

### **ABIRATERONE**

#### **Products Affected**

• abiraterone acetate

#### • ZYTIGA ORAL TABLET 500 MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Castration-resistant metastatic prostate cancer and used in combination with prednisone, or B.) High risk, castration-sensitive metastatic prostate cancer and used in combination with prednisone |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or urologist   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **ACTIMMUNE**

### **Products Affected**

ACTIMMUNE

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Chronic granulomatous disease for use in reducing the frequency and severity of serious infections, or B.) Severe, malignant osteopetrosis (SMO) |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **ADEMPAS**

### **Products Affected**

ADEMPAS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) Concomitant administration with nitrates or nitric oxide donors (such as amyl nitrate) in any form, B.) Concomitant administration with phosphodiesterase inhibitors, including specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or non-specific PDE inhibitors (such as dipyridamole or theophylline), C.) Pregnancy, or D.) Patients with pulmonary hypertension associated with idiopathic interstitial pneumonia  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Pulmonary arterial hypertension (WHO group I) and diagnosis was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.), or B.) Chronic thromboembolic pulmonary hypertension (CTEPH, WHO group 4) and patient has persistent or recurrent disease after surgical treatment (e.g., pulmonary endarterectomy) or has CTEPH that is inoperable (Female patients must be enrolled in the ADEMPAS REMS program) |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist or cardiologist  |
| Coverage<br>Duration               | Initial: 6 months, Renewal: 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **AFINITOR DISPERZ**

### **Products Affected**

• AFINITOR DISPERZ

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Tuberous sclerosis complex (TSC)-associated partial-onset seizures, or B.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or neurologist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **ALECENSA**

### **Products Affected**

ALECENSA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer as detected by an FDA-approved test |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **ALPHA-1 PROTEINASE INHIBITOR**

### **Products Affected**

 PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency in adult patients with emphysema |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | B vs D determination required per CMS guidance  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **ALUNBRIG**

### **Products Affected**

ALUNBRIG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of anaplastic lymphoma kinase-positive (ALK) metastatic non-small cell lung cancer (NSCLC) |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or hematologist                                  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **ALYQ**

### **Products Affected**

• ALYQ

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Concurrent use of organic nitrate or guanylate cyclase stimulators (includes intermittent use)   |
| Required<br>Medical<br>Information | Diagnosis of Pulmonary arterial hypertension (PAH) confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization. |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **AMBRISENTAN**

### **Products Affected**

• ambrisentan

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) Pregnancy, or B.) Idiopathic pulmonary fibrosis (IPF), including those with pulmonary hypertension  |
| Required<br>Medical<br>Information | Diagnosis of pulmonary arterial hypertension classified as WHO Group I, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist or cardiologist  |
| Coverage<br>Duration               | Initial: 6 months, Renewal: 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **AMPHETAMINES**

#### **Products Affected**

- amphetamine-dextroamphet er
- dextroamphetamine sulfate oral

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Concomitant use or use within 14 days of MAOI administration, except if prescriber is a psychiatrist with experience prescribing both MAOI and amphetamine/dextroamphetamine drugs  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Attention deficit hyperactivity disorder (ADHD), or B.) Narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **ARCALYST**

#### **Products Affected**

ARCALYST

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells Syndrome (MWS) |
| Age Restrictions                   | 12 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **ARIKAYCE**

### **Products Affected**

ARIKAYCE

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of pulmonary Mycobacterium avium complex (MAC) infection and used as part of a combination antibacterial regimen in treatment refractory patients |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an infectious disease specialist or pulmonologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **AURYXIA**

### **Products Affected**

AURYXIA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Iron overload syndrome (e.g. hemochromatosis)  |
| Required<br>Medical<br>Information | Diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a hematologist or nephrologist                     |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | Ferric Citrate is NOT approvable for iron deficiency anemia per Part D law               |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **AUSTEDO**

### **Products Affected**

AUSTEDO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following A.) Suicidal ideation and/or untreated or inadequately treated depression, B.) Hepatic impairment, C.) Taking MAOIs, reserpine, or tetrabenazine |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Chorea associated with Huntington's disease (Huntington's chorea), or B.) Tardive dyskinesia                                    |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or psychiatrist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **AYVAKIT**

### **Products Affected**

AYVAKIT

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of unresectable or metastatic gastrointestinal stromal tumor, with a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **BALVERSA**

### **Products Affected**

BALVERSA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 or FGFR2 genetic alterations and patient has progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or urologist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **BOSENTAN**

### **Products Affected**

bosentan

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) Concomitant cyclosporine A or glyburide therapy, or B.) Pregnancy   |
| Required<br>Medical<br>Information | Diagnosis of pulmonary arterial hypertension (WHO Group I) and patient has New York Heart Association (NYHA) Functional Class II-IV, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.) |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with pulmonologist or cardiologist  |
| Coverage<br>Duration               | Initial: 6 months, Renewal: 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **BOSULIF**

### **Products Affected**

BOSULIF

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or inadequate response to prior therapy, or B.) Newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) CML |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **BRAFTOVI**

### **Products Affected**

• BRAFTOVI ORAL CAPSULE 75 MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) unresectable or metastatic melanoma with documented BRAF V600E or V600K mutation as detected by an FDA-approved test and used in combination with binimetinib, or B.) metastatic colorectal cancer with documented BRAF V600E mutation as detected by an FDA-approved test, patient has received prior therapy, and braftovi used in combination with cetuximab. |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **BRUKINSA**

### **Products Affected**

BRUKINSA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of A.) Mantle Cell Lymphoma (MCL) and patient has received at least one prior therapy |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **CABLIVI**

### **Products Affected**

CABLIVI

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) and used in combination with plasma exchange and immunosuppression therapy |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a hematologist or oncologist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **CABOMETYX**

