the following:<br>a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH<br>functional level below the lower limit of normal. For prophylaxis against<br>HAE attacks. Not used in combination with other approved treatments for<br>prophylaxis against HAE attacks. |
| Age Restrictions                   | HAE (prophylaxis): Patient is 6 years of age or older   |
| Prescriber<br>Restrictions         | HAE (prophylaxis): Prescribed by or in consultation with an immunologist or an allergist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | N/A   |

# **COMETRIQ (S)**

### **Products Affected**

• Cometriq

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

# CORLANOR (S)

### **Products Affected**

• Corlanor

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

| Other Criteria | CHF, DCM (reauth): Documentation of positive clinical response to therapy. |
|----------------|--|
|                | therapy.   |

# **CORTROPHIN (S)**

### **Products Affected**

• Cortrophin

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Infantile Spasms (IS) (West Syndrome) [off-label]: Diagnosis of IS (West<br>Syndrome). Multiple Sclerosis (MS): Diagnosis of acute exacerbation of<br>MS. One of the following: 1) Both of the following: a) Patient is new to<br>therapy with corticotropin AND b) Trial and failure, contraindication, or<br>intolerance (TF/C/I) to treatment with two high dose corticosteroid<br>treatments (e.g., prednisone, IV methylprednisolone) OR 2) All of the<br>following: a) Patient's MS exacerbations have been treated in the past<br>with corticotropin AND b) Patient has benefitted from treatment with<br>corticotropin for acute exacerbations of MS AND c) Medication is being<br>used to treat a new exacerbation of MS. Other FDA-Approved<br>Indications: Diagnosis of one of the following: 1) Rheumatic disorders:<br>As adjunctive therapy for short-term administration in: psoriatic arthritis,<br>rheumatoid arthritis, juvenile rheumatoid arthritis (selected cases may<br>require low-dose maintenance therapy), ankylosing spondylitis, or acute<br>gouty arthritis, OR 2) Collagen diseases: During an exacerbation or as<br>maintenance therapy in selected cases of: systemic lupus erythematosus or<br>systemic dermatomyositis (polymyositis), OR 3) Dermatologic diseases:<br>Severe erythema multiforme, Stevens-Johnson syndrome, or severe<br>psoriasis, OR 4) Allergic states: Serum sickness or atopic dermatitis, OR<br>5) Ophthalmic diseases: Severe acute and chronic allergic and<br>inflammatory processes involving the eye and its adnexa, such as one of<br>the following: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and<br>choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation,<br>or allergic conjunctivitis, OR 6) Respiratory diseases: Symptomatic<br>sarcoidosis, OR 7) Edematous state: To induce a diuresis or a remission of<br>proteinuria in the nephrotic syndrome without uremia of the idiopathic<br>type or that due to lupus erythematosus. TF/C/I to treatment with two<br>corticosteroids (e.g., prednisone, methylprednisolone). |
| Age Restrictions                   | IS: less than 2 years old   |

| Prescriber<br>Restrictions | IS, MS: neurologist. Rheumatic disorder, collagen disease:<br>rheumatologist. Dermatologic: dermatologist. Allergic state: allergist,<br>immunologist. Ophthalmic disease: optometrist, ophthalmologist.<br>Respiratory diseases: pulmonologist. Edematous state: nephrologist,<br>rheumatologist.   |
|----------------------------|--|
| Coverage<br>Duration       | IS: 4 weeks. MS: 3 weeks. Other FDA-Approved Indications: 3 months.  |
| Other Criteria             | IS: Dosing for IS (West Syndrome) is in accordance with the United<br>States Food and Drug Administration (FDA) approved labeling: not to<br>exceed 150U/m <sup>2</sup> daily. MS: Dosing for MS is in accordance with the<br>United States FDA approved labeling: not to exceed 120 units once daily.<br>Other FDA-Approved Indications: Dosing is in accordance with the<br>United States FDA approved labeling: not to exceed 80 units per day. |

# COSENTYX (S)

### **Products Affected**

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

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

| Coverage<br>Duration | All uses (initial): 6 months. All uses (reauth): 12 months   |
|----------------------|--|
| Other Criteria       | <ul> <li>PsA (Reauth): Documentation of 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):</li> <li>Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS, nr-axSpA (Reauth): Documentation of 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): Documentation of 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, fatigue, inflammation), of total active (swollen and tender) joint count. ERA (Reauth): Documentation of 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.</li> </ul> |

# **COTELLIC** (S)

### **Products Affected**

• Cotellic

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

# **CUPRIMINE (S)**

### **Products Affected**

• Penicillamine CAPS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Initial: One of the following: 1) Diagnosis of Wilson's disease (i.e.,<br>hepatolenticular degeneration), 2) Diagnosis of cystinuria AND trial and<br>failure, contraindication, or intolerance to Thiola (tiopronin), or 3)<br>Diagnosis of severe active rheumatoid arthritis AND patient has been<br>unresponsive to conventional therapy (e.g., traditional DMARDs [e.g.,<br>methotrexate, sulfasalazine], TNF inhibitor [e.g., Humira (adalimumab),<br>Enbrel (etanercept)], Non-TNF biologic [e.g., Rinvoq (upadacitinib),<br>Xeljanz (tofacitinib)]). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | Reauth: Documentation of a positive clinical response to therapy   |

### **Products Affected**

• Cyltezo

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

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

| Prescriber<br>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<br>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): Documentation of 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): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the BSA involvement from baseline, OR reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction of positive clinical response to therapy as evidenced by ione of the following: reduction of positive clinical response to therapy as evidenced by improvement from baseline. OR to therapy as evidenced by ione of the following: reduction of positive clinical response to therapy as evidenced by inprovement 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): Documentation of positive clinical response to therapy as evidenced by at least one of the fo |
|----------------|--|
|                | following: improvement in intestinal inflammation (eg, mucosal healing,  |

## **DALIRESP (S)**

#### **Products Affected**

• Daliresp

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Chronic Obstructive Pulmonary Disease (COPD) (initial): Diagnosis of Medical COPD. History of COPD exacerbations which required the use of Information 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 N/A Restrictions Coverage COPD (init, reauth): 12 months **Duration Other Criteria** COPD (reauth): Documentation of positive clinical response to therapy.

• Roflumilast

# **DARAPRIM (S)**

### **Products Affected**

• Pyrimethamine TABS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Toxoplasmosis: 1) Patient is using pyrimethamine for the treatment of toxoplasmic encephalitis, secondary prophylaxis of toxoplasmic encephalitis, or treatment of congenital toxoplasmosis OR 2) Patient is using pyrimethamine for the primary prophylaxis of toxoplasmic encephalitis, 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: Patient is using pyrimethamine for the treatment of acute malaria or chemoprophylaxis of malaria. Patient does not have megaloblastic anemia due to folate deficiency. The provider acknowledges that pyrimethamine is not recommended by the Centers for Disease Control and Prevention (CDC) for the treatment and/or prophylaxis of malaria. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an infectious disease specialist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Toxoplasmosis only: 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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Acute myeloid leukemia (AML): Diagnosis of newly-diagnosed acute<br>myeloid leukemia (AML) AND Used in combination with low-dose<br>cytarabine AND One of the following: 1) Patient is greater than or equal<br>to 75 years old, or 2) Patient has comorbidities that preclude the use of<br>intensive induction chemotherapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of<br>chronic iron overload due to blood transfusions (transfusional<br>hemosiderosis). Patient has a baseline ferritin level more than 1,000<br>mcg/L. Patient has required the transfusion of at least 100 mL/kg packed<br>red blood cells. Myelodysplastic Syndrome (MDS) (Initial): Diagnosis of<br>MDS. Patient has Low or Intermediate-1 disease or is a potential<br>transplant patient. Patient has received more than 20 red blood cell<br>transfusions. Chronic iron overload due to non-transfusion-dependent<br>thalassemia (NTDT) (Initial): Diagnosis of chronic iron overload due to<br>NTDT. Liver iron concentration (LIC) 5 milligrams of iron per gram of<br>liver dry weight (mg Fe/g dw) or higher. Serum ferritin level greater than<br>300 mcg/L. |
| Age Restrictions                   | Iron Overload Due to Blood Transfusions (initial): 2 years of age or older.<br>NTDT (initial): 10 years of age or older   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Iron Overload Due to Blood Transfusions, MDS (initial, reauth):12 mo.<br>NTDT (initial, reauth): 6mo.   |
| Other Criteria                     | Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient<br>experienced a reduction from baseline in serum ferritin level or LIC.<br>NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient<br>experienced a reduction from baseline in serum ferritin level or LIC.  |

# **DIACOMIT (S)**

### **Products Affected**

• Diacomit

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>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<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | Approve for continuation of prior therapy.   |

# **DOXEPIN TOPICAL (S)**

### **Products Affected**

• Doxepin Hydrochloride CREA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Diagnosis of moderate pruritus. Patient has atopic dermatitis or lichen<br>simplex chronicus. Trial and failure, contraindication, or intolerance to at<br>least one medium potency topical corticosteroid, or is not a candidate for<br>topical corticosteroids (e.g., treatment is on face, axilla, or groin). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 14 days  |
| Other Criteria                     | N/A  |

# **DUPIXENT (S)**

### **Products Affected**

• Dupixent

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Atopic dermatitis (AD) (init): Diagnosis (dx) of mod to severe AD. One<br>of the following: a) Involvement of at least 10% body surface area (BSA),<br>or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25.<br>Trial and failure of a minimum 30-day supply (14-day supply for topical<br>corticosteroids), contraindication (eg, safety concerns, not indicated for<br>patient's age/weight), or intolerance to at least one of the following: a)<br>Medium or higher potency topical corticosteroid, b) Pimecrolimus cream,<br>c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. Eosinophilic<br>Asthma (EA) (init): Dx of mod to severe asthma. Asthma is an<br>eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral<br>blood eosinophil level greater than or equal to 150 cells/microliter. One of<br>the following: 1) Patient has had two or more asthma exacerbations<br>requiring systemic corticosteroids (eg, prednisone) within the past 12 mo,<br>2) Prior asthma-related hospitalization within the past 12 mo.<br>Corticosteroid Dependent Asthma (CDA) (init): Dx of mod to severe<br>asthma. Patient is currently dependent on oral corticosteroids for the<br>treatment of asthma. EA, CDA (init): Patient is currently being treated<br>with one of the following unless there is a contraindication or intolerance<br>to these medications: a) Both of the following: i) High-dose inhaled<br>corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate<br>equivalent/day] and ii) additional asthma controller medication [e.g.,<br>leukotriene receptor antagonist (eg, montelukast), long-acting beta-2<br>agonist (LABA) (eg, salmeterol), tiotropium], OR b) One max-dosed<br>combination ICS/LABA product [e.g., Advair (fluticasone<br>propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta<br>(fluticasone/vilanterol)]. |
| Age Restrictions                   | Asthma (initial): Patient is 6 years of age or older. AD (initial): Patient is 6 months or age or older. CRSwNP, PN: no age restriction. EoE (initial): Patient is at least 12 years of age.  |

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

| Other Criteria | Chronic rhinosinusitis with nasal polyposis (CRSwNP) (initial):<br>Diagnosis of CRSwNP. Unless contraindicated, the patient has had an<br>inadequate response to 2 months of treatment with an intranasal<br>corticosteroid (eg, fluticasone, mometasone). Used in combination with<br>another agent for CRSwNP. Eosinophilic esophagitis (EoE) (initial): Dx<br>of EoE. Patient has symptoms of esophageal dysfunction (eg, dysphagia,<br>food impaction, gastroesophageal reflux disease [GERD]/heartburn<br>symptoms, chest pain, abdominal pain). Patient has at least 15<br>intraepithelial eosinophils per high power field (HPF). Other causes of<br>esophageal eosinophils per high power field (HPF). Other causes of<br>esophageal eosinophilis have been excluded. Patient weighs at least 40<br>kg. Trial and failure, contraindication, or intolerance to at least an 8-week<br>trial of one of the following: proton pump inhibitors (eg, pantoprazole,<br>omeprazole) or topical (esophageal) corticosteroids (eg, budesonide,<br>fluticasone). PN (init): Diagnosis of PN. TF/C/I to one medium or higher<br>potency topical corticosteroid. AD (reauth): Documentation of a positive<br>clinical response to therapy as evidenced by at least one of the following:<br>a) Reduction in BSA involvement from baseline, or b) Reduction in<br>SCORAD index value from baseline. EA (reauth): Documentation of a<br>positive clinical response to therapy (e.g., reduction in exacerbations,<br>improvement in forced expiratory volume in 1 second [FEV1], decreased<br>use of rescue medications). CDA (reauth): Documentation of a positive<br>clinical response to therapy (e.g., reduction in exacerbations,<br>improvement in FEV1, reduction in oral corticosteroid dose). EA, CDA<br>(reauth): Patient continues to be treated with an inhaled corticosteroid<br>(ICS) (e.g., fluticasone, budesonide) with or without additional asthma<br>controller medication (e.g., leukotriene receptor antagonist [e.g.,<br>montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol],<br>tiotropium) unless there is a contraindication or intolerance to these<br>medications. CRSwNP (reauth |
|----------------|---|
|                | measures (eg, esophageal intraepithelial eosinophil count), or endoscopic<br>measures (eg, edema, furrows, exudates, rings, strictures). PN (reauth):<br>Documentation of a positive clinical response to therapy.  |