### **Products Affected**

CABOMETYX

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Advanced renal cell carcinoma, or B.) Advanced hepatocellular carcinoma (HCC) and patient has been previously treated with sorafenib |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



# **CALQUENCE**

### **Products Affected**

• CALQUENCE

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Mantle cell lymphoma (MCL) and patient has received at least 1 prior therapy, B.) Chronic lymphocytic leukemia (CLL), or C.) Small lymphocytic lymphoma (SLL) |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or hematologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **CAPRELSA**

### **Products Affected**

CAPRELSA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Congenital long QT syndrome   |
| Required<br>Medical<br>Information | Diagnosis of metastatic or unresectable locally advanced medullary thyroid cancer (MTC) AND disease is symptomatic or progressive |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **CAYSTON**

### **Products Affected**

CAYSTON

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has suspected or confirmed Pseudomonas aeruginosa infection |
| Age Restrictions                   | 7 years of age and older  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **CINRYZE**

### **Products Affected**

CINRYZE

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) hereditary angioedema, used in prevention of angioedema attacks, or B.) hereditary angioedema, used in prevention of acute abdominal, facial, or laryngeal attacks |
| Age Restrictions                   | 6 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a hematologist, immunologist, or allergist   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **CNS STIMULANTS**

### **Products Affected**

• armodafinil

• modafinil

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Obstructive sleep apnea (OSA) confirmed by sleep lab evaluation, B.) Narcolepsy confirmed by sleep lab evaluation, or C.) Shift work disorder (SWD) |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **COMETRIQ**

#### **Products Affected**

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

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of progressive, metastatic medullary thyroid cancer |
| Age Restrictions                   | 18 years of age and older                                     |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.                           |
| Off-Label Uses                     | N/A   |



### **COPIKTRA**

#### **Products Affected**

COPIKTRA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A) chronic lymphocytic leukemia, OR B) small lymphocytic lymphoma, OR C) follicular lymphoma, AND disease is relapsed or refractory, AND patient has history of at least 2 prior therapies |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or hematologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **CORLANOR**

#### **Products Affected**

• CORLANOR ORAL TABLET

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) Decompensated acute heart failure, B.) hypotension (i.e. blood pressure less than 90/50 mmHg), C.) sick sinus syndrome or sinoatrial block or 3rd degree AV block (unless a functioning demand pacemaker is present), D.) bradycardia (i.e., resting heart rate less than 60 bpm prior to treatment), or E.) Severe hepatic impairment (Child-Pugh C)   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) stable, symptomatic chronic heart failure with left ventricular ejection fraction 35% or less, who are in sinus rhythm with resting heart rate 70 beats per minute or more and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use, or B.) stable, symptomatic heart failure due to dilated cardiomyopathy in patients who are in sinus rhythm with an elevated heart rate |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **COSENTYX**

#### **Products Affected**

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

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Ankylosing spondylitis and patient has failed or is intolerant to Humira and Enbrel, B.) Moderate to severe plaque psoriasis and patient has failed or is intolerant to Humira and Enbrel, C.) Active psoriatic arthritis and patient has failed or is intolerant to Humira and Enbrel, or D.) Non-radiographic axial spondyloarthritis |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Screening for latent tuberculosis infection is required prior to initiation of treatment  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **COTELLIC**

### **Products Affected**

COTELLIC

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of unresectable or metastatic malignant melanoma with BRAF V600E OR V600K mutation, and documentation of combination therapy with vemurafenib (Zelboraf) |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **CYSTARAN**

### **Products Affected**

CYSTARAN

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) Demonstrated cysteamine hypersensitivity, B.) Demonstrated penicillamine hypersensitivity |
| Required<br>Medical<br>Information | Diagnosis of cystinosis and patient has corneal cystine crystal accumulation                                       |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **DALFAMPRIDINE**

### **Products Affected**

• dalfampridine er

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) History of seizure. B.) Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute)   |
| Required<br>Medical<br>Information | Diagnosis of multiple sclerosis and patient must demonstrate sustained walking impairment, but with the ability to walk 25 feet (with or without assistance) prior to starting dalfampridine |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **DAURISMO**

#### **Products Affected**

DAURISMO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of newly diagnosed acute myeloid leukemia (AML) and used in combination with cytarabine in patients 75 years of age or older OR in patients that have comorbidities that preclude use of intensive induction chemotherapy |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or hematologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **DEFERASIROX**

### **Products Affected**

• deferasirox

|                                    | T  |
|------------------------------------|--|
| PA Criteria                        | Criteria Details   |
| Exclusion<br>Criteria              | Any of the following A.) Creatinine clearance less than 40 mL/min, B.) Poor performance status, C.) Platelet count less than 50 x 10(9)/L, D.) Advanced malignancy, E.) High-risk myelodysplastic syndrome (MDS)   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes who have liver iron concentrations of at least 5 mg Fe/g dry weight AND serum ferritin level greater than 300 mcg/L, or B.) Chronic iron overload due to blood transfusions (transfusion hemosiderosis) as evidenced by transfusion of at least 100 mL/kg packed red blood cells AND serum ferritin level greater than 1000 mcg/L |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **DICLOFENAC TOPICAL**

#### **Products Affected**

• diclofenac sodium transdermal gel 3 %

| PA Criteria                        | Criteria Details                    |
|------------------------------------|-------------------------------------|
| Exclusion<br>Criteria              | None                                |
| Required<br>Medical<br>Information | Diagnosis of Actinic keratosis      |
| Age Restrictions                   | None                                |
| Prescriber<br>Restrictions         | None                                |
| Coverage<br>Duration               | 12 months                           |
| Other Criteria                     | None                                |
| Indications                        | All Medically-accepted Indications. |
| Off-Label Uses                     | N/A                                 |