# **EMGALITY (S)**

### **Products Affected**

• Emgality

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Episodic Migraines (EM) (120 mg/mL strength only) (initial): Diagnosis<br>of EM. Patient has 4 to 14 migraine days per month, but no more than 14<br>headache days per month. Chronic Migraines (CM) (120 mg strength/mL<br>only) (initial): Diagnosis of CM. Medication overuse headache has been<br>considered and potentially offending medication(s) have been<br>discontinued. Patient has greater than or equal to 15 headache days per<br>month, of which at least 8 must be migraine days for at least 3 months.<br>Episodic Cluster Headache (ECH) (100 mg/mL strength only) (initial):<br>Diagnosis of episodic cluster headache. Patient has experienced at least 2<br>cluster periods lasting from 7 days to 365 days, separated by pain-free<br>periods lasting at least three months. Medication will not be used in<br>combination with another injectable CGRP inhibitor. EM, CM (120<br>mg/mL strength only) (initial): Two of the following: a) History of failure<br>(after at least a two month trial) or intolerance to Elavil (amitriptyline) or<br>Effexor (venlafaxine), OR patient has a contraindication to both Elavil<br>(amitriptyline) and Effexor (venlafaxine), b) History of failure (after at<br>least a two month trial) or intolerance to Depakote/Depakote ER<br>(divalproex sodium) or Topamax (topiramate), OR patient has a<br>contraindication to both Depakote/Depakote ER (divalproex sodium) and<br>Topamax (topiramate), c) History of failure (after at<br>least a two month<br>trial) or intolerance to one of the following beta blockers: atenolol,<br>propranolol, nadolol, timolol, or metoprolol, OR patient has a<br>contraindication to all of the following beta blockers: atenolol,<br>propranolol, nadolol, timolol, metoprolol, or d) History of failure (after at<br>least a two month trial) or intolerance to Atacand (candesartan), OR<br>patient has a contraindication to Atacand (candesartan). Medication will<br>not be used in combination with another CGRP inhibitor for the<br>preventive treatment of migraines. |
| Age Restrictions                   | EM, CM, ECH (initial): 18 years of age or older.   |

| Prescriber<br>Restrictions | N/A  |
|----------------------------|--|
| Coverage<br>Duration       | EM, CM (initial): 6 months. ECH (initial): 3 months. EM, CM, ECH (reauth): 12 months.  |
| Other Criteria             | EM, CM (120 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. 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. |

# **ENBREL** (S)

### **Products Affected**

• Enbrel INJ 25MG/0.5ML, 50MG/ML

- Enbrel Mini
- Enbrel Sureclick

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

# **EPCLUSA PREFERRED (S)**

### **Products Affected**

• Sofosbuvir/velpatasvir

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Criteria will be applied consistent with current AASLD/IDSA guideline.<br>Diagnosis of chronic hepatitis C. Not used in combination with another<br>HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with one of the following: Hepatologist,<br>Gastroenterologist, Infectious disease specialist, HIV specialist certified<br>through the American Academy of HIV Medicine.           |
| Coverage<br>Duration               | 12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.  |
| Other Criteria                     | N/A   |

# **EPIDIOLEX (S)**

### **Products Affected**

• Epidiolex

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

| Coverage       | CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo.  |
|----------------|---|
| Duration       | 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. Documentation of a 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. Documentation of a 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. Documentation of a positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 32% or less. Documentation of a positive clinical response to therapy from pre-treatment level. MDS (Reauth): Most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 12 g/dl or less. Documentation of 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. |

# **ERIVEDGE (S)**

### **Products Affected**

• Erivedge

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

# **ESBRIET** (S)

### **Products Affected**

• Esbriet CAPS

• Pirfenidone

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

# **EVRYSDI (S)**

### **Products Affected**

• Evrysdi

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

| Coverage<br>Duration | Initial, Reauth: 12 months   |
|----------------------|--|
| Other Criteria       | SMA (Reauth): Documentation of positive clinical response to therapy.<br>Patient (Pt) continues to not be dependent on both of the following: 1)<br>Invasive ventilation or tracheostomy AND 2) use of non-invasive<br>ventilation beyond use for naps and nighttime sleep. Pt is not to receive<br>concomitant chronic survival motor neuron (SMN) modifying therapy for<br>the treatment of SMA (e.g., Spinraza). One of the following: a) pt has not<br>previously received gene replacement therapy for the treatment of SMA<br>(e.g., Zolgensma) or b) pt has previously received gene therapy for the<br>treatment of SMA (e.g., Zolgensma) AND submission of medical records<br>(e.g., chart notes) documenting that there has been an inadequate response<br>to gene therapy (e.g., sustained decrease in at least one motor test score<br>over a period of 6 months). |

## EXKIVITY (S)

### **Products Affected**

• Exkivity

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: a) locally advanced or b) metastatic. Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation 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). Patient has progressed on or following prior treatment with a platinum-containing regimen (e.g., carboplatin, cisplatin). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | Approve for continuation of prior therapy.   |

## FASENRA (S)

### **Products Affected**

• Fasenra Pen

• Fasenra

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>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. 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 [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium), OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)]. |
| Age Restrictions                   | Asthma (Initial): Patient is 12 years of age or older  |
| Prescriber<br>Restrictions         | Asthma (Initial/Reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist   |
| Coverage<br>Duration               | Asthma (init): 6 months. Asthma (reauth): 12 months  |

| Other Criteria | Asthma (Reauth): Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory |
|----------------|---|
|                | volume in 1 second [FEV1], decreased use of rescue medications). 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 [e.g., montelukast], long-  |
|                | acting beta-2 agonist [LABA] [e.g., salmeterol], 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<br>Criteria              | N/A   |
| Required<br>Medical<br>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 $\mu$ g/hr, Oxycodone at a dose of greater than or equal to 8 mg/day, Oral hydromorphone 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<br>Restrictions         | Prescribed by or in consultation with one of the following: Pain specialist,<br>Oncologist, Hematologist, Hospice care specialist, or Palliative care<br>specialist.  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | N/A   |

## **FERRIPROX (S)**

#### **Products Affected**

• Deferiprone

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Transfusional iron overload (Initial): Diagnosis of transfusional iron Medical overload due to one of the following: thalassemia syndromes, sickle cell Information disease, or other transfusion-dependent anemias. Patient has Absolute Neutrophil Count (ANC) greater than 1.5 x 10<sup>9</sup>/L. One of the following: A) Trial and failure to one chelation therapy (e.g., generic deferasirox) OR B) History of contraindication or intolerance to one chelation therapy (e.g., generic deferasirox). **Age Restrictions** N/A Prescriber N/A Restrictions Coverage 12 months Duration **Other Criteria** All uses (reauth): Documentation of positive clinical response to therapy. ANC greater than  $1.5 \ge 10^9/L$ .

Ferriprox Twice-a-day

•

## FINTEPLA (S)

### **Products Affected**

• Fintepla

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

### **Products Affected**

• Sajazir

• Icatibant Acetate

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE.<br>Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or<br>dysfunction (Type I or II HAE) as documented by one of the following:<br>a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH<br>functional level below the lower limit of normal. For the treatment of<br>acute HAE attacks. Not used in combination with other approved<br>treatments for acute HAE attacks. |
| Age Restrictions                   | Patient is 18 years of age or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an immunologist or an allergist  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Diagnosis of advanced or metastatic prostate cancer. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Diagnosis of renal cell carcinoma. Disease is one of the following:<br>relapsed or refractory. Patient has received two or more prior systemic<br>therapies (e.g., cabozantinib + nivolumab, lenvatinib + pembrolizumab,<br>etc.). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | Approve for continuation of prior therapy.   |

## FULPHILA (S)

### **Products Affected**

• Fulphila

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

# GATTEX (S)

### **Products Affected**

• Gattex

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Short Bowel Syndrome (SBS) (Initial): Diagnosis of SBS. Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 months. |
| Age Restrictions                   | SBS (initial): Patient is 1 year of age or older.  |
| Prescriber<br>Restrictions         | SBS (Init, reauth): Prescribed by or in consultation with a gastroenterologist.  |
| Coverage<br>Duration               | SBS (Init): 6 months. SBS (Reauth): 12 months.   |
| Other Criteria                     | SBS (Reauth): Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on therapy.                     |

# GAVRETO (S)

### **Products Affected**

• Gavreto

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Presence of metastatic rearranged during transfection (RET) gene fusion-positive tumor(s). 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                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy   |

## GILENYA (S)

#### **Products Affected**

• Fingolimod

### • Gilenya CAPS 0.5MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| Required<br>Medical<br>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<br>Restrictions         | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | MS (initial, reauth): 12 months  |
| Other Criteria                     | MS (reauth): Documentation of 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Non-small cell lung cancer (NSCLC): A) Diagnosis of advanced or<br>metastatic (stage IIIB or IV) NSCLC AND B) One of the following: 1)<br>Both of the following: a) Tumors have non-resistant epidermal growth<br>factor (EGFR) mutations as detected by a U.S. Food and Drug<br>Administration (FDA)-approved test or a test performed at a facility<br>approved by Clinical Laboratory Improvement Amendments (CLIA)<br>AND b) GILOTRIF will be used as first-line treatment, OR 2) All of the<br>following: a) disease progressed after platinum-based chemotherapy (e.g.,<br>cisplatin, carboplatin) and b) squamous NSCLC. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| Required<br>Medical<br>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<br>Restrictions         | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | MS (initial, reauth): 12 months  |
| Other Criteria                     | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).                                      |

• Glatopa

# **GLEEVEC** (S)

### **Products Affected**

• Imatinib Mesylate

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

## **GROWTH HORMONE, PREFERRED (S)**

#### **Products Affected**

• Genotropin Miniquick

• Genotropin

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

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

## H.P. ACTHAR GEL (S)

### **Products Affected**

• Acthar

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Infantile Spasms (IS) (West Syndrome): Diagnosis of IS (West<br>Syndrome). Multiple Sclerosis (MS): Diagnosis of acute exacerbation of<br>MS. One of the following: 1) Both of the following: a) Patient is new to<br>therapy with corticotropin AND b) Trial and failure, contraindication, or<br>intolerance (TF/C/I) to treatment with two high dose corticosteroid<br>treatments (e.g., prednisone, IV methylprednisolone) OR 2) All of the<br>following: a) Patient's MS exacerbations have been treated in the past<br>with corticotropin AND b) Patient has benefitted from treatment with<br>corticotropin for acute exacerbations of MS AND c) Medication is being<br>used to treat a new exacerbation of MS. Other FDA-Approved<br>Indications: Diagnosis of one of the following: 1) Rheumatic disorders:<br>As adjunctive therapy for short-term administration in: psoriatic arthritis,<br>rheumatoid arthritis, juvenile rheumatoid arthritis (selected cases may<br>require low-dose maintenance therapy), ankylosing spondylitis, or acute<br>gouty arthritis, OR 2) Collagen diseases: During an exacerbation or as<br>maintenance therapy in selected cases of: systemic lupus erythematosus,<br>or systemic dermatomyositis (polymyositis), OR 3) Dermatologic<br>diseases: Severe erythema multiforme, Stevens-Johnson syndrome, or<br>severe psoriasis, OR 4) Allergic states: Severe acute and chronic allergic<br>and inflammatory processes involving the eye and its adnexa, such as one<br>of the following: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and<br>choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation,<br>or allergic conjunctivitis, OR 6) Respiratory diseases: Symptomatic<br>sarcoidosis, OR 7) Edematous state: To induce a diuresis or a remission of<br>proteinuria in the nephrotic syndrome without uremia of the idiopathic<br>type or that due to lupus erythematosus. TF/C/I to treatment with two<br>corticosteroids (e.g., prednisone, methylprednisolone). |
| Age Restrictions                   | Infantile spasms: less than 2 years old   |

| Prescriber<br>Restrictions | Infantile Spasm, MS: neurologist. Rheumatic disorder, collagen disease:<br>rheumatologist. Dermatologic: dermatologist. Allergic state: allergist,<br>immunologist. Ophthalmic disease: optometrist, ophthalmologist.<br>Respiratory diseases: pulmonologist. Edematous state: nephrologist,<br>rheumatologist.   |
|----------------------------|---|
| Coverage<br>Duration       | Infantile Spasms: 4 weeks. MS: 3 weeks. All other FDA-approved uses: 3 months.  |
| Other Criteria             | IS: Dosing for IS (West Syndrome) is in accordance with the United<br>States Food and Drug Administration (FDA) approved labeling: not to<br>exceed 150U/m^2 daily. MS: Dosing for MS is in accordance with the<br>United States FDA approved labeling: not to exceed 120 units once daily.<br>Other FDA-Approved Indications: Dosing is in accordance with the<br>United States FDA approved labeling: not to exceed 80 units per day. |

## HARVONI (S)

### **Products Affected**

• Ledipasvir/sofosbuvir

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Criteria will be applied consistent with current AASLD/IDSA guideline.<br>All (including patients with genotype 5 or 6 infection AND<br>decompensated cirrhosis): A) Diagnosis of chronic hepatitis C, B) Patient<br>is not receiving ledipasvir/sofosbuvir in combination with another HCV<br>direct acting antiviral agent [eg, Sovaldi (sofosbuvir)]. ONE of the<br>following: Trial and failure, intolerance, or contraindication (eg, safety<br>concerns, not indicated for patient's age/weight) to a) Mavyret (except<br>patients with decompensated cirrhosis, and b) sofosbuvir/velpatasvir, OR<br>for continuation of prior ledipasvir/sofosbuvir therapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with one of the following: Hepatologist,<br>Gastroenterologist, Infectious disease specialist, HIV specialist certified<br>through the American Academy of HIV Medicine.  |
| Coverage<br>Duration               | 12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.   |
| Other Criteria                     | N/A  |

## HETLIOZ (S)

#### **Products Affected**

• Hetlioz

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Non-24-Hour Sleep-Wake Disorder (Non-24) (initial): Both of the Medical following: 1) Diagnosis of non-24-hour sleep-wake disorder (also known Information as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome), AND 2) patient is totally blind (has no light perception). Smith-Magenis Syndrome (SMS) (initial): Diagnosis of Smith-Magenis Syndrome (SMS). Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking). **Age Restrictions** SMS (initial): 16 years of age or older Prescriber Non-24 (initial): Prescribed by or in consultation with a specialist in sleep Restrictions disorders or neurologist. SMS (initial): Prescribed by or in consultation with a specialist in sleep disorders or neurologist. Coverage Non-24, SMS (initial): 6 mo. (reauth): 12 mo Duration **Other Criteria** Non-24 (reauth): Documentation of positive clinical response to therapy. SMS (reauth): Documentation of positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality)

Tasimelteon

•

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

| Prescriber<br>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<br>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): Documentation of 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): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by inprovement 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): Document |
|----------------|--|
|                | following: improvement in intestinal inflammation (eg, mucosal healing,  |

## **IBRANCE (S)**

### **Products Affected**

• Ibrance

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

## **IMBRUVICA (S)**

#### **Products Affected**

- Imbruvica CAPS
- Imbruvica SUSP

• Imbruvica TABS 140MG, 280MG, 420MG

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

## **INCRELEX (S)**

### **Products Affected**

• Increlex

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>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<br>Restrictions         | Initial: Prescribed by or in consultation with an endocrinologist   |
| Coverage<br>Duration               | Initial, reauth: 12 months  |
| Other Criteria                     | (Reauth): Documentation of 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<br>Criteria              | N/A   |
| Required<br>Medical<br>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<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Myelofibrosis: Diagnosis of one of the following: primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

#### **Products Affected**

• Gefitinib

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A **Exclusion** N/A Criteria Required Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC Medical AND Patient has known active epidermal growth factor receptor (EGFR) Information 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 N/A **Restrictions** Coverage 12 months Duration **Other Criteria** Approve for continuation of prior therapy.

• Iressa

# **IVERMECTIN (S)**

#### **Products Affected**

• Ivermectin TABS

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

#### **Products Affected**

• Octagam INJ 1GM/20ML, 2GM/20ML

• Gamunex-c INJ 1GM/10ML

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | All uses (initial, reauth): Contraindications to immune globulin therapy<br>(i.e., IgA deficiency with antibodies to IgA and a history of<br>hypersensitivity or product specific contraindication). Octagam only:<br>Allergy to corn.  |
| Required<br>Medical<br>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<br>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<br>Duration       | 4 months: Solid organ transplant. 12 months: all other diagnoses.  |
| Other Criteria             | <ul> <li>[D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-Barr<sub>6</sub> syndrome. 3)</li> <li>Inflammatory myopathies (dermatomyositis or polymyositis) AND</li> <li>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).</li> <li>[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 transplan 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. For SCIG (Gamunex-C only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunologic evaluation including IgG levels below the normal laboratory value for the patient<sub>i</sub> s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the i</li></ul> |

### JAKAFI (S)

### **Products Affected**

• Jakafi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Myelofibrosis: Diagnosis of primary myelofibrosis, OR post-<br>polycythemia vera myelofibrosis, OR post-essential thrombocythemia<br>myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera, AND<br>trial and failure, contraindication, or intolerance to hydroxyurea. Acute<br>graft versus host disease (aGVHD): Diagnosis of aGVHD. Disease is<br>steroid-refractory. Chronic graft versus host disease (cGVHD): Diagnosis<br>of cGVHD. Trial and failure of at least one or more lines of systemic<br>therapy (e.g., corticosteroids, mycophenolate, etc.). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Diagnosis of mantle cell lymphoma (MCL). Disease is one of the<br>following: a) relapsed, or b) refractory. Patient has received at least two<br>prior therapies for MCL, one of which is a Bruton Tyrosine Kinase (BTK)<br>inhibitor therapy [e.g., Imbruvica (ibrutinib), Calquence (acalabrutinib),<br>Brukinsa (zanubrutinib)]. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

### **JUXTAPID** (S)

### **Products Affected**

# Juxtapid CAPS 10MG, 20MG, 30MG, 5MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Homozygous familial hypercholesterolemia (HoFH) (initial): Submission<br>of medical records (eg, chart notes, laboratory values) documenting<br>diagnosis of HoFH as confirmed by one of the following: a) genetic<br>confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL<br>receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the<br>following: 1) either untreated/pre-treatment LDL-C greater than 500<br>mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma<br>before 10 years of age or evidence of heterozygous FH in both parents.<br>One of the following: a) patient is receiving other lipid-lowering therapy,<br>or b) patient has an inability to take other lipid-lowering therapy. Trial<br>and failure, contraindication, or intolerance to Repatha therapy. Not used<br>in combination with a proprotein convertase subtilisin/kexin type 9<br>(PCSK9) inhibitor. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | HoFH (initial, reauth): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.   |
| Coverage<br>Duration               | HoFH (initial): 6 months. (reauth): 12 months   |
| Other Criteria                     | HoFH (reauthorization): One of the following: a) patient continues to<br>receive other lipid-lowering therapy, or b) patient has an inability to take<br>other lipid-lowering therapy. Submission of medical records (eg, chart<br>notes, laboratory values) documenting LDL-C reduction from baseline<br>while on therapy. Not used in combination with a proprotein convertase<br>subtilisin/kexin type 9 (PCSK9) inhibitor.  |

# KALYDECO (S)

#### **Products Affected**

- Kalydeco TABS
- Kalydeco PACK 13.4MG, 25MG, 50MG, 75MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Cystic Fibrosis (CF) (Initial): Diagnosis of cystic fibrosis. Patient has at<br>least one mutation in the cystic fibrosis transmembrane conductance<br>regulator (CFTR) gene that is responsive to ivacaftor potentiation based<br>on clinical and/or in vitro assay data as detected by a U.S. Food and Drug<br>Administration (FDA)-cleared cystic fibrosis mutation test or a test<br>performed at a facility approved by Clinical Laboratory Improvement<br>Amendments (CLIA). |
| Age Restrictions                   | CF (initial): Patient is 1 month of age or older.  |
| Prescriber<br>Restrictions         | CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist   |
| Coverage<br>Duration               | CF (initial, reauth): 12 months  |
| Other Criteria                     | CF (Reauth): Documentation of 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.  |

# **KERENDIA** (S)

### **Products Affected**

• Kerendia

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>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. 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<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Initial, Reauth: 12 months   |
| Other Criteria                     | Reauth: Documentation of 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.  |

# **KEVEYIS** (S)

### **Products Affected**

• Keveyis

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Periodic paralysis (Initial): Diagnosis of one of the following: Primary<br>hyperkalemic periodic paralysis, Primary hypokalemic periodic paralysis,<br>or Paramyotonia Congenita with periodic paralysis. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | All uses (initial): Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | All uses (Initial): 3 months. (Reauth): 12 months  |
| Other Criteria                     | All uses (Reauth): Documentation of 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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Breast cancer: Diagnosis of breast cancer. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Breast cancer: Diagnosis of breast cancer. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 12 months                                  |
| Other Criteria                     | Approve for continuation of prior therapy. |

# KORLYM (S)

### **Products Affected**

• Korlym

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Cushing's syndrome (Initial): Diagnosis of endogenous Cushing's<br>syndrome (i.e., hypercortisolism is not a result of chronic administration<br>of high dose glucocorticoids). Diagnosis of either type 2 diabetes mellitus<br>or diagnosis of glucose intolerance. Patient has either failed surgery or<br>patient is not a candidate for surgery. Patient is not pregnant. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | Initial: Prescribed by or in consultation with an endocrinologist.  |
| Coverage<br>Duration               | Initial, reauth: 6 months   |
| Other Criteria                     | Reauth: Documentation of 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Neurofibromatosis Type 1 (NF1): Diagnosis of NF1. Patient has<br>plexiform neurofibromas that are both of the following: inoperable and<br>causing significant morbidity (e.g., disfigurement, motor dysfunction,<br>pain, airway dysfunction, visual impairment). Patient is able to swallow a<br>capsule whole. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is<br>one of the following: locally advanced or metastatic. Disease is KRAS<br>G12C-mutated as detected by a U.S. Food and Drug Administration<br>(FDA)-approved test or a test performed at a facility approved by Clinical<br>Laboratory Improvement Amendments (CLIA). Patient has received at<br>least one prior systemic therapy (e.g., chemotherapy, immunotherapy). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient will have<br>blood Phe levels measured after 1 week of therapy (new starts to therapy<br>only) and periodically for up to 2 months of therapy to determine<br>response. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | PKU (Init): 2 months (Reauth): 12 months   |
| Other Criteria                     | PKU (reauth): Documentation of a positive clinical response to therapy.<br>Patient will continue to have blood Phe levels measured periodically<br>during 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Differentiated thyroid cancer (DTC): Diagnosis of DTC. Renal Cell<br>Carcinoma (RCC): Diagnosis of RCC. One of the following: 1) Both of<br>the following: a) Used as first-line treatment and b) Used in combination<br>with Keytruda (pembrolizumab), or 2) Both of the following: a)<br>Treatment follows one prior anti-angiogenic therapy and b) Used in<br>combination with everolimus. Hepatocellular Carcinoma (HCC):<br>Diagnosis of HCC. Endometrial Carcinoma (EC): Diagnosis of advanced<br>endometrial carcinoma that is not microsatellite instability-high (MSI-H)<br>or mismatch repair deficient (dMMR). Patient has disease progression<br>following systemic therapy. Used in combination with Keytruda<br>(pembrolizumab) therapy. Patient is not a candidate for curative surgery<br>or radiation. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

### LETAIRIS (S)

### **Products Affected**

• Ambrisentan

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

### **LEUPROLIDE BRAND (S)**

#### **Products Affected**

• Leuprolide Acetate INJ 22.5MG

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

### LIDOCAINE TOPICAL (S)

#### **Products Affected**

• Lidocaine OINT 5%

- Lidocaine Hcl SOLN 4%
- Lidocaine/prilocaine CREA

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

## LONSURF (S)

### **Products Affected**

• Lonsurf

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Colorectal Cancer: Diagnosis of metastatic colorectal cancer AND One of<br>the following: Used as a single agent or Used in combination with<br>bevacizumab AND trial and failure, contraindication, or intolerance to at<br>least one component in the following: fluoropyrimidine-, oxaliplatin-, and<br>irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI)<br>AND trial and failure, contraindication, or intolerance to at least one anti-<br>VEGF therapy (e.g., bevacizumab)) AND One of the following: A)<br>patient has RAS wild-type tumors and trial and failure, contraindication,<br>or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux)<br>OR B) Patient has RAS mutant tumors. Gastric/Gastroesophageal<br>Junction Adenocarcinoma: Diagnosis of metastatic gastric cancer or<br>diagnosis of metastatic gastroesophageal junction adenocarcinoma. Trial<br>and failure, contraindication or intolerance to at least two of the<br>following: fluropyrimidine-based chemotherapy (e.g. fluorouracil),<br>Platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin),<br>Taxane (e.g., docetaxel, paclitaxel) or irinotecan-based chemotherapy,<br>HER2/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>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<br>Restrictions         | N/A  |
| Coverage<br>Duration               | IBS (initial): 12 weeks. IBS (reauth): 6 mo.   |
| Other Criteria                     | IBS (reauth): Symptoms of IBS continue to persist. Documentation of 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is<br>one of the following: a) locally advanced or b) metastatic. Tumor is<br>KRAS G12C-mutated as detected by a U.S. Food and Drug<br>Administration (FDA)-approved test or a test performed at a facility<br>approved by Clinical Laboratory Improvement Amendments (CLIA).<br>Patient has received at least one prior systemic therapy (e.g.,<br>chemotherapy, immunotherapy). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Prostate CA: 12 months  |
| Other Criteria                     | Approve for continuation of prior therapy.                            |

# LUPRON DEPOT (S)

#### **Products Affected**

- Lupron Depot (1-month) INJ 3.75MG
- 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prostate Cancer (7.5 mg, 22.5 mg, 30 mg, 45 mg): Diagnosis of advanced<br>or metastatic prostate cancer. Endometriosis (3.75 mg, 11.25 mg):<br>Diagnosis of endometriosis. One of the following: Patient has had surgical<br>ablation to prevent recurrence, or trial and failure, contraindication, or<br>intolerance to one NSAID (e.g., diclofenac, ibuprofen, meloxicam,<br>naproxen) and one oral contraceptive (e.g., norethindrone-ethinyl<br>estradiol, estradiol and norethindrone). Uterine Leiomyomata (UL) (3.75<br>mg, 11.25 mg): a) For use prior to surgery to reduce size of fibroids to<br>facilitate a surgical procedure (eg, myomectomy, hysterectomy) OR b) all<br>of the following: treatment of anemia, anemia is caused by uterine<br>leiomyomata (fibroids), and for use prior to surgery. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Prostate CA: 12 mo. Endomet:6mo. UL (anemia):3 mo (fibroids):4 mo   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

### LUPRON DEPOT PED (S)

#### **Products Affected**

- Lupron Depot-ped (1-month) INJ 7.5MG
- Lupron Depot-ped (3-month) INJ 11.25MG
- Lupron Depot-ped (6-month)

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

### Lynparza Tablet (s)

#### **Products Affected**

• Lynparza TABS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis<br>of one of the following: epithelial ovarian cancer, fallopian tube cancer, or<br>primary peritoneal cancer. Breast cancer: Diagnosis of breast cancer.  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | Pancreatic adenocarcinoma: Diagnosis of pancreatic adenocarcinoma.<br>Prostate cancer: Diagnosis of castration-resistant prostate cancer. BRCA-<br>mutated (BRCAm) metastatic castration-resistant prostate cancer<br>(mCRPC): Diagnosis of metastatic castration-resistant prostate cancer<br>(mCRPC). Presence of a deleterious or suspected deleterious BRCA-<br>mutation as detected by an FDA-approved test or a test performed at a<br>facility approved by Clinical Laboratory Improvement Amendments<br>(CLIA). Used in combination with abiraterone and one of the following:<br>a) prednisone or b) prednisolone. All indications: Approve for<br>continuation of prior therapy. |

# LYTGOBI (S)

### **Products Affected**

• Lytgobi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>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<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Nausea and Vomiting Associated with Cancer Chemotherapy (CINV):<br>Patient is receiving cancer chemotherapy. Trial and failure,<br>contraindication, or intolerance to one 5HT-3 receptor antagonist (eg,<br>Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]).<br>Trial and failure, contraindication, or intolerance to one of the following<br>Compazine (prochlorperazine), Decadron (dexamethasone), Haldol<br>(haloperidol), Zyprexa (olanzapine). AIDS anorexia: Diagnosis of<br>anorexia with weight loss in patients with AIDS. Patient is on<br>antiretroviral therapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Criteria will be applied consistent with current AASLD/IDSA guideline.<br>All patients: Diagnosis of chronic hepatitis C, patient is without<br>decompensated liver disease (defined as Child-Pugh Class B or C), and<br>not used in combination with another HCV direct acting antiviral agent<br>[e.g., Harvoni, Zepatier]. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with one of the following: Hepatologist,<br>Gastroenterologist, Infectious disease specialist, HIV specialist certified<br>through the American Academy of HIV Medicine.   |
| Coverage<br>Duration               | 8 to 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.   |
| Other Criteria                     | N/A   |