### **DIMETHYL FUMARATE**

#### **Products Affected**

• dimethyl fumarate oral

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **DOJOLVI**

#### **Products Affected**

DOJOLVI

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of Long-chain fatty acid oxidation disorder (LC-FAOD) |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.                             |
| Off-Label Uses                     | N/A   |



### **DRONABINOL**

#### **Products Affected**

dronabinol

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Sesame oil hypersensitivity  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Anorexia associated to AIDS, or B.) Chemotherapy-induced nausea and vomiting |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 6 months   |
| Other Criteria                     | B vs D determination required per CMS guidance   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **DUPIXENT**

#### **Products Affected**

DUPIXENT

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Moderate to severe atopic dermatitis and patient has trial and failure, contraindication, or intolerance to two medium to high potency topical corticosteroids (e.g., mometasone, triamcinolone, fluocinolone, betamethasone, etc), or B.) Eosinophilic phenotype or oral corticosteroid- dependent moderate to severe asthma and used as an adjunct treatment, or C.) Chronic rhinosinusitis with nasal polyposis and used as an adjunct treatment |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an allergist, dermatologist, immunologist, otolaryngologist, pulmonologist, or rheumatologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **ENBREL**

#### **Products Affected**

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML
- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED
- ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, or E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | Screening for latent tuberculosis infection is required prior to initiation of treatment   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **ENDARI**

#### **Products Affected**

ENDARI

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Acute sickle cell disease, or B.) Short bowel syndrome and combined with recombinant human growth hormone |
| Age Restrictions                   | 5 years of age and older  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **ENSPRYNG**

#### **Products Affected**

ENSPRYNG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following A.) Active Hepatitis B infection, or B.) Active or untreated latent tuberculosis                     |
| Required<br>Medical<br>Information | Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or immunologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **ENTRESTO**

#### **Products Affected**

ENTRESTO

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) History of angioedema related to previous ACE inhibitor or ARB therapy, B.) Concomitant use or use within 36 hours of ACE inhibitors, or C.) Concomitant use of aliskiren in patients with diabetes |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Chronic heart failure, NYHA Class II to IV, or B.) Symptomatic heart failure with systemic left ventricular systolic dysfunction   |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **EPIDIOLEX**

#### **Products Affected**

EPIDIOLEX

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Lennox-Gastaut syndrome, or B.) Severe myoclonic epilepsy in infancy (Dravet syndrome), or C.) Seizures associated with tuberous sclerosis complex |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **EPOETIN THERAPY**

#### **Products Affected**

RETACRIT

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Pretreatment hemoglobin levels of less than 10g/dL. Dose reduction or interruption if hemoglobin exceeds 10 g/dL (CKD not on dialysis-adult, cancer), 11 g/dL (CKD on dialysis), 12 g/dL (pediatric CKD) in addition to supporting statement of diagnosis from physician. |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | B vs D determination required per CMS guidance  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **ERLEADA**

#### **Products Affected**

ERLEADA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Nonmetastatic, castration-resistant prostate cancer, or B.) Metastatic, castration-sensitive prostate cancer |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or urologist   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **ERLOTINIB**

#### **Products Affected**

• erlotinib hcl

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



### **ESBRIET**

#### **Products Affected**

• ESBRIET ORAL CAPSULE • ESBRIET ORAL TABLET 801 MG

| PA Criteria                        | Criteria Details                                      |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of idiopathic pulmonary fibrosis            |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.                   |
| Off-Label Uses                     | N/A   |



### **EVEROLIMUS**

#### **Products Affected**

- AFINITOR ORAL TABLET 10 MG
- everolimus oral tablet 2.5 mg, 5 mg, 7.5 mg

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery, B.) Advanced hormone receptor-positive, HER2 negative breast cancer in postmenopausal women and taken in combination with exemestane, after failure with letrozole or anastrozole, C.) Progressive, well-differentiated, nonfunctional neuroendocrine tumors of gastrointestinal or lung origin and disease is unresectable, locally advanced, or metastatic, D.) Pancreatic progressive neuroendocrine tumors and disease is unresectable, locally advanced, or metastatic, E.) Advanced renal cell carcinoma (RCC) after failure with sunitinib or sorafenib, F.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or neurologist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **EVRYSDI**

#### **Products Affected**

EVRYSDI

| PA Criteria                        | Criteria Details                                    |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of spinal muscular atrophy (SMA)          |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.                 |
| Off-Label Uses                     | N/A   |



### **FARYDAK**

#### **Products Affected**

• FARYDAK ORAL CAPSULE 10 MG, 20 MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Must meet all of the following 1.) Diagnosis of multiple myeloma, 2.) Medication is being used in combination with Velcade (bortezomib) and dexamethasone, 3.) Patient has received at least two prior treatment regimens, including Velcade (bortezomib) and an immunomodulatory agent [e.g., Revlimid (lenalidomide), Thalomid (thalidomide)] |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or hematologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **FENTANYL ORAL**

#### **Products Affected**

• fentanyl citrate buccal lozenge on a handle

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) Management of acute or postoperative pain (including headache/migraine, dental pain, and use in the emergency room), B.) Use in opioid non-tolerant patients  |
| Required<br>Medical<br>Information | Must meet all of the following 1.) Diagnosis of cancer-related breakthrough pain, 2.) Patient is currently receiving/tolerant to around-the-clock opioid therapy for persistent cancer pain, and 3.) Patient and prescriber are enrolled in the TIRF REMS Access Program |
| Age Restrictions                   | 16 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **FINTEPLA**

#### **Products Affected**

FINTEPLA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI |
| Required<br>Medical<br>Information | Diagnosis of Severe myoclonic epilepsy in infancy (Dravet syndrome)                                     |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **FIRAZYR**

#### **Products Affected**

FIRAZYR

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of hereditary angioedema AND medication will be used for the treatment of acute attacks. |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a hematologist, immunologist, or allergist                   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **FIRDAPSE**