### MAYZENT (S)

#### **Products Affected**

• Mayzent

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

Mayzent Starter Pack

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### **MEKINIST (S)**

### **Products Affected**

• Mekinist

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Melanoma: Diagnosis of unresectable or metastatic melanoma AND<br>cancer is BRAF V600E or V600K mutant type as detected by a U.S. Food<br>and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a<br>test performed at a facility approved by Clinical Laboratory Improvement<br>Amendments (CLIA). Adjuvant Treatment for Melanoma: Diagnosis of<br>melanoma. Cancer is BRAF V600E or V600K mutant type as detected by<br>an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility<br>approved by Clinical Laboratory Improvement Amendments (CLIA).<br>Involvement of lymph nodes following complete resection. Used as<br>adjunctive therapy. Medication is used in combination with Tafinlar<br>(dabrafenib).Non-small Cell Lung Cancer (NSCLC): All of the following:<br>diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF<br>V600E mutant type as detected by an FDA-approved test (THxID-BRAF<br>Kit) or a test performed at a facility approved by Clinical Laboratory<br>Improvement Amendments (CLIA) AND medication is used in<br>combination with Tafinlar (dabrafenib). Anaplastic Thyroid Cancer<br>(ATC): Diagnosis of locally advanced or metastatic ATC. Cancer is<br>BRAF V600E mutant type as detected by an FDA-approved test (THxID-<br>BRAF Kit) or a test performed at a facility approved by Clinical<br>Laboratory Improvement Amendments (CLIA). Cancer may not be<br>treated with standard locoregional treatment options. Medication is used<br>in combination with Tafinlar (dabrafenib). |
| Age Restrictions                   | Solid tumors, Low-grade glioma: Patient is 1 year of age or older.  |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |

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

### **Products Affected**

• Mektovi

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

### **METHYLTESTOSTERONE (S)**

#### **Products Affected**

• Methyltestosterone CAPS

• Methitest

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

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

### MIGRANAL (S)

#### **Products Affected**

• Dihydroergotamine Mesylate SOLN

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Initial: Diagnosis of migraine headaches with or without aura. Will be<br>used for the acute treatment of migraine. One of the following: Trial and<br>failure or intolerance to one triptan (e.g., eletriptan, rizatriptan,<br>sumatriptan) or contraindication to all triptans. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.  |
| Coverage<br>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 (NON-PREFERRED) (S)

#### **Products Affected**

- Rebif
- Rebif Rebidose

- Rebif Rebidose Titration Pack
- Rebif Titration Pack

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.   |
| Required<br>Medical<br>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). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following: Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Extavia (interferon beta-1b), Plegridy (peginterferon beta-1a), or 2) for continuation of prior therapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | MS (initial, reauth): Prescribed by or in consultation with a neurologist   |
| Coverage<br>Duration               | MS (initial, reauth): 12 months   |
| Other Criteria                     | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).   |

# MS INTERFERONS (PREFERRED) (S)

#### **Products Affected**

• Avonex INJ 30MCG/0.5ML

- Betaseron
- Plegridy

• Avonex Pen

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| Required<br>Medical<br>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<br>Restrictions         | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | MS (initial, reauth): 12 months  |
| Other Criteria                     | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).                                      |

### **MYALEPT (S)**

#### **Products Affected**

• Myalept

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Lipodystrophy (initial): Diagnosis of congenital or acquired generalized<br>lipodystrophy AND one of the following: 1) Diabetes mellitus or insulin<br>resistance despite insulin therapy at maximum tolerated doses OR 2)<br>Hypertriglyceridemia. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | Initial: Prescribed by or in consultation with an endocrinologist   |
| Coverage<br>Duration               | Initial, reauth: 12 months  |
| Other Criteria                     | Lipodystrophy (reauth): Documentation of positive clinical response to therapy.   |

### NATPARA (S)

#### **Products Affected**

• Natpara

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Hypocalcemia (Initial): Diagnosis of hypocalcemia due to chronic<br>hypoparathyroidism. Not used in the setting of acute post-surgical<br>hypoparathyroidism. Patient does not have a known calcium-sensing<br>receptor mutation. Patient has a documented parathyroid hormone<br>concentration that is inappropriately low for the level of calcium, recorded<br>on at least two occasions within the previous 12 months. Patient has<br>normal thyroid-stimulating hormone concentrations if not on thyroid<br>hormone replacement therapy (or if on therapy, the dose had to have been<br>stable for greater than or equal to 3 months). Patient has normal<br>magnesium and serum 25-hydroxyvitamin D concentrations. Will be used<br>as an adjunct treatment. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | Hypocalcemia (initial): Prescribed by or in consultation with an endocrinologist.  |
| Coverage<br>Duration               | Initial: 6 months. Reauth: 12 months   |
| Other Criteria                     | Hypocalcemia (Reauth): Documentation of positive clinical response to therapy.   |

### NERLYNX (S)

#### **Products Affected**

• Nerlynx

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

### **NEULASTA (S)**

#### **Products Affected**

• Neulasta

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

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### NEXAVAR (S)

#### **Products Affected**

• Sorafenib Tosylate TABS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Renal cell carcinoma (RCC): Diagnosis of RCC. Hepatocellular<br>carcinoma (HCC): Diagnosis of HCC. Differentiated thyroid carcinoma<br>(DTC): Diagnosis of DTC (ie, follicular carcinoma, Hurthle cell<br>carcinoma, or papillary carcinoma). One of the following: locally<br>recurrent disease, metastatic disease, or unresectable disease. One of the<br>following: patient has symptomatic disease or patient has progressive<br>disease. Disease is refractory to radioactive iodine (RAI) treatment.<br>Medullary thyroid carcinoma (MTC): Diagnosis of MTC. One of the<br>following: 1) Disease is progressive or 2) Disease is symptomatic with<br>distant metastases. Trial and failure, contraindication, or intolerance to<br>Caprelsa (vandetanib) or Cometriq (cabozantinib). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Multiple myeloma: Diagnosis of multiple myeloma. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Neurogenic orthostatic hypotension (NOH) (init): Diagnosis of<br>symptomatic NOH. NOH is caused by one of the following conditions:<br>primary autonomic failure (eg, Parkinson's disease, multiple system<br>atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency,<br>non-diabetic autonomic neuropathy. Trial and failure, contraindication, or<br>intolerance to one of the following agents: fludrocortisone acetate,<br>midodrine. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | NOH (init): Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist  |
| Coverage<br>Duration               | NOH (init): 1 month (reauth): 12 months   |
| Other Criteria                     | NOH (reauth): Documentation of 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prophylaxis of systemic fungal infections (SFI): Used as prophylaxis of<br>invasive fungal infections caused by Aspergillus or Candida for one of the<br>following conditions: 1) Patient is at high risk of infections due to severe<br>immunosuppression from hematopoietic stem cell transplant (HSCT) with<br>graft-versus-host disease (GVHD) or hematologic malignancies with<br>prolonged neutropenia from chemotherapy OR 2) patient has a prior<br>fungal infection requiring secondary prophylaxis. Oropharyngeal<br>Candidiasis (OPC): Diagnosis of OPC. One of the following: 1) Trial and<br>failure, contraindication, or intolerance to fluconazole OR 2)<br>Susceptibility results demonstrate resistance to fluconazole. |
| Age Restrictions                   | Prophylaxis of SFI, OPC: Patient is 13 years or older.  |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Prophylaxis of SFI: 6 months. OPC: 1 month.   |
| Other Criteria                     | N/A   |

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# NUBEQA (S)

#### **Products Affected**

• Nubeqa

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

#### **Products Affected**

• Nuplazid TABS 10MG

• Nuplazid CAPS

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

# NUVIGIL (S)

#### **Products Affected**

• Armodafinil

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

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| Other Criteria | OSA, Narcolepsy (Reauth): Documentation of positive clinical response<br>to armodafinil therapy. SWD (Reauth): Documentation of positive clinical |
|----------------|---|
|                | response to armodafinil therapy.  |

### OCALIVA (S)

#### **Products Affected**

• Ocaliva

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Primary Biliary Cholangitis (PBC) (initial): Diagnosis of PBC (aka<br>primary biliary cirrhosis). One of the following: a) patient has failed to<br>achieve an alkaline phosphatase (ALP) level of less than 1.67 times the<br>upper limit of normal (ULN) after treatment with ursodeoxycholic acid<br>(UDCA) (e.g., Urso, Urso Forte, ursodiol) AND used in combination<br>with UDCA, OR b) contraindication or intolerance to UDCA. Patient<br>does not have evidence of advanced cirrhosis (i.e., cirrhosis with current<br>or prior evidence of hepatic decompensation including encephalopathy or<br>coagulopathy). Patient does not have evidence of portal hypertension<br>(e.g., ascites, gastroesophageal varices, persistent thrombocytopenia). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | PBC (initial): Prescribed by or in consultation with a hepatologist or gastroenterologist.   |
| Coverage<br>Duration               | PBC (initial): 6 months, (reauth): 12 months   |
| Other Criteria                     | PBC (reauthorization): Submission of medical records (eg, laboratory values) documenting a reduction in ALP level from pre-treatment baseline (ie, prior obeticholic acid therapy) while on therapy. Patient does not have evidence of advanced cirrhosis (i.e., cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy). Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).   |

### **ODOMZO**(S)

#### **Products Affected**

• Odomzo

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

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| Coverage<br>Duration | Initial, reauth: 12 months  |
|----------------------|---|
| Other Criteria       | IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (reauth): Documentation of positive clinical response to therapy. |

### OJJAARA (S)

#### **Products Affected**

• Ojjaara

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Diagnosis of ONE of the following: a) Primary myelofibrosis, b) Post-<br>polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia<br>myelofibrosis. Disease is intermediate or high risk. Patient has anemia. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Acute Myeloid Leukemia (AML): Diagnosis of acute myeloid leukemia<br>(AML). Patient has received previous treatment with an intensive<br>induction chemotherapy regimen (e.g., cytarabine + daunorubicin,<br>cytarabine + idarubicin, etc.). Patient has achieved one of the following:<br>a) first complete remission (CR) or b) complete remission with<br>incomplete blood count recovery (CRi). Patient is not able to complete<br>intensive curative therapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH<br>is symptomatic. One of the following: A) Diagnosis of PAH was<br>confirmed by right heart catheterization or B) Patient is currently on any<br>therapy for the diagnosis of PAH. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.  |
| Coverage<br>Duration               | PAH: Initial: 6 months. Reauth: 12 months.   |
| Other Criteria                     | PAH (Reauth): Documentation of positive clinical response to therapy.  |

# **ORENITRAM (S)**

#### **Products Affected**

- Orenitram
- Orenitram Titration Kit Month 1
- Orenitram Titration Kit Month 2
- Orenitram Titration Kit Month 3

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

# **ORGOVYX** (S)

#### **Products Affected**

• Orgovyx

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prostate Cancer: Diagnosis of advanced prostate cancer. Disease is one of<br>the following: 1) Evidence of biochemical or clinical relapse following<br>local primary intervention with curative intent or 2) Newly diagnosed<br>androgen-sensitive metastatic disease or 3) Advanced localized disease<br>unlikely to be cured by local primary intervention with curative intent. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Patient is homozygous for<br>the F508del mutation in the CF transmembrane conductance regulator<br>(CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)-<br>cleared cystic fibrosis mutation test or a test performed at a facility<br>approved by Clinical Laboratory Improvement Amendments (CLIA). |
| Age Restrictions                   | CF (Initial): Patient is 6 years of age or older   |
| Prescriber<br>Restrictions         | CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Diagnosis of breast cancer. Disease is advanced or metastatic. Disease is<br>estrogen receptor (ER)-positive. Disease is human epidermal growth<br>factor receptor 2 (HER2)-negative. Presence of estrogen receptor (ESR1)<br>mutation(s) as detected with a U.S. Food and Drug Administration<br>(FDA)-approved test or a test performed at a facility approved by Clinical<br>Laboratory Improvement Amendments (CLIA). Disease has progressed<br>following at least one line of endocrine therapy [e.g., Faslodex<br>(fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin<br>(exemestane)]. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

# **OXBRYTA (S)**

#### **Products Affected**

• Oxbryta TBSO

• Oxbryta TABS 300MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Initial: Diagnosis of Sickle Cell Disease. Documentation of 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<br>Restrictions         | Initial: Prescribed by or in consultation with one of the following: 1)<br>Hematologist/Oncologist or 2) Specialist w/ expertise in the diagnosis and<br>management of sickle cell disease.   |
| Coverage<br>Duration               | Initial, Reauth: 12 months.   |
| Other Criteria                     | Reauth: Documentation of positive clinical response to therapy (e.g., an increase in hemoglobin level of 1 g/dL or greater from baseline, decreased annualized incidence rate of vaso-occlusive crises [VOCs]). Documentation of hemoglobin level that does not exceed 10.5 g/dL. |

### PEGASYS (S)

#### **Products Affected**

• Pegasys

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and<br>patient is without decompensated liver disease. Chronic Hepatitis C:<br>Criteria will be applied consistent with current AASLD-IDSA guidance. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is one of<br>the following: unresectable locally advanced or metastatic. Disease has<br>presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other<br>rearrangement as detected by an FDA-approved test or a test performed at<br>a facility approved by Clinical Laboratory Improvement Amendments<br>(CLIA). Patient has been previously treated. Myeloid/lymphoid<br>neoplasms: Diagnosis of myeloid/lymphoid neoplasms (MLNs). Disease<br>is relapsed or refractory. Disease has presence of a fibroblast growth<br>factor receptor 1 (FGFR1) rearrangement. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | Approve for continuation of prior therapy.   |

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### **Products Affected**

# • Diclofenac Sodium EXTERNAL SOLN 1.5%

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Osteoarthritis of the knees (initial): Diagnosis of osteoarthritis of the knees. Patient meets one of the following: 1) Treatment failure with at least two prescription strength topical or oral non-steroidal anti-<br>inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) OR 2) History of peptic ulcer disease/gastrointestinal bleed OR 3) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Initial, reauth: 12 months  |
| Other Criteria                     | Osteoarthritis of the knees (reauth): Documentation of positive clinical response to therapy (e.g., improvement in pain symptoms of osteoarthritis).  |

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

### **POSACONAZOLE (S)**

### **Products Affected**

• Noxafil SUSP

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prophylaxis of systemic fungal infections (SFI): Used as prophylaxis of<br>invasive fungal infections caused by Aspergillus or Candida for one of the<br>following conditions: 1) Patient is at high risk of infections due to severe<br>immunosuppression from hematopoietic stem cell transplant (HSCT) with<br>graft-versus-host disease (GVHD) or hematologic malignancies with<br>prolonged neutropenia from chemotherapy OR 2) patient has a prior<br>fungal infection requiring secondary prophylaxis. Treatment (Tx) of SFI:<br>Used as treatment of systemic fungal infections caused by Aspergillus.<br>Oropharyngeal Candidiasis (OPC): Diagnosis of OPC. One of the<br>following: 1) Candidiasis is refractory or resistant to treatment with<br>fluconazole OR 2) Trial and failure, contraindication, or intolerance to<br>fluconazole. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Prophylaxis of SFI: 6 months. Tx of SFI: 3 months. OPC: 1 month.  |
| Other Criteria                     | N/A   |