#### **Products Affected**

FIRDAPSE

| PA Criteria                        | Criteria Details                               |
|------------------------------------|--|
| Exclusion<br>Criteria              | History of seizures                            |
| Required<br>Medical<br>Information | Diagnosis of Lambert-Eaton myasthenic syndrome |
| Age Restrictions                   | 18 years of age and older                      |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months                                      |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.            |
| Off-Label Uses                     | N/A  |



### **GALAFOLD**

#### **Products Affected**

GALAFOLD

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of Fabry disease with an amenable galactosidase alpha gene (GLA) mutation |
| Age Restrictions                   | 16 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **GATTEX**

#### **Products Affected**

GATTEX

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of short bowel syndrome and patient is dependent on parenteral support |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **GAVRETO**

#### **Products Affected**

GAVRETO

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **GILENYA**

#### **Products Affected**

• GILENYA ORAL CAPSULE 0.5 MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| 1 A CITICITA                       | Criteria Details   |
| Exclusion<br>Criteria              | Any of the following A.) Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure, B.) History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker, C.) Baseline QTC interval greater than or equal to 500 milliseconds, D.) Receiving concurrent treatment with Class Ia or Class III anti-arrhythmic drugs (quinidine, procainamide, amiodarone, sotalol) |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis   |
| Age Restrictions                   | 10 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **GILOTRIF**

#### **Products Affected**

GILOTRIF

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have nonresistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test, or B.) Metastatic squamous NSCLC with progression after platinum-based chemotherapy |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **GLATIRAMER**

#### **Products Affected**

• COPAXONE SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

• glatiramer acetate

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **GROWTH HORMONE**

#### **Products Affected**

- OMNITROPE SUBCUTANEOUS SOLUTION
- OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following A.) Use for growth promotion in pediatric patients with closed epiphyses, B.) Acute critical illness caused by complications following open-heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure, C.) Active malignancy, D.) Active proliferative or severe nonproliferative diabetic retinopathy, E.) Prader-Willi Syndrome in patients who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment  |
| Required<br>Medical<br>Information | Diagnosis of pediatric indication: A.) GHD and bone age at least 1 year or 2 standard deviations (SD) delayed compared with chronological age and 2 stim tests with peak GH secretion below 10 ng/mL or IGF-1/IGFBP3 level more than 2 SDS below mean if CNS pathology, h/o irradiation, or proven genetic cause, B.) SGA and birth weight or length 2 or more SDS below mean for gestational age and fails to manifest catch up growth by age 2 (height 2 or more SDS below mean for age and gender), C.) CRI and nutritional status has been optimized, metabolic abnormalities have been corrected, and patient has not had renal transplant D.) SHOX deficiency or Noonan syndrome E.) PWS confirmed by genetic testing, F.) Turner Syndrome confirmed by chromosome analysis. For GHD, CRI, SHOX deficiency, Noonan syndrome, and PWS one of the following height more than 3 SDS below mean for age and gender, or height more than 2 SDS below mean with GV more than 1 SDS below mean, or GV over 1 year 2 SDS below mean. OR Diagnosis of an adult indication: A.) childhood- or adult-onset GHD confirmed by 2 standard GH stim tests (provide assay): 1 test must be insulin tolerance test (ITT) with blood glucose nadir less than 40 mg/dL (2.2 mmol/L). If contraindicated, use a standardized stim test (i.e. arginine plus GH releasing hormone [preferred], glucagon, arginine), B.) GHD with at least 1 other pituitary hormone deficiency and failed at least 1 GH stim test (ITT preferred), C.) GHD with panhypopituitarism (3 or more pituitary hormone deficiencies), D.) GHD with irreversible hypothalamic-pituitary structural lesions due to tumors, surgery or |



| PA Criteria                | Criteria Details   |
|----------------------------|--|
|                            | radiation of pituitary or hypothalamus region AND a subnormal IGF-1 (after at least 1 month off GH therapy) AND Objective evidence of GHD complications, such as: low bone density, increased visceral fat mass, or cardiovascular complications AND Completed linear growth (GV less than 2 cm/year) AND GH has been discontinued for at least 1 month (if previously receiving GH) |
| Age Restrictions           | None   |
| Prescriber<br>Restrictions | Prescribed by or in consultation with an Endocrinologist or Nephrologist   |
| Coverage<br>Duration       | 12 months  |
| Other Criteria             | None   |
| Indications                | All Medically-accepted Indications.  |
| Off-Label Uses             | N/A  |



### **HEPATITIS C**

#### **Products Affected**

MAVYRET

VOSEVI

sofosbuvir-velpatasvir

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of HCV genotype, subtype and quantitative HCV RNA (viral load) testing any time prior to therapy. Must document the following within 12 weeks of starting therapy: CBC, INR, hepatic function panel, and GFR. Must document cirrhosis status, prior treatment history (if any), and planned duration of treatment. All genotypes will require trial/failure, contraindication to, or intolerance to Mavyret or Sofosbuvir-Velpatasvir prior to the approval of Vosevi. |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist   |
| Coverage<br>Duration               | Duration of approval per AASLD Guidelines  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **HETLIOZ**

#### **Products Affected**

HETLIOZ

| PA Criteria                        | Criteria Details                                      |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of Non-24-hour-sleep-wake disorder (Non-24) |
| Age Restrictions                   | 18 years of age and older                             |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.                   |
| Off-Label Uses                     | N/A   |



### **HRM - SKELETAL MUSCLE RELAXANTS**

#### **Products Affected**

- chlorzoxazone oral tablet 375 mg, 500 mg, cyclobenzaprine hcl oral tablet 10 mg, 5 mg 750 mg

  - methocarbamol oral

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | For patients greater than or equal to 65 years, coverage determination is approved for FDA-approved indications not otherwise excluded from Part D. |
| Age Restrictions                   | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **HUMIRA**