### **POSACONAZOLE TABLET (S)**

#### **Products Affected**

• Posaconazole Dr

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

### **PRALUENT (S)**

#### **Products Affected**

• Praluent

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | HeFH/ASCVD/Primary HLD (init): One of the following dx: A)HeFH as<br>confirmed by one of the following: 1)Both of the following:<br>a)Untreated/pre-treatment LDL greater than 190 mg/dL in an adult, AND<br>b)One of the following: i) Family hx of tendinous xanthomas and/or arcus<br>cornealis in 1st degree relative, or 2nd degree relative, ii)Hx of<br>myocardial infarction (MI) in 1st-degree relative less than 60 years of age,<br>iii)Family hx of MI in 2nd-degree relative less than 50 years of age,<br>iii)Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree<br>relative, v)Family hx of FH in 1st- or 2nd-degree relative, or<br>2)Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult<br>AND one of the following: presence of tendinous xanthoma in pt, arcus<br>cornealis before age 45, or functional mutation in the LDL receptor,<br>ApoB, or PCSK9 gene, B)ASCVD as confirmed by ACS, hx of MI, stable<br>or unstable angina, coronary or other arterial revascularization, stroke,<br>TIA, or peripheral arterial disease presumed to be of atherosclerotic<br>origin, OR C)Primary hyperlipidemia (HLD). HoFH (init): Dx of HoFH<br>as confirmed by one of the following: 1)Gen confirmation of 2 mutations<br>in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2)either<br>untreated LDL greater than 500 or treated LDL greater than 300, AND<br>either xanthoma before 10 yo or evidence of HeFH in both parents.<br>HeFH/ASCVD/Primary HLD (init): One of the following: set A)Both of<br>the following: 1) One of the following: a) One of the following LDL<br>values while on max tolerated lipid lowering regimen w/in the last 120<br>days: i)LDL greater than or equal to 100 mg/dL w/ASCVD or ii)LDL<br>greater than or equal to 130 mg/dL w/o ASCVD, OR b) Both of the<br>following: i) Patient has been receiving PCSK9 therapy as adjunct to<br>maximally tolerated lipid lowering therapy and ii) LDL-C values drawn<br>within the past 12 months while on maximally tolerated lipid lowering<br>therapy has shown a reduction from baseline, AND Continued in Other<br>Criteria |

| Age Restrictions           | N/A                                  |
|----------------------------|--------------------------------------|
| Prescriber<br>Restrictions | N/A                                  |
| Coverage<br>Duration       | Initial: 6 months. Reauth: 12 months |

| Other Criteria | Set A (cont, initial): 2)One of the following: a)Pt has been receiving at<br>least 12 wks of one high-intensity (HI) statin therapy (tx) and will<br>continue to receive a HI statin [ie, atorvastatin 40-80 mg, rosuvastatin 20-<br>40 mg] at max tolerated dose, OR b) Both of the following: i) Pt unable to<br>tolerate HI statin as evidenced by intolerable and persistent (ie, more than<br>2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis<br>(muscle symptoms w/ CK elevations less than 10 times ULN) AND ii)<br>One of the following: (1) Pt has been receiving at least 12 wks of one<br>moderate-intensity (MI) or low-intensity (LI) statin tx and will continue to<br>receive a MI or LI statin [ie, atorvastatin 10-20 mg, rosuvastatin 5-10 mg,<br>simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol<br>XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin)<br>1-4 mg] at max tolerated dose, OR (2) Pt is unable to tolerate MI or LI<br>statin as evidenced by intolerable and persistent (ie, more than 2 weeks)<br>myalgia (muscle symptoms w/o CK elevations) or myositis (muscle<br>symptoms w/ CK elevations less than 10 times ULN), OR c) Pt has a<br>labeled contraindication to all statins, OR d) Pt has experienced<br>rhabdomyolysis or muscle symptoms w/ statin treatment w/ CK elevations<br>greater than 10 times ULN on one statin tx. OR set B) Both of the<br>following: 1) One of the following LDL values while on max tolerated<br>lipid lowering regimen w/in the last 120 days: a) LDL b/t 55 and 99<br>mg/dL w/ASCVD or b) LDL b/t 100 and 129 mg/dL w/o ASCVD, AND<br>2) Both of the following: a) One of the following: i) Pt has been receiving<br>at least 12 wks of one max-tolerated statin tx and will continue to receive<br>a statin at max tolerated dose, ii) pt is unable to tolerate statin tx as<br>evidenced by intolerable and persistent (ie, more than 2 wks) myalgia<br>(muscle symptoms w/ CK elevations) or myositis (muscle symptoms w/<br>CK elevations less than 10 times ULN, iii) Patient has a labeled<br>contraindication to all statins, or iv) Pt has experienced rhabdomyoly |
|----------------|--|
|                | receive other lipid-lowering tx (eg statins, ezetimibe) at max tolerated dose (unless pt has documented inability to take these medications).  |

### **PROMACTA (S)**

#### **Products Affected**

• Promacta

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

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

### **PROVIGIL (S)**

#### **Products Affected**

• Modafinil

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

| Prescriber<br>Restrictions | N/A  |
|----------------------------|--|
| Coverage<br>Duration       | Narcolepsy: Init, Reauth: 12 mo. All other indications: Init, Reauth: 6 mo.  |
| Other Criteria             | OSA, Narcolepsy, Idiopathic Hypersonnia (Reauth): Documentation of<br>positive clinical response to modafinil therapy. SWD (Reauth):<br>Documentation of positive clinical response to modafinil therapy. MS<br>Fatigue (reauth): Patient is experiencing relief of fatigue with modafinil<br>therapy. Depression (reauth): Documentation of positive clinical response<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Cystic Fibrosis (CF) (Initial, Reauth): Diagnosis of CF.   |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Initial: Diagnosis of hemolytic anemia confirmed by the presence of Medical chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated Information 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 Initial, Reauth: Prescribed by or in consultation with a hematologist. Restrictions Coverage Initial: 6 months. Reauth: 12 months. **Duration Other Criteria** Reauth: Documentation of positive clinical response to therapy.

• Pyrukynd Taper Pack

# QINLOCK (S)

### **Products Affected**

• Qinlock

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Gastrointestinal Stromal Tumor (GIST): Diagnosis of gastrointestinal<br>stromal tumor (GIST). Disease is advanced. Patient has received prior<br>treatment with three or more kinase inhibitors (e.g., sunitinib,<br>regorafenib), one of which must include imatinib. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | Excluded if used solely for the treatment or prevention of nocturnal leg cramps.   |
| Required<br>Medical<br>Information | Malaria: Diagnosis of uncomplicated malaria. One of the following: 1)<br>Treatment in areas of chloroquine-sensitive malaria, and trial and failure,<br>contraindication, or intolerance to chloroquine or hydroxychloroquine,<br>OR 2) Treatment in areas of chloroquine-resistant malaria. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 7 days   |
| Other Criteria                     | N/A  |

# **RAVICTI (S)**

### **Products Affected**

• Ravicti

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Urea cycle disorders (UCDs) (Initial): Both of the following: 1) Diagnosis<br>of UCD AND 2) One of the following deficiencies: a) carbamylphosphate<br>synthetase (CPS), b) ornithine transcarbamylase (OTC), or c)<br>argininosuccinic acid synthetase (AS). Molecular genetic testing confirms<br>mutations in the CPS1, OTC, or ASS1 gene. Inadequate response to one<br>of the following: 1) Dietary protein restriction or 2) Amino acid<br>supplementation. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | UCDs (initial): Prescribed by or in consultation with a specialist focused<br>on the treatment of metabolic disorders.  |
| Coverage<br>Duration               | UCDs (Initial, reauth): 12 months   |
| Other Criteria                     | UCDs (reauth): Documentation of positive clinical response to therapy (e.g., plasma ammonia or amino acid levels within normal limits).   |

# **REGRANEX (S)**

#### **Products Affected**

• Regranex

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Diabetic neuropathic ulcers: Patient has a lower extremity diabetic<br>neuropathic ulcer. Treatment will be given in combination with ulcer<br>wound care (eg, debridement, infection control, and/or pressure relief). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 5 months  |
| Other Criteria                     | N/A   |

## **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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | HeFH/ASCVD/Primary HLD (init): One of the following dx: A)HeFH as<br>confirmed by one of the following: 1)Both of the following:<br>a)Untreated/pre-treatment LDL greater than 190 mg/dL in an adult, AND<br>b)One of the following: i) Family hx of tendinous xanthomas and/or arcus<br>cornealis in 1st degree relative, or 2nd degree relative, ii)Hx of<br>myocardial infarction (MI) in 1st-degree relative less than 60 years of age,<br>iii)Family hx of MI in 2nd-degree relative less than 50 years of age,<br>iii)Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree<br>relative, v)Family hx of FH in 1st- or 2nd-degree relative, or<br>2)Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult<br>AND one of the following: presence of tendinous xanthoma in pt, arcus<br>cornealis before age 45, or functional mutation in the LDL receptor,<br>ApoB, or PCSK9 gene, B)ASCVD as confirmed by ACS, hx of MI, stable<br>or unstable angina, coronary or other arterial revascularization,<br>stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic<br>origin, OR C)Primary hyperlipidemia (HLD). HoFH (init): Dx of HoFH<br>as confirmed by one of the following: 1)Gen confirmation of 2 mutations<br>in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2)either<br>untreated LDL greater than 500 or treated LDL greater than 300, AND<br>either xanthoma before 10 yo or evidence of HeFH in both parents.<br>HeFH/ASCVD/Primary HLD (init): One of the following: set A)Both of<br>the following: 1) One of the following: a) One of the following LDL<br>values while on max tolerated lipid lowering regimen w/in the last 120<br>days: i)LDL greater than or equal to 100 mg/dL w/ASCVD or ii)LDL<br>greater than or equal to 130 mg/dL w/o ASCVD, OR b) Both of the<br>following: i) Patient has been receiving PCSK9 therapy as adjunct to<br>maximally tolerated lipid lowering therapy and ii) LDL-C values drawn<br>within the past 12 months while on maximally tolerated lipid lowering<br>therapy has shown a reduction from baseline, AND Continued in Other<br>Criteria |

| Age Restrictions           | (Initial) HeFH/HoFH: 10 years or older. |
|----------------------------|---|
| Prescriber<br>Restrictions | N/A                                     |
| Coverage<br>Duration       | Initial: 6 months. Reauth: 12 months    |

| Other Criteria | Set A (cont, initial): 2) One of the following: a) Pt has been receiving at<br>least 12 wks of one high-intensity (HI) statin therapy (tx) and will<br>continue to receive a HI statin [ie, atorvastatin 40-80 mg, rosuvastatin 20-<br>40 mg] at max tolerated dose, OR b) Both of the following: i) Pt unable to<br>tolerate HI statin as evidenced by intolerable and persistent (ie, more than<br>2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis<br>(muscle symptoms w/ CK elevations less than 10 times ULN) AND ii)<br>One of the following: (1) Pt has been receiving at least 12 wks of one<br>moderate-intensity (MI) or low-intensity (LI) statin tx and will continue to<br>receive a MI or LI statin [ie, atorvastatin 10-20 mg, rosuvastatin 5-10 mg,<br>simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol<br>XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin)<br>1-4 mg] at max tolerated dose, OR (2) Pt is unable to tolerate MI or LI<br>statin as evidenced by intolerable and persistent (ie, more than 2 weeks)<br>myalgia (muscle symptoms w/o CK elevations) or myositis (muscle<br>symptoms w/ CK elevations less than 10 times ULN), OR c) Pt has a<br>labeled contraindication to all statins, OR d) Pt has experienced<br>rhabdomyolysis or muscle symptoms w/ statin treatment w/ CK elevations<br>greater than 10 times ULN on one statin tx. OR set B) Both of the<br>following: 1) One of the following LDL values while on max tolerated<br>lipid lowering tx w/in the last 120 days: a) LDL b/t 55 and 99 mg/dL w/<br>ASCVD or b) LDL b/t 100 and 129 mg/dL w/o ASCVD, AND 2) Both of<br>the following: a) One of the following: i) Pt has been receiving at least 12<br>wks of one max-tolerated statin tx and will continue to receive a statin at<br>max tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by<br>intolerable and persistent (ie, more than 2 wks) myalgia (muscle<br>symptoms w/ CK elevations) or myositis (muscle symptoms w/ CK<br>elevations less than 10 times ULN, iii) Patient has a labeled<br>contraindication to all statins, or iv) Pt has experienced rhabdomyolysi |
|----------------|--|
|                | dose (unless pt has documented inability to take these medications).   |

# **RETACRIT (S)**

#### **Products Affected**

• Retacrit

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>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. 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<br>Restrictions         | N/A  |

| Coverage       | CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo.   |
|----------------|--|
| Duration       | 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. Documentation of a 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. Documentation of a 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. Documentation of a positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 32% or less. Documentation of a positive clinical response to therapy from pre-treatment level. MDS (Reauth): Most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 36% or less. OR most recent or avg Hct over 3 months is 12 g/dl or less. Documentation of a positive clinical response to therapy from pre-treatment level. Other Offlabel 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. |

## **RETEVMO (S)**

### **Products Affected**

• Retevmo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Non-Small Cell Lung Cancer: Diagnosis of non-small cell lung cancer<br>(NSCLC). Disease is locally advanced or metastatic. Disease has presence<br>of RET gene fusion-positive tumor(s). Medullary Thyroid Cancer (MTC):<br>Diagnosis of medullary thyroid cancer (MTC). Disease is advanced or<br>metastatic. Disease has presence of RET gene mutation tumor(s). Disease<br>requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of<br>thyroid cancer. Disease is advanced or metastatic. Disease has presence of<br>RET gene fusion-positive tumor(s). Disease requires treatment with<br>systemic therapy. Patient is radioactive iodine-refractory or radioactive<br>iodine therapy is not appropriate. Solid Tumors: Diagnosis of solid<br>tumors. Disease is locally advanced or metastatic. Disease has presence of<br>RET gene fusion-positive tumor(s). ONE of the following: a) Disease has<br>progressed on or following prior systemic treatment (e.g., chemotherapy),<br>OR b) There are no satisfactory alternative treatment options. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH<br>is symptomatic. One of the following: A) Diagnosis of PAH was<br>confirmed by right heart catheterization or B) Patient is currently on any<br>therapy for the diagnosis of PAH. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.  |
| Coverage<br>Duration               | PAH: Initial: 6 months. Reauth: 12 months.   |
| Other Criteria                     | PAH (Reauth): Documentation of positive clinical response to therapy.  |

### **REVATIO SUSPENSION (S)**

#### **Products Affected**

• Sildenafil Citrate SUSR

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH<br>is symptomatic. One of the following: A) Diagnosis of PAH was<br>confirmed by right heart catheterization or B) Patient is currently on any<br>therapy for the diagnosis of PAH. One of the following: A) Intolerance to<br>generic Revatio tablets, OR B) Patient is unable to ingest a solid dosage<br>form (e.g., an oral tablet or capsule) due to one of the following: age, oral-<br>motor difficulties, or dysphagia. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.  |
| Coverage<br>Duration               | PAH: Initial: 6 months. Reauth: 12 months.   |
| Other Criteria                     | PAH (Reauth): Documentation of 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | N/A   |

### **REVLIMID** (S)

#### **Products Affected**

• Lenalidomide

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A **Exclusion** N/A Criteria Required Multiple myeloma (MM): Diagnosis of MM. Myelodysplastic syndromes Medical (MDS): Diagnosis of transfusion-dependent anemia due to low- or Information 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 N/A Restrictions Coverage 12 months **Duration Other Criteria** Approve for continuation of prior therapy.