#### **Products Affected**

- HUMIRA PEDIATRIC CROHNS ST SUBCUTANEOUS PREFILLED SYRINGE KIT 80 MG/0.8ML, 80 MG/0.8ML & 40MG/0.4ML
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT
- HUMIRA PEDIATRIC CROHNS START HUMIRA PEN-CD/UC/HS STARTER
  - HUMIRA PEN-PS/UV/ADOL HS START
  - HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate, F.) Moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy, G.) Moderate to severe ulcerative colitis in patients who have had an inadequate response to immunosuppressants (e.g. corticosteroids, azathioprine), H.) Noninfectious uveitis (including intermediate, posterior, and panuveitis), or I.) Moderate to severe hidradenitis suppurativa |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | Screening for latent tuberculosis infection is required prior to initiation of treatment  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **IBRANCE**

#### **Products Affected**

IBRANCE

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer used in combination with fulvestrant and disease has progressed following endocrine therapy, or B.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer used in combination with an aromatase inhibitor in postmenopausal women or men |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **ICLUSIG**

#### **Products Affected**

• ICLUSIG

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



### **IDHIFA**

#### **Products Affected**

IDHIFA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase 2 (IDH2) mutation as detected by an FDA approved test |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or hematologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **IMBRUVICA**

### **Products Affected**

IMBRUVICA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Mantle cell lymphoma (MCL) and patient has received at least one prior therapy, B.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL), C.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion, D.) Waldenstrom's macroglobulinemia (WM), E.) Marginal zone lymphoma (MZL) and patient requires systemic therapy and has received at least one prior anti-CD20-based therapy, or F.) Chronic graft vs host disease (cGVHD) after failure of a least one first-line corticosteroid therapy |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **INBRIJA**

### **Products Affected**

INBRIJA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) Concurrent use with nonselective monoamine oxidase inhibitors (MAOIs) (e.g. phenelzine and tranylcypromine), B.) Recent use (within 2 weeks) with a nonselective MAOI                     |
| Required<br>Medical<br>Information | Must meet all of the following A.) Diagnosis of Parkinson's disease, B.) Concurrent therapy with carbidopa/levodopa, C.) Patient has tried and failed or has contraindication to one generic formulary alternative |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **INCRELEX**

### **Products Affected**

INCRELEX

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following: A.) active or suspected malignancy, B.) use for growth promotion in patients with closed epiphyses, C.) Intravenous administration   |
| Required<br>Medical<br>Information | Prescribed for treatment of growth failure in pediatric patient AND patient has diagnosis of one of the following A.) Severe primary insulin-like growth factor-1 (IGF-1) deficiency, or B.) Growth hormone (GH) gene deletion and patient has developed neutralizing antibodies to GH |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **INQOVI**

### **Products Affected**

INQOVI

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **INREBIC**

### **Products Affected**

INREBIC

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF). |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or hematologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **INTRAROSA**

### **Products Affected**

INTRAROSA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) Vaginal bleeding or dysfunctional uterine bleeding of an undetermined origin, or B.) Known or suspected estrogendependent neoplasia |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) moderate to severe dyspareunia due to menopause, or B.) atrophic vaginitis due to menopause                            |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | Initial: 3 months, Renewal: 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **IRESSA**

### **Products Affected**

IRESSA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of metastatic non-small cell lung cancer (NSCLC) and must meet both of the following 1.) tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility, AND 2.) Used as first-line treatment |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **ISTURISA**

### **Products Affected**

ISTURISA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of Cushing's disease in patients for whom pituitary surgery is not an option or has not been curative |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an endocrinologist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **ITRACONAZOLE**

### **Products Affected**

• itraconazole oral

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following A.) Ventricular dysfunction (e.g., congestive heart failure (CHF) or history of CHF), B.) Concurrent therapy with a CYP3A4 substrate (e.g., methadone, lovastatin, simvastatin, etc.)  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), or B.) Onychomycosis confirmed by one of the following positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 6 months  |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### ITRACONAZOLE SOLN

### **Products Affected**

• itraconazole oral

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) Ventricular dysfunction (e.g., congestive heart failure (CHF) or history of CHF), B.) Concurrent therapy with a CYP3A4 substrate (e.g., methadone, lovastatin, simvastatin, etc.) |
| Required<br>Medical<br>Information | Diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole  |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 6 months   |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **IVIG**

#### **Products Affected**

- GAMMAGARD
- GAMMAGARD S/D LESS IGA
- GAMUNEX-C

- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 2 GM/20ML
- PRIVIGEN INTRAVENOUS SOLUTION 20 GM/200ML

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following A.) IgA deficiency with antibody formation and a history of hypersensitivity, or B.) History of anaphylaxis or severe systemic reaction to human immune globulin |
| Required<br>Medical<br>Information | Supporting statement of diagnosis from the physician  |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | B vs D determination required per CMS guidance  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **JAKAFI**

### **Products Affected**

JAKAFI

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis, B.) Polycythemia vera AND patient has had an inadequate response to or is intolerant of hydroxyurea, OR C.) Acute graft versus host disease AND disease is refractory to steroid therapy |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 6 months  |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **KALYDECO**

### **Products Affected**

KALYDECO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of cystic fibrosis (CF) and the patient has 1 mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **KESIMPTA**

### **Products Affected**

KESIMPTA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Active Hepatitis B infection   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **KISQALI**

### **Products Affected**

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

• KISQALI (600 MG DOSE)

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Hormone receptor (HR)-positive, HER-2 negative advanced or metastatic breast cancer in pre/perimenopausal or postmenopausal women and used in combination with an aromatase inhibitor, or B.) Hormone receptor (HR)-positive, HER-2 negative advanced or metastatic breast cancer in postmenopausal women and used in combination with fulvestrant |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## KISQALI FEMARA