• Revlimid

## **REYVOW** (S)

### **Products Affected**

• Reyvow

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Initial: Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Patient has less than 15 headache days per month. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. 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 8 hours after taking each dose of Reyvow. |
| Age Restrictions                   | Initial: 18 years of age or older.   |
| Prescriber<br>Restrictions         | Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.   |
| Coverage<br>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.   |

# **REZLIDHIA (S)**

### **Products Affected**

• Rezlidhia

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

## **RILUTEK (S)**

### **Products Affected**

• Riluzole

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Amyotrophic lateral sclerosis (ALS): Diagnosis of amyotrophic lateral sclerosis (ALS). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | ALS: 12 months   |
| Other Criteria                     | N/A  |

## **RINVOQ**(S)

### **Products Affected**

• Rinvoq

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

| Prescriber<br>Restrictions | RA, 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<br>Duration       | RA, PsA, AS, NRAS, CD, UC, AD (init): 6 months, (reauth): 12 months.   |

| 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. Not used in combination with other JAK-I, biological therapies for CD, or potent immunosuppressants (e.g., azathioprine, cyclosporine). 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). Not used in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine). CD, UC (init): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab). RA (reauth): Documentation of 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): Documentation of positive clinical response to therapy as evidenced by at least one of the following: device (swollen and tender) joint count from baseline, OR reduction in the BSA involvement from baseline. AS, NRAS (Reauth): Documentation of positive (eg, pain, stiffness, puritus, inflammation, stiffness), lab values (ESR, CRP level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. AD (reauth): Documentation of a positive clinical response to thera |
|--|
| state. Not used in combination with other JAK inhibitors, biological therapies for CD/UC, or potent immunosuppressants (eg, azathioprine, cyclosporine).   |
|  |

### **ROZLYTREK (S)**

#### **Products Affected**

• Rozlytrek CAPS

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

## **RUCONEST (S)**

### **Products Affected**

• Ruconest

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

### RYDAPT (S)

### **Products Affected**

• Rydapt

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

# SABRIL (S)

#### **Products Affected**

• Vigabatrin

• Vigadrone

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

## SAMSCA (S)

### **Products Affected**

• Tolvaptan

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Diagnosis of significant hyponatremia (euvolemic or hypervolemic).<br>Treatment has been initiated or re-initiated in a hospital setting prior to<br>discharge within the past 30 days. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 30 days   |
| Other Criteria                     | N/A   |

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

# **SCEMBLIX (S)**

### **Products Affected**

• Scemblix

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

# **SIGNIFOR (S)**

### **Products Affected**

• Signifor

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

### SKYRIZI (S)

#### **Products Affected**

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

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

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

# SOMAVERT (S)

### **Products Affected**

• Somavert

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Acromegaly (initial): Diagnosis of acromegaly AND Failure to surgery<br>and/or radiation therapy and/or other medical therapies (such as dopamine<br>agonists [e.g., bromocriptine, cabergoline]) unless patient is not a<br>candidate for these treatment options AND trial and failure or intolerance<br>to generic octreotide (a somatostatin analogue) |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an endocrinologist   |
| Coverage<br>Duration               | Initial and reauth: 12 months  |
| Other Criteria                     | Acromegaly (reauth): Patient has experienced a positive clinical response<br>to therapy (biochemical control, decrease or normalization of IGF-1<br>levels).   |

#### **Products Affected**

• Itraconazole SOLN

• Itraconazole CAPS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | One of the following: 1) patient has a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), OR 2) all of the following:<br>a) patient has a diagnosis of onychomycosis confirmed by one of the following (CAPSULE ONLY): i) positive potassium hydroxide (KOH) preparation, OR ii) fungal culture, OR iii) nail biopsy, AND b) patient has had a trial and failure, contraindication, or intolerance to oral terbinafine, OR 3) both of the following (ORAL SOLUTION ONLY): a) patient has a diagnosis of candidiasis (esophageal or oropharyngeal), AND b) one of the following: i) candidiasis is refractory or resistant to treatment with fluconazole OR ii) trial and failure, contraindication, or intolerance to fluconazole. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Systemic fungal infxn:6mo.Candidiasis:1mo.Fingernail onycho:5wks.Toenail onycho, other:3mo.   |
| Other Criteria                     | N/A   |

## **SPRYCEL (S)**

### **Products Affected**

• Sprycel

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

### **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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe<br>plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of<br>moderate to severe plaque psoriasis. Patient's weight is greater than 100<br>kg (220 lbs). Plaque psoriasis (Initial): One of the following: at least 3%<br>body surface area (BSA) involvement, severe scalp psoriasis, OR<br>palmoplantar (ie, palms, soles), facial, or genital involvement. Psoriatic<br>arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA<br>(Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater<br>than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe<br>psoriasis. PsA (Initial): One of the following: actively inflamed joints,<br>dactylitis, enthesitis, axial disease, or active skin and/or nail involvement.<br>Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active<br>Crohn's disease. Will be used as a maintenance dose following the<br>intravenous induction dose. |
| Age Restrictions                   | N/A   |
| Prescriber<br>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<br>Duration               | All uses (Initial): 6 months. All uses (reauth): 12 months  |

| Other Criteria | Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely<br>active UC. Will be used as a maintenance dose following the intravenous<br>induction dose. PsA (Reauth): Documentation of positive clinical<br>response to therapy as evidenced by at least one of the following:<br>reduction in the total active (swollen and tender) joint count from<br>baseline, improvement in symptoms (eg, pain, stiffness, pruritus,<br>inflammation) from baseline, OR reduction in the BSA involvement from<br>baseline. Plaque psoriasis (Reauth): Documentation of positive clinical<br>response to therapy as evidenced by one of the following: reduction in the<br>body surface area (BSA) involvement from baseline, OR improvement in<br>symptoms (eg, pruritus, inflammation) from baseline. CD (Reauth), UC<br>(Reauth): Documentation of positive clinical response to therapy as<br>evidenced by at least one of the following: improvement in intestinal<br>inflammation (eg, mucosal healing, improvement of lab values [platelet<br>counts, erythrocyte sedimentation rate. C-reactive protein levell) from |
|----------------|--|
|                | 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Metastatic colorectal cancer (mCRC): Diagnosis of mCRC.<br>Gastrointestinal stromal tumor (GIST): Diagnosis of locally advanced,<br>unresectable or metastatic GIST. Hepatocellular Carcinoma (HCC):<br>Diagnosis of HCC. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

### **SUTENT (S)**

### **Products Affected**

• Sunitinib Malate

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

### SYMLIN (S)

#### **Products Affected**

• Symlinpen 120

• Symlinpen 60

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Initial: One of the following diagnoses: A) Type 1 diabetes OR B) Type 2 diabetes. Patient has failed to achieve desired glucose control despite optimal insulin therapy. Patient is taking concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Reauth: Patient has experienced an objective response to therapy<br>demonstrated by an improvement in HbA1c from baseline. Patient is<br>receiving concurrent mealtime insulin therapy (e.g., Humulin, Humalog,<br>Novolin, Novolog).                                       |

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# SYNRIBO (S)

### **Products Affected**

• Synribo

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Chronic myelogenous leukemia (CML): Diagnosis of CML in the chronic or accelerated phase. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

# **SYPRINE (S)**

### **Products Affected**

• Trientine Hydrochloride CAPS 250MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Initial: Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration).<br>Trial and failure, contraindication, or intolerance to a penicillamine<br>product (e.g., Depen, Cuprimine) |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Reauth: Documentation of a 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Diagnosis of non-small cell lung cancer (NSCLC). Disease is metastatic.<br>Presence of mesenchymal-epithelial transition (MET) exon 14 skipping<br>positive tumors as detected with an FDA-approved test or a test<br>performed at a facility approved by Clinical Laboratory Improvement<br>Amendments (CLIA). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

# TADLIQ (S)

### **Products Affected**

• Tadliq

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

# **TAFAMIDIS (S)**

### **Products Affected**

• Vyndamax

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM)<br>(initial): Diagnosis of transthyretin-mediated amyloidosis with<br>cardiomyopathy (ATTR-CM). One of the following: 1) Patient has a<br>transthyretin (TTR) mutation (e.g., V122I), 2) Cardiac or noncardiac<br>tissue biopsy demonstrating histologic confirmation of TTR amyloid<br>deposits, OR 3) All of the following: i) echocardiogram or cardiac<br>magnetic resonance imaging suggestive of amyloidosis, ii) scintigraphy<br>scan suggestive of cardiac TTR amyloidosis, and iii) absence of light-<br>chain amyloidosis. One of the following: 1) History of heart failure (HF),<br>with at least one prior hospitalization for HF, OR 2) Presence of clinical<br>signs and symptoms of HF (e.g., dyspnea, edema). Patient has New York<br>Heart Association (NYHA) Functional Class I, II, or III heart failure. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist  |
| Coverage<br>Duration               | ATTR-CM (initial, reauth): 12 months   |
| Other Criteria                     | ATTR-CM (reauth): Documentation of positive clinical response to<br>therapy. Patient continues to have New York Heart Association (NYHA)<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Melanoma: Diagnosis of unresectable or metastatic melanoma AND<br>cancer is BRAF V600E mutant type as detected by an FDA-approved test<br>(THxID-BRAF Kit) or a test performed at a facility approved by Clinical<br>Laboratory Improvement Amendments (CLIA) OR both of the following:<br>cancer is BRAF V600E or V600K mutant type as detected by an FDA-<br>approved test (THxID-BRAF Kit) or a test performed at a facility<br>approved by Clinical Laboratory Improvement Amendments (CLIA) and<br>medication is used in combination with Mekinist (trametinib). Adjuvant<br>Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF<br>V600E or V600K mutant type as detected by an FDA-approved test<br>(THxID-BRAF Kit) or a test performed at a facility approved by Clinical<br>Laboratory Improvement Amendments (CLIA). Involvement of lymph<br>nodes following complete resection. Used as adjunctive therapy.<br>Medication is used in combination with Mekinist (trametinib). Non-small<br>Cell Lung Cancer (NSCLC): Diagnosis of metastatic non-small cell lung<br>cancer AND cancer is BRAF V600E mutant type as detected by an FDA-<br>approved test (THxID-BRAF Kit) or a test performed at a facility<br>approved test (THxID-BRAF Kit) or a test performed at a facility<br>approved test (THxID-BRAF Kit) or a test performed at a facility<br>approved test (THxID-BRAF Kit) or a test performed at a facility<br>approved test (THxID-BRAF Kit) or a test performed at a facility<br>approved by Clinical Laboratory Improvement Amendments (CLIA)<br>AND medication is used in combination with Mekinist (trametinib).<br>Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or<br>metastatic anaplastic thyroid cancer. Cancer is BRAF V600E mutant type<br>as detected by an FDA-approved test (THxID-BRAF Kit) or a test<br>performed at a facility approved by Clinical Laboratory Improvement<br>Amendments (CLIA). Cancer may not be treated with standard<br>locoregional treatment options. Medication is used in combination with<br>Mekinist (trametinib) . |
| Age Restrictions                   | Solid tumors, Low-grade glioma: Patient is 1 year of age or older.   |
| Prescriber<br>Restrictions         | N/A  |

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| Coverage<br>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 test (THxID-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<br>Criteria              | N/A  |
| Required<br>Medical<br>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 test or a test performed at a facility approved test or a test performed at a facility 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. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | Approve for continuation of prior therapy.   |

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## TALZENNA (S)

### **Products Affected**

• Talzenna

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>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<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Non-small cell lung cancer (NSCLC): Diagnosis of locally advanced or<br>metastatic (Stage III or IV) NSCLC AND Patient has known active<br>epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21<br>(L858R) substitution mutation as detected by a U.S. Food and Drug<br>Administration (FDA)-approved test or a test performed at a facility<br>approved by Clinical Laboratory Improvement Amendments (CLIA).<br>Pancreatic Cancer: Diagnosis of locally advanced, unresectable, or<br>metastatic pancreatic cancer AND erlotinib will be used in combination<br>with gemcitabine. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Cutaneous T-Cell Lymphoma (CTCL): Diagnosis of CTCL. Trial and<br>failure, contraindication, or intolerance to at least one prior therapy<br>(including skin-directed therapies [eg, corticosteroids {ie, clobetasol,<br>diflorasone, halobetasol, augmented betamethasone dipropionate}] or<br>systemic therapies [eg, interferons]). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Epithelioid sarcoma: Diagnosis of epithelioid sarcoma. Disease is one of<br>the following: metastatic or locally advanced. Patient is not eligible for<br>complete resection. Follicular lymphoma: Diagnosis of follicular<br>lymphoma. Disease is one of the following: relapsed or refractory. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| Required<br>Medical<br>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<br>Restrictions         | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | MS (initial, reauth): 12 months  |
| Other Criteria                     | MS (reauth): Documentation of 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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis)<br>(initial): Diagnosis of hATTR amyloidosis with polyneuropathy. Patient<br>has a transthyretin (TTR) mutation (e.g., V30M). One of the following: 1)<br>Patient has a baseline polyneuropathy disability (PND) score less than or<br>equal to IIIb, 2) Patient has baseline familial amyloidotic polyneuropathy<br>(FAP) stage of 1 or 2, OR 3) Patient has a baseline neuropathy<br>impairment score (NIS) between 10 and 130. Presence of clinical signs<br>and symptoms of the disease (e.g., peripheral/autonomic neuropathy). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | hATTR amyloidosis (initial): Prescribed by or in consultation with a neurologist   |
| Coverage<br>Duration               | hATTR amyloidosis (initial, reauth): 12 months   |
| Other Criteria                     | hATTR amyloidosis (reauth): Patient has demonstrated a benefit from<br>therapy (e.g., improved neurologic impairment, slowing of disease<br>progression, quality of life assessment). One of the following: 1) Patient<br>continues to have a PND score less than or equal to IIIb, 2) Patient<br>continues to have a FAP stage of 1 or 2, OR 3) Patient continues to have a<br>NIS between 10 and 130.  |

# **ТЕРМЕТКО (S)**

### **Products Affected**

• Tepmetko

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

### **TERIPARATIDE (S)**

#### **Products Affected**

• Forteo INJ 600MCG/2.4ML

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

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

### **TESTOSTERONE (S)**

#### **Products Affected**

- Testosterone GEL 20.25MG/1.25GM, 40.5MG/2.5GM
- PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at Required Medical birth AND one of the following: 1) Two pre-treatment serum total Information 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. **Age Restrictions** HG (init): Patient is 18 years of age or older. Prescriber N/A **Restrictions** HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reauth): Coverage Duration 12 mo. GD: 12 mo.