#### **Products Affected**

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

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of hormone receptor (HR)-positive, HER-2 negative advanced or metastatic breast cancer in pre/perimenopausal or postmenopausal women |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **KORLYM**

### **Products Affected**

KORLYM

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following A.) pregnancy, B.) coadministration with simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges, C.) concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses, D.) history of unexplained vaginal bleeding, E.) endometrial hyperplasia with atypia or endometrial carcinoma |
| Required<br>Medical<br>Information | Diagnosis of endogenous Cushing syndrome in patients with type 2 diabetes mellitus or glucose intolerance and both of the following 1.) Used to control hyperglycemia secondary to hypercortisolism, AND 2.) Patient has failed or is not a candidate for surgery   |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an endocrinologist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **KOSELUGO**

### **Products Affected**

KOSELUGO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of neurofibromatosis type 1 (NF1) in a patient who has symptomatic, inoperable plexiform neurofibromas (PN) |
| Age Restrictions                   | 2 years of age to 17 years of age   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **KUVAN**

### **Products Affected**

KUVAN

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of hyperphenylalaninemia (HPA) caused by tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | Initial: 2 months, Renewal: 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **LENVIMA**

#### **Products Affected**

- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer, B.) Advanced renal cell carcinoma, in combination with everolimus, following one prior anti-angiogenic therapy, C.) Unresectable hepatocellular carcinoma, first-line therapy, D.) Advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, in combination with pembrolizumab, when disease has progressed following prior systemic therapy AND patient is not a candidate for curative surgery or radiation |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **LEUPROLIDE**

#### **Products Affected**

- leuprolide acetate injection
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Advanced or metastatic prostate cancer and patient has failed or is intolerant to Eligard (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, & 45 mg 6-month depots only), B.) Endometriosis (3.75 mg 1-month & 11.25 mg 3-month depots only), C.) Anemia due to uterine leiomyomata (Fibroids) (3.75 mg 1-month &11.25 mg 3-month depots only) and patient is preoperative, or D.) Central precocious puberty (idiopathic or neurogenic) in children |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | B vs D determination required per CMS guidance  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### LIDOCAINE PATCH

### **Products Affected**

• lidocaine external patch 5 %

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Pain associated with diabetic neuropathy, B.) Pain associated with cancer-related neuropathy, C.) Postherpetic neuralgia |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **LONSURF**

### **Products Affected**

LONSURF

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Metastatic colorectal cancer, previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based regimens, an anti-VEGF therapy, and if RAS wild-type, an anti-EGFR therapy, or B.) Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **LORBRENA**

#### **Products Affected**

LORBRENA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Concomitant use with strong CYP3A4 inducers  |
| Required<br>Medical<br>Information | Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) and one of the following 1.) Disease has progressed on alectinib as the first ALK inhibitor therapy for metastatic disease, OR 2.) Disease has progressed on ceritinib as the first ALK inhibitor therapy for metastatic disease, OR 3.) Disease has progressed on crizotinib AND at least 1 other ALK inhibitor for metastatic disease |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **LYNPARZA**

### **Products Affected**

• LYNPARZA ORAL TABLET

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) HER2-negative, deleterious or suspected deleterious germline BRCA mutated metastatic breast cancer AND patient has been previously treated with chemotherapy in neoadjuvant, adjuvant, or metastatic setting, B.) Advanced ovarian cancer with known or suspected BRCA mutation as detected by an FDA-approved test AND patient has trial and failure, contraindication, or intolerance to 3 or more prior lines of chemotherapy, C.) Recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer AND used for maintenance treatment in patients who are in complete or partial response to platinum-based chemotherapy (e.g. cisplatin, carboplatin), D.) Deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients with complete or partial response to first-line platinum-based chemotherapy, E.) Deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma and disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen, F.) Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA-mutation, and/or genomic instability. Used in combination with bevacizumab for maintenance treatment., or G.) Deleterious or suspected deleterious germline or somatic homologous recombination repair gene mutated metastatic castration-resistant prostate cancer in patients who have progressed following prior treatment with enzalutamide or abiraterone. |
| Age Restrictions                   | None  |



| PA Criteria                | Criteria Details                    |
|----------------------------|-------------------------------------|
| Prescriber<br>Restrictions | None                                |
| Coverage<br>Duration       | 12 months                           |
| Other Criteria             | None                                |
| Indications                | All Medically-accepted Indications. |
| Off-Label Uses             | N/A                                 |



### **MAYZENT**

#### **Products Affected**

MAYZENT

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) CYP2C9*3/*3 genotype, B.) In the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, Class III-IV heart failure, or C.) Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker |
| Required<br>Medical<br>Information | Diagnosis of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease and the following A.) Patients with relapsing forms of multiple sclerosis have history of/or contraindication to Avonex, Betaseron, Copaxone, Gilenya, or Tecfidera                                   |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **MEKINIST**

#### **Products Affected**

MEKINIST

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and used in combination with dabrafenib and no locoregional treatment options, B.) Malignant melanoma with lymph node involvement and following complete resection with BRAF V600E or V600K mutations and used in combination with dabrafenib, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutations and used in combination with dabrafenib or as monotherapy, or D.) Metastatic nonsmall cell lung cancer, with BRAF V600E mutation, in combination with dabrafenib |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **MEKTOVI**

### **Products Affected**

MEKTOVI

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of unresectable or metastatic malignant melanoma with documented BRAF V600E or V600K mutation as detected by an FDA approved test AND used in combination with encorafenib |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **METHYLPHENIDATES**

#### **Products Affected**

- methylphenidate hcl er oral tablet extended methylphenidate hcl er oral tablet extended release 10 mg, 18 mg, 20 mg, 27 mg, 36 mg, 54 mg
  - release 24 hour
  - methylphenidate hcl oral solution
  - methylphenidate hcl oral tablet

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following A.) Symptoms of marked anxiety, tension, or agitation, B.) Glaucoma, C.) Family history/diagnosis of Tourette's syndrome or presence of motor tics, D.) Concurrent use with MAOIs                                    |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Attention deficit hyperactivity disorder (ADHD), or B.) Narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **MIGLUSTAT**

### **Products Affected**

• miglustat

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of mild to moderate type 1 Gaucher disease and patient is not a candidate for enzyme replacement therapy |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **MS INTERFERONS**

#### **Products Affected**

• AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT

- AVONEX PREFILLED INTRAMUSCULAR PREFILLED SYRINGE KIT
- BETASERON SUBCUTANEOUS KIT

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **NATPARA**

### **Products Affected**

NATPARA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of hypoparathyroidism and used to control hypocalcemia |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.                              |
| Off-Label Uses                     | N/A  |



### **NERLYNX**

### **Products Affected**

NERLYNX

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Early stage HER2-positive breast cancer and used following adjuvant trastuzumab therapy, or B.) Advanced or metastatic HER2-positive breast cancer, used in combination with capecitabine, AND patient has received 2 or more prior anti-HER2-based regimens in the metastatic setting |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **NEXAVAR**

### **Products Affected**

NEXAVAR

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Squamous cell lung cancer being treated with carboplatin and paclitaxel  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment, or C.) Unresectable hepatocellular carcinoma |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **NINLARO**

### **Products Affected**

NINLARO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of multiple myeloma, used in combination with lenalidomide and dexamethasone, AND patient has history of at least 1 prior therapy |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **NORTHERA**

#### **Products Affected**

NORTHERA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (e.g., Parkinson disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **NUBEQA**

#### **Products Affected**

• NUBEQA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of non-metastatic, castration-resistant prostate cancer |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or urologist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.                               |
| Off-Label Uses                     | N/A   |



### **NUCALA**

#### **Products Affected**

NUCALA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Severe asthma with eosinophilic phenotype, or B.) Eosinophilic granulomatosis with polyangiitis (EGPA) |
| Age Restrictions                   | 6 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **NUEDEXTA**

#### **Products Affected**

NUEDEXTA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following A.) History of prolonged QT interval, congenital long QT syndrome or Torsades de pointes, B.) Heart failure, C.) Complete AV block without an implanted pacemaker or high risk of complete AV block, D.) Concomitant use with quinidine, quinine, mefloquine, or drugs that prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), E.) Concomitant use with MAOIs or within 14 days of MAOI therapy |
| Required<br>Medical<br>Information | Diagnosis of pseudobulbar affect  |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **NUPLAZID**

#### **Products Affected**

NUPLAZID ORAL CAPSULE
 NUPLAZID ORAL TABLET 10 MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of hallucinations and delusions associated with Parkinson disease psychosis |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **OCTREOTIDE**

#### **Products Affected**

• octreotide acetate injection solution 100 mcg/ml, 1000 mcg/ml, 200 mcg/ml, 50 mcg/ml, 500 mcg/ml

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Acromegaly and patient has inadequate response to or is ineligible for surgery, radiation, or bromocriptine mesylate, or B.) Metastatic carcinoid syndrome, or C.) Vasoactive intestinal peptide-secreting tumors (VIPomas) with associated diarrhea |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **ODOMZO**

#### **Products Affected**

ODOMZO

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Pregnancy  |
| Required<br>Medical<br>Information | Diagnosis of locally advanced basal cell carcinoma of the skin and one of the following A.) Cancer has recurred following surgery or radiation therapy, B.) Patient is not a candidate for surgery or radiation therapy. |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **OFEV**

#### **Products Affected**

OFEV

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Idiopathic pulmonary fibrosis (IPF), B.) Systemic sclerosis-associated interstitial lung disease (ILD), or C.) Chronic fibrosing interstitial lung disease with a progressive phenotype |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **OPSUMIT**

#### **Products Affected**

OPSUMIT

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Pregnancy   |
| Required<br>Medical<br>Information | Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.) |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist or cardiologist   |
| Coverage<br>Duration               | Initial: 6 months, Renewal: 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **ORILISSA**

#### **Products Affected**

ORILISSA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following: A.) Pregnancy, B.) Known osteoporosis, C.) Severe hepatic impairment, D.) Concurrent use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors |
| Required<br>Medical<br>Information | Diagnosis of moderate to severe pain associated with endometriosis  |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **ORKAMBI**

#### **Products Affected**

ORKAMBI

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of cystic fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test                           |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **OSPHENA**

#### **Products Affected**

OSPHENA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following: A.) Undiagnosed abnormal genital bleeding, B.) Known or suspected estrogen-dependent neoplasia, C.) Active deep vein thrombosis (DVT), pulmonary embolism (PE), or a history of these conditions, D.) Active arterial thromboembolic disease (eg. stroke, myocardial infarction) or a history of these conditions, or E.) Pregnancy |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause, or B.) Moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause   |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **OXANDROLONE**

#### **Products Affected**

• oxandrolone oral

| DA Cuitania                        | Chitamin Dataille  |
|------------------------------------|--|
| PA Criteria                        | Criteria Details   |
| Exclusion<br>Criteria              | Any of the following: A.) Known or suspected carcinoma of the prostate or breast in males, B.) Carcinoma of the breast in famles with hypercalcemia, C.) Pregnancy, D.) Nephrosis or nephrotic phase of nephritis, E.) Hypercalcemia   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Bone pain associated with osteoporosis, B.) Protein catabolism associated with chronic corticosteroid administration, or C.) Used as adjunctive therapy to promote weight gain after weight loss associated with one of the following 1.) Extensive surgery, 2.) Chronic infections, 3.) Severe trauma, or 4.) Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 3 months   |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **PEGYLATED INTERFERON**

#### **Products Affected**

• PEGASYS PROCLICK SUBCUTANEOUS• PEGASYS SUBCUTANEOUS SOLUTION SOLUTION 180 MCG/0.5ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) Autoimmune hepatitis or other autoimmune condition known to be exacerbated by interferon, B.) Uncontrolled depression   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Chronic hepatitis B infection, or B.) Chronic hepatitis C and required criteria will be applied consistent with current AASLD-IDSA guidance with compensated liver disease |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist   |
| Coverage<br>Duration               | HBV: 12 months, HCV: based on current AASLD guidelines   |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **PEMAZYRE**

#### **Products Affected**

PEMAZYRE

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with confirmed fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist, gastroenterologist, or hepatologist   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **PIQRAY**

#### **Products Affected**

- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of hormone receptor (HR) positive, HER2-negative, PIK3CA-mutated, advanced or metastatic breast cancer AND must meet all of the following 1.) Used in combination with fulvestrant, AND 2.) Disease has progressed on or after an endocrine-based regimen, AND 3.) Patient is a male OR postmenopausal female |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **POMALYST**

#### **Products Affected**

POMALYST

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Pregnancy  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) AIDS-related Kaposi sarcoma and patient has failure on highly active antiretroviral therapy (HAART), B.) Kaposi sarcoma in HIV-negative adults, or C.) Multiple myeloma and in combination with dexamethasone in adults who have received at least 2 prior therapies (including lenalidomide and a proteasome inhibitor) and have demonstrate disease progression on or within 60 days of completion of the last therapy |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **PROMACTA**

#### **Products Affected**

PROMACTA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Chronic idiopathic thrombocytopenic purpura (ITP), B.) Chronic hepatitis C infection associated thrombocytopenia, or C.) Severe aplastic anemia with insufficient response to immunosuppressive therapy or in combination with standard immunosuppressive therapy |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



## **QINLOCK**

#### **Products Affected**

QINLOCK

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of advanced gastrointestinal stromal tumor (GIST) and patient has received prior treatment with 3 or more kinase inhibitors, including imatinib |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **REGRANEX**

#### **Products Affected**

REGRANEX

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Known neoplasm at the site of application   |
| Required<br>Medical<br>Information | Diagnosis of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply |
| Age Restrictions                   | 16 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **REPATHA**

#### **Products Affected**

REPATHA

- REPATHA SURECLICK
- REPATHA PUSHTRONEX SYSTEM

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH), B.) homozygous familial hypercholesterolemia, C.) established cardiovascular disease and myocardial infarction prophylaxis, stroke prophylaxis, or coronary revascularization prophylaxis is required, or D.) clinical atherosclerotic cardiovascular disease (CVD) as defined as one of the following 1.) acute coronary syndrome, 2.) history of myocardial infarction, 3.) stable/unstable angina, 4.) coronary or other arterial revascularization, 5.) stroke, 6.) transient ischemic stroke (TIA), or 7.) peripheral arterial disease presumed to be atherosclerotic region |
| Age Restrictions                   | 13 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | Initial: 2 months, Renewal: 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **RETEVMO**

#### **Products Affected**

RETEVMO

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Advanced or metastatic RET-mutant medullary thyroid cancer (MTC) in patients who require systemic therapy, B.) Metastatic RET fusion-positive non-small cell lung cancer (NSCLC), or C.) Advanced or metastatic RET fusion-positive thyroid cancer in patients who require systemic therapy and are refractory to radioactive iodine, if appropriate |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **REVLIMID**

#### **Products Affected**

REVLIMID

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Pregnancy   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Multiple myeloma and medication will be used in combination with dexamethasone, B.) Autologous hematopoietic stem-cell transplantation (HSCT) in multiple myeloma patients, C.) Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality or without additional cytogenetic abnormalities, D.) Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib, E.) Follicular lymphoma and used in combination with rituximab, or F.) Marginal zone lymphoma and used in combination with rituximab |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **ROZLYTREK**

#### **Products Affected**

ROZLYTREK

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



### **RUBRACA**

#### **Products Affected**

RUBRACA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Epithelial ovarian, fallopian tube, or primary peritoneal cancer with deleterious BRCA mutation (germline and/or somatic) as detected by an FDA-approved test and patient has been treated with 2 or more prior lines of chemotherapy, B.) Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, used as maintenance treatment, and patient is in complete or partial response to platinum-based chemotherapy, or C.) Deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer and patient has been treated with androgen receptor-directed therapy and a taxane-based chemotherapy |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or hematologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **RYDAPT**

#### **Products Affected**

RYDAPT

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) treatment naive FLT3 mutation-positive acute myelogenous leukemia (AML) and must be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation therapy, or B.) systemic mastocytosis or mast cell leukemia |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or hematologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **SAMSCA**

#### **Products Affected**

SAMSCA

• tolvaptan

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following: A.) Diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD), B.) Urgent need to raise serum sodium acutely, C.) Inability to sense or appropriately respond to thirst, D.) Hypovolemic hyponatremia, E.) Concomitant use of strong CYP 3A Inhibitors (eg. clarithromycin, ketoconazole, ritonavir), F.) Anuria |
| Required<br>Medical<br>Information | Diagnosis of clinically significant hypervolemic or euvolemic hyponatremia (serum sodium less than 125 mEq/L or less marks hyponatremia that is symptomatic and has resisted correction with fluid restriction), including in patients with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH)                           |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 1 month  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **SIGNIFOR**

#### **Products Affected**

SIGNIFOR

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of Cushing disease and patient has had inadequate response to or is not a candidate for surgery. For renewal: Documentation of a clinically meaningful reduction in 24-hour urinary free cortisol (UFC) levels or improvement in signs or symptoms