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• Testosterone Pump GEL 1.62%

| normal lim<br>outside of r<br>adjusted, C<br>thyroid dis<br>of the follo<br>or below th<br>free or bioa | h): 1) Follow-up total serum T level within or below the<br>its of the reporting lab, or 2) Follow-up total serum T level<br>upper limits of normal for the reporting lab and the dose is<br>OR 3) Has a condition that may cause altered SHBG (eg,<br>order, HIV disease, liver disorder, diabetes, obesity), and one<br>owing: Follow-up calculated free or bioavailable T level within<br>ne normal limits of the reporting lab, or follow-up calculated<br>available T level outside of upper limits of normal for the<br>ab 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Multiple myeloma (MM): Diagnosis of MM. Used in combination with<br>dexamethasone, unless the patient has an intolerance to steroids.<br>Erythema nodosum leprosum (ENL): Diagnosis of moderate to severe<br>ENL with cutaneous manifestations. Thalomid is not used as<br>monotherapy if moderate to severe neuritis is present. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Relapsed or refractory Acute Myeloid Leukemia (AML): Diagnosis of<br>AML. Disease is relapsed or refractory. Newly-Diagnosed AML:<br>Diagnosis of newly-diagnosed AML. One of the following: 1) patient is<br>greater than or equal to 75 years old OR 2) patient has comorbidities that<br>preclude use of intensive induction chemotherapy. Locally Advanced or<br>Metastatic Cholangiocarcinoma: Diagnosis of cholangiocarcinoma.<br>Disease is locally advanced or metastatic. Patient has been previously<br>treated. All indications: Patient has an isocitrate dehydrogenase-1 (IDH1)<br>mutation as detected by a U.S. Food and Drug Administration (FDA)-<br>approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a<br>facility approved by Clinical Laboratory Improvement Amendments<br>(CLIA). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

### **TOPICAL RETINOID (S)**

#### **Products Affected**

- Tretinoin CREA
- Tretinoin GEL

• Tretinoin Microsphere GEL 0.04%, 0.1%

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

# TRIKAFTA (S)

### **Products Affected**

• Trikafta

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Cystic Fibrosis (CF) (initial): Diagnosis of CF. Patient has at least one of<br>the following mutations in the cystic fibrosis transmembrane conductance<br>regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis<br>mutation test or a test performed at a Clinical Laboratory Improvement<br>Amendments (CLIA)-approved facility: F508del mutation OR a mutation<br>in the CFTR gene that is responsive based on in vitro data. |
| Age Restrictions                   | CF (initial): For granule packets: patient is at least 2 to less than 6 years of age. For tablets: patient is 6 years of age or older.  |
| Prescriber<br>Restrictions         | CF (initial): Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center.   |
| Coverage<br>Duration               | CF (initial, reauth): 12 months   |
| Other Criteria                     | CF (reauth): Documentation of positive clinical response to therapy (e.g., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations).  |

### TUKYSA (S)

#### **Products Affected**

• Tukysa

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

### **TURALIO (S)**

### **Products Affected**

• Turalio CAPS 125MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Tenosynovial Giant Cell Tumor (TGCT): Diagnosis of TGCT. Patient is<br>symptomatic. Patient is not a candidate for surgery due to worsening<br>functional limitation or severe morbidity with surgical removal. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Breast Cancer: Diagnosis of human epidermal growth factor receptor 2<br>(HER2)-positive metastatic or recurrent breast cancer. Used in<br>combination with one of the following: Trastuzumab, Xeloda<br>(capecitabine), or aromatase inhibitors [eg, Aromasin (exemestane),<br>Femara (letrozole), Arimidex (anastrozole)]. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

### **UBRELVY (S)**

### **Products Affected**

• Ubrelvy

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>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. |
| Age Restrictions                   | Initial: 18 years of age or older.  |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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.   |

### **UDENYCA (S)**

#### **Products Affected**

• Udenyca

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

### UPTRAVI (S)

#### **Products Affected**

• Uptravi TABS

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Pulmonary arterial hypertension (PAH) (initial): Diagnosis of PAH. PAH Medical is symptomatic. One of the following: A) Diagnosis of PAH was Information confirmed by right heart catheterization OR B) Patient is currently on any therapy for the diagnosis of PAH. One of the following: A) Trial and failure, contraindication, or intolerance to a PDE5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)] or Adempas (riociguat), and trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g., Letairis (ambrisentan), Opsumit (macitentan), or Tracleer (bosentan)] OR B) For continuation of prior therapy. Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]. N/A **Age Restrictions** Prescriber PAH (initial): Prescribed by or in consultation with a pulmonologist or Restrictions cardiologist. Initial: 6 months. Reauth: 12 months Coverage Duration **Other Criteria** PAH (Reauth): Documentation of positive clinical response to therapy. Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)].

• Uptravi Titration Pack

### VALCHLOR (S)

#### **Products Affected**

• Valchlor

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL)<br>(initial): All of the following: 1) diagnosis of Stage IA MF-CTCL, OR<br>diagnosis of Stage IB MF-CTCL, AND 2) patient has received at least<br>one prior skin-directed therapy [e.g., topical corticosteroids, bexarotene<br>topical gel (Targretin topical gel), etc.]. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Acute Myeloid Leukemia (AML): Diagnosis of AML. Patient has a FMS-<br>like tyrosine kinase 3 (FLT3) internal tandem duplication (FLT3-ITD)<br>mutation as detected by a U.S. Food and Drug Administration (FDA)-<br>approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test<br>performed at a facility approved by Clinical Laboratory Improvement<br>Amendments (CLIA). Both of the following: a) Used in combination with<br>standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin)<br>induction and cytarabine consolidation, and b) Used as maintenance<br>monotherapy following consolidation chemotherapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Approve for continuation of prior therapy.  |

### VENCLEXTA (S)

#### **Products Affected**

• Venclexta

**PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A **Exclusion** N/A Criteria Required Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma Medical (SLL): Diagnosis of CLL or SLL. Acute Myeloid Leukemia (AML): Information 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 N/A **Restrictions** Coverage 12 months Duration **Other Criteria** Approve for continuation of prior therapy.

•

Venclexta Starting Pack

### **VENTAVIS (S)**

#### **Products Affected**

• Ventavis

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

## VITRAKVI (S)

#### **Products Affected**

• Vitrakvi

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Presence of solid tumors (e.g., salivary gland, soft tissue sarcoma,<br>infantile fibrosarcoma, thyroid cancer, lung, melanoma, colon, etc.).<br>Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene<br>fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.).<br>Disease is without a known acquired resistance mutation [e.g., TRKA<br>G595R substitution, TRKA G667C substitution, or other recurrent kinase<br>domain (solvent front and xDFG) mutations]. Disease is one of the<br>following: metastatic or unresectable (including cases where surgical<br>resection is likely to result in severe morbidity). One of the following:<br>Disease has progressed on previous treatment (e.g., surgery, radiotherapy,<br>or systemic therapy) OR Disease has no satisfactory alternative<br>treatments. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is<br>metastatic. Disease is positive for one of the following epidermal growth<br>factor receptor (EGFR) mutations: exon 19 deletion or exon 21 L858R<br>substitution. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Diagnosis of ONE of the following: a) Primary myelofibrosis, b) Post-<br>polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia<br>myelofibrosis. Disease is intermediate or high risk. Pre-treatment platelet<br>count below 50 x 10^9/L. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Invasive aspergillosis: Diagnosis of invasive aspergillosis (IA).<br>Candidemia: Diagnosis of candidemia. One of the following: (1) patient is<br>non-neutropenic or (2) infection is located in skin, abdomen, kidney,<br>bladder wall, or wounds. Esophageal Candidiasis: Diagnosis of<br>esophageal candidiasis. Mycosis: Diagnosis of fungal infection caused by<br>Scedosporium apiospermum (asexual form of Pseudallescheria boydii) or<br>Fusarium spp. including Fusarium solani. For fusariosis: Patient is<br>intolerant of, or refractory to, other therapy (e.g., liposomal amphotericin<br>B, amphotericin B lipid complex). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 12 weeks  |
| Other Criteria                     | N/A   |

# **VOTRIENT (S)**

#### **Products Affected**

• Votrient

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

### **VUMERITY (S)**

#### **Products Affected**

• Vumerity

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| Required<br>Medical<br>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) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | MS (initial, reauth): 12 months  |
| Other Criteria                     | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).  |

### WELIREG (S)

#### **Products Affected**

• Welireg

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Diagnosis of von Hippel-Lindau (VHL) disease. Patient requires therapy<br>for one of the following: a) renal cell carcinoma (RCC), b) central<br>nervous system (CNS) hemangioblastoma, or c) pancreatic<br>neuroendocrine tumor (pNET). Patient does not require immediate<br>surgery. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Non-small cell lung cancer (NSCLC): Diagnosis of advanced or<br>metastatic NSCLC AND One of the following: A) Patient has an<br>anaplastic lymphoma kinase (ALK)-positive tumor as detected with a<br>U.S. Food and Drug Administration (FDA)-approved test or a test<br>performed at a facility approved by Clinical Laboratory Improvement<br>Amendments (CLIA) or B) Patient has MET amplification- or ROS1<br>rearrangement-positive tumor as detected with an FDA-approved test or a<br>test performed at a facility approved by Clinical Laboratory Improvement<br>Amendments (CLIA). Anaplastic Large Cell Lymphoma (ALCL):<br>Diagnosis of systemic ALCL. Disease is relapsed or refractory. Patient<br>has an anaplastic lymphoma kinase (ALK)-positive tumor as detected<br>with a U.S. Food and Drug Administration (FDA)-approved test or a test<br>performed at a facility approved by Clinical Laboratory Improvement<br>Amendments (CLIA). Inflammatory Myofibroblastic Tumor (IMT):<br>Diagnosis of IMT. Disease is one of the following: a) unresectable, b)<br>recurrent, or c) refractory. Patient has an anaplastic lymphoma kinase<br>(ALK)-positive tumor as detected with a U.S. Food and Drug<br>Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement<br>Amendments (CLIA). Inflammatory Myofibroblastic Tumor (IMT):<br>Diagnosis of JMT. Disease is one of the following: a) unresectable, b)<br>recurrent, or c) refractory. Patient has an anaplastic lymphoma kinase<br>(ALK)-positive tumor as detected with a U.S. Food and Drug<br>Administration (FDA)-approved test or a test performed at a facility<br>approved by Clinical Laboratory Improvement Amendments (CLIA). |
| Age Restrictions                   | IMT: Patient is 1 year of age or older.   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Diagnosis of partial onset seizures.       |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 12 months                                  |
| Other Criteria                     | Approve for continuation of prior therapy. |

### **Products Affected**

• Xeljanz Xr

• Xeljanz

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Xeljanz tab/Xeljanz XR tab: Rheumatoid arthritis (RA) (Initial):<br>Diagnosis of moderately to severely active RA. Minimum duration of a 3-<br>month trial and failure, contraindication, or intolerance (TF/C/I) to one of<br>the following conventional therapies at maximally tolerated doses:<br>methotrexate, leflunomide, sulfasalazine. Psoriatic arthritis (PsA) (Initial):<br>Diagnosis of active PsA. One of the following: actively inflamed joints,<br>dactylitis, enthesitis, axial disease, or active skin and/or nail involvement.<br>Ankylosing spondylitis (AS) (Initial): Diagnosis of active AS. Minimum<br>duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory<br>drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses.<br>RA, PsA, AS (Initial): Patient has had an inadequate response or<br>intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept).<br>Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely<br>active UC. One of the following: greater than 6 stools per day, frequent<br>blood in the stools, frequent urgency, presence of ulcers, abnormal lab<br>values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to,<br>corticosteroids. TF/C/I to one of the following conventional therapies: 6-<br>mercaptopurine, aminosalicylate (e.g., mesalamine, olsalazine,<br>sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). Patient<br>has had an inadequate response or intolerance to one or more TNF<br>inhibitors (eg, adalimumab). Not used in combination with other Janus<br>kinase (JAK) inhibitors, biological therapies for UC, or potent<br>immunosuppressants (e.g., azathioprine, cyclosporine). |
| Age Restrictions                   | N/A  |
| Prescriber<br>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<br>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):<br>Diagnosis of active polyarticular course juvenile idiopathic arthritis.<br>Minimum duration of a 6-week TF/C/I to one of the following<br>conventional therapies at maximally tolerated doses: leflunomide or<br>methotrexate. Patient has had an inadequate response or intolerance to one<br>or more TNF inhibitors (eg, adalimumab, etanercept). RA, PsA, AS, PJIA<br>(Initial): Not used in combination with other JAK inhibitors, biologic<br>disease-modifying antirheumatic drugs (DMARDs), or potent<br>immunosuppressants (eg, azathioprine, cyclosporine). RA, PJIA (Reauth):<br>Documentation of positive clinical response to therapy as evidenced by at<br>least one of the following: reduction in the total active (swollen and<br>tender) joint count from baseline OR improvement in symptoms (eg, pain,<br>stiffness, inflammation) from baseline. PsA (Reauth): Documentation of<br>positive clinical response to therapy as evidenced by at least one of the<br>following: reduction in the total active (swollen and tender) joint count<br>from baseline, improvement in symptoms (eg, pain, stiffness, pruritus,<br>inflammation) from baseline, OR reduction in the BSA involvement from<br>baseline. AS (Reauth): Documentation of positive clinical response to<br>therapy as evidenced by improvement from baseline for at least one of the<br>following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab<br>values (erythrocyte sedimentation rate, C-reactive protein level), function,<br>axial status (eg, lumbar spine motion, chest expansion), OR total active<br>(swollen and tender) joint count. RA, PsA, AS, PJIA (reauth): Not used in<br>combination with other JAK inhibitors, biologic DMARDs, or potent<br>immunosuppressants (eg, azathioprine, cyclosporine). UC (Reauth):<br>Documentation of positive clinical response to therapy as evidenced by at<br>least one of the following: improvement in intestinal inflammation (eg,<br>mucosal healing, improvement of lab values [platelet counts, erythrocyte<br>sedimentation rate, C-reactive protein level]) |

## XENAZINE (S)

#### **Products Affected**

• Tetrabenazine

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

## XERMELO (S)

### **Products Affected**

• Xermelo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Carcinoid syndrome diarrhea (Initial): Diagnosis of carcinoid syndrome<br>diarrhea AND diarrhea is inadequately controlled by a stable dose of<br>somatostatin analog (SSA) therapy (e.g., octreotide [Sandostatin,<br>Sandostatin LAR], lanreotide [Somatuline Depot]) for at least 3 months<br>AND used in combination with SSA therapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | Initial: Prescribed by or in consultation with an oncologist,<br>endocrinologist, or gastroenterologist  |
| Coverage<br>Duration               | Initial: 6 months. Reauth: 12 months   |
| Other Criteria                     | Carcinoid syndrome diarrhea (Reauthorization): Documentation of a 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Multiple Myeloma (MM)/Bone metastasis from solid tumors (BMST):<br>One of the following: 1) Both of the following: a) Diagnosis of multiple<br>myeloma and b) Trial and failure, contraindication (e.g., renal<br>insufficiency), or intolerance to one bisphosphonate therapy, OR 2) Both<br>of the following: a) Diagnosis of solid tumors (eg, breast cancer, kidney<br>cancer, lung cancer, prostate cancer, thyroid cancer) and b) Documented<br>evidence of one or more metastatic bone lesions. Giant cell tumor of bone<br>(GCTB): Both of the following: 1) Diagnosis of giant cell tumor of bone<br>AND 2) One of the following: a) tumor is unresectable, OR b) surgical<br>resection is likely to result in severe morbidity. Hypercalcemia of<br>malignancy (HCM): Both of the following: 1) Diagnosis of hypercalcemia<br>of malignancy, AND 2) Trial and failure, contraindication, or intolerance<br>to one bisphosphonate therapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Travelers' diarrhea (TD) (200 mg strength only): Diagnosis of travelers' diarrhea, AND 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 of hepatic encephalopathy (HE) recurrence (550mg strength only): Used for the prophylaxis of hepatic encephalopathy recurrence, AND trial and failure, contraindication or intolerance to lactulose. Treatment of HE: Used for the treatment of HE. Trial and failure, contraindication, or intolerance to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (550mg strength only) (initial): Diagnosis of IBS-D, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide]. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | TD: 14 days. HE (prophylaxis, treatment): 12 months. IBS-D (initial, reauth): 2 weeks.   |
| Other Criteria                     | IBS-D (reauth): Patient experiences IBS-D symptom recurrence.  |

### XOLAIR (S)

#### **Products Affected**

• Xolair

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Asthma (init): Diagnosis of moderate to severe persistent allergic asthma.<br>Positive skin test or in vitro reactivity to a perennial aeroallergen.<br>Pretreatment serum immunoglobulin (Ig)E level between 30 to 700<br>IU/mL for patients 12 years of age and older OR 30 to 1300 IU/mL for<br>patients 6 years to less than 12 years of age. Patient is currently being<br>treated with one of the following unless there is a contraindication or<br>intolerance to these medications: a) Both of the following: i) High-dose<br>inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone<br>propionate equivalent/day] and ii) additional asthma controller medication<br>(e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-<br>2 agonist [LABA] [e.g., salmeterol], tiotropium), OR b) One maximally-<br>dosed combination ICS/LABA product [e.g., Advair (fluticasone<br>propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta<br>(fluticasone/vilanterol)]. Chronic Spontaneous Urticaria (CSU) (init):<br>Diagnosis of CSU. Persistent symptoms (itching and hives) with a second<br>generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is<br>a contraindication or intolerance to H1 antihistamines. Patient has tried<br>and had an inadequate response or intolerance or contraindication to at<br>least one of the following additional therapies: H2 antagonist (e.g.,<br>famotidine, cimetidine), leukotriene receptor antagonist (e.g.,<br>montelukast), H1 antihistamine, hydroxyzine, doxepin. Used concurrently<br>with an H1 antihistamine, unless there is a contraindication or intolerance<br>to H1 antihistamines. Chronic Rhinosinusitis with Nasal polyps<br>(CRSwNP) (init): Diagnosis of CRSwNP. Unless contraindicated, the<br>patient has had an inadequate response to an intranasal corticosteroid<br>(e.g., fluticasone, mometasone). Used in combination with another agent<br>for chronic rhinosinusitis with nasal polyps. |
| Age Restrictions                   | N/A   |

| Prescriber<br>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.   |
|----------------------------|--|
| Coverage<br>Duration       | Asthma, init: 6 mo, reauth: 12 mo. CSU, init: 3 mo, reauth: 6 mo. CRSwNP, init/reauth: 12 mo.  |
| Other Criteria             | Asthma (reauth): Documentation of positive clinical response to therapy<br>(e.g., Reduction in asthma exacerbations, improvement in forced<br>expiratory volume in 1 second (FEV1), decreased use of rescue<br>medications). Patient continues to be treated with an inhaled<br>corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without<br>additional asthma controller medication (e.g., leukotriene receptor<br>antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g.,<br>salmeterol], tiotropium) unless there is a contraindication or intolerance to<br>these medications. CSU (reauth): Patient's disease status has been re-<br>evaluated since the last authorization to confirm the patient's condition<br>warrants continued treatment. Patient has experienced one or both of the<br>following: Reduction in itching severity from baseline or Reduction in the<br>number of hives from baseline. CRSwNP (reauth): Documentation of a<br>positive clinical response to therapy (e.g., reduction in nasal polyps score<br>[NPS: 0-8 scale], improvement in nasal congestion/obstruction score<br>[NCS: 0-3 scale]). Used in combination with another agent for chronic<br>rhinosinusitis with nasal polyps. |

### XOSPATA (S)

### **Products Affected**

• Xospata

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

### **XPOVIO (S)**

#### **Products Affected**

• Xpovio

- Xpovio 60 Mg Twice Weekly
- Xpovio 80 Mg Twice Weekly

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Multiple Myeloma (MM), Diffuse large B-cell lymphoma (DLBCL):<br>Diagnosis of one of the following: 1) DLBCL OR 2) Multiple Myeloma. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Castration-resistant or castration-recurrent prostate cancer (CRPC):<br>Diagnosis of castration-resistant (chemical or surgical) or recurrent<br>prostate cancer. Castration-sensitive prostate cancer (CSPC): Diagnosis of<br>castration-sensitive prostate cancer. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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 N/A Criteria Required Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of Medical narcolepsy as confirmed by sleep study (unless the prescriber provides Information 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. N/A **Age Restrictions** Prescriber All uses (initial): Prescribed by or in consultation with one of the Restrictions following: neurologist, psychiatrist, or sleep medicine specialist. Coverage All uses (initial): 6 months. All uses (reauth): 12 months Duration 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.

• Xyrem

#### **Products Affected**

• Yuflyma 1-pen Kit

#### **PA** Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely Medical active RA. Minimum duration of a 3-month trial and failure, Information 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

Yuflyma 2-syringe Kit

| Prescriber<br>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<br>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): Documentation of 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): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the BSA involvement from baseline, OR reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction of 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): Documentation of positive clinical response to therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of |
|----------------|---|
|                | following: improvement in intestinal inflammation (eg, mucosal healing,   |

# ZAVESCA (S)

## **Products Affected**

• Miglustat

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

# ZEPOSIA (S)

### **Products Affected**

• Zeposia

- Zeposia 7-day Starter Pack
- Zeposia Starter Kit

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS<br>(e.g., clinically isolated syndrome, relapsing-remitting disease, secondary<br>progressive disease, including active disease with new brain lesions). One<br>of the following: a) Failure after a trial of at least 4 weeks,<br>contraindication, or intolerance to two of the following disease-modifying<br>therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or<br>3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of<br>prior therapy. Ulcerative Colitis (UC) (init): Diagnosis of moderately to<br>severely active UC. One of the following: greater than 6 stools per day,<br>frequent blood in the stools, frequent urgency, presence of ulcers,<br>abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or<br>refractory to, corticosteroids. One of the following: a) Trial and failure,<br>contraindication, or intolerance to two of the following: Humira<br>(adalimumab)/Cyltezo/or Yuflyma, Stelara (ustekinumab), Rinvoq<br>(upadacitinib), or Xeljanz IR (tofacitinib IR)/Xeljanz XR (tofacitinib XR),<br>OR b) for continuation of prior therapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | MS (initial, reauth): Prescribed by or in consultation with a neurologist.<br>UC (init): Prescribed by or in consultation with a gastroenterologist.  |
| Coverage<br>Duration               | MS (initial, reauth): 12 months. UC (init): 12 weeks, (reauth): 12 months.  |

| Other Criteria | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). UC (reauth): Documentation of 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.  |

# ZOKINVY (S)

## **Products Affected**

• Zokinvy

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

# **ZORBTIVE (S)**

## **Products Affected**

• Zorbtive

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Short Bowel Syndrome (SBS): Diagnosis of SBS. Patient is currently receiving specialized nutritional support (eg, intravenous parenteral nutrition, fluid, and micronutrient supplements). Patient has not previously received 4 weeks of treatment with Zorbtive (somatropin). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a gastroenterologist.   |
| Coverage<br>Duration               | SBS: 4 weeks.   |
| Other Criteria                     | N/A   |

# ZTALMY (S)

## **Products Affected**

• Ztalmy

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>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<br>Restrictions         | Prescribed by or in consultation with a neurologist.   |
| Coverage<br>Duration               | 12 months  |
| 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<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Used in<br>combination with Rituxan (rituximab). The patient has relapsed on at least<br>one prior therapy (eg, purine analogues [fludarabine, pentostatin,<br>cladribine], alkylating agents [chlorambucil, cyclophosphamide], or<br>monoclonal antibodies [rituximab]). Patient is a candidate for Rituxan<br>(rituximab) monotherapy due to presence of other comorbidities (eg,<br>coronary artery disease, peripheral vascular disease, diabetes mellitus,<br>pulmonary disease [COPD]). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC that is<br>metastatic or recurrent. Tumor is anaplastic lymphoma kinase (ALK)-<br>positive as detected by a U.S. Food and Drug Administration (FDA)-<br>approved test or a test performed at a facility approved by Clinical<br>Laboratory Improvement Amendments (CLIA). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>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<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Castration-Resistant Prostate Cancer (CRPC): Diagnosis of castration-<br>resistant (chemical or surgical) or recurrent prostate cancer. Castration-<br>Sensitive Prostate Cancer (CSPC): Diagnosis of castration-sensitive<br>prostate cancer. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | CRPC, CSPC: 12 months  |
| Other Criteria                     | Approve for continuation of prior therapy  |

## PART B VERSUS PART D

#### **Products Affected**

- Abelcet
- Acetylcysteine SOLN
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Ambisome
- Amphotericin B INJ
- Amphotericin B Liposome
- Aprepitant CAPS
- Arformoterol Tartrate
- Astagraf XL
- Azathioprine TABS
- Budesonide SUSP
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix E 2.75%/dextrose 5% INJ 570MG/100ML; 316MG/100ML; 33MG/100ML; 5GM/100ML; 515MG/100ML; 132MG/100ML; 165MG/100ML; 201MG/100ML; 159MG/100ML; 51MG/100ML; 154MG/100ML; 454MG/100ML; 187MG/100ML; 161MG/100ML; 116MG/100ML; 50MG/100ML; 11MG/100ML; 160MG/100ML
- Clinimix E 4.25%/dextrose 10%
- Clinimix E 4.25%/dextrose 5%
- Clinimix E 5%/dextrose 15%
- Clinimix E 5%/dextrose 20%
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclophosphamide TABS
- Cyclosporine CAPS
- Cyclosporine Modified
- Emend SUSR

- Engerix-b
- Envarsus Xr
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Formoterol Fumarate NEBU
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hydrochloride TABS
- Heplisav-b
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU 0.31MG/3ML, 1.25MG/3ML
- Levalbuterol Hydrochloride NEBU 0.63MG/3ML
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nutrilipid
- Ondansetron Hcl SOLN
- Ondansetron Hydrochloride TABS
- Ondansetron Odt
- 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

- Premasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 492MG/100ML; 526MG/100ML; 356MG/100ML; 356MG/100ML; 390MG/100ML; 34MG/100ML; 152MG/100ML
- Prograf PACK
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- Rabavert
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- Sirolimus SOLN
- Sirolimus TABS
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- Travasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 492MG/100ML; 526MG/100ML; 356MG/100ML; 500MG/100ML; 34MG/100ML; 152MG/100ML
- Trimethobenzamide Hydrochloride
- Trophamine INJ 0.54GM/100ML; 1.2GM/100ML; 0.32GM/100ML; 0; 0; 0.5GM/100ML; 0.36GM/100ML; 0.48GM/100ML; 0.82GM/100ML; 1.4GM/100ML; 1.2GM/100ML; 0.34GM/100ML; 0.48GM/100ML; 0.68GM/100ML; 0.38GM/100ML; 5MEQ/L; 0.025GM/100ML; 0.42GM/100ML; 0.2GM/100ML; 0.24GM/100ML; 0.78GM/100ML

### 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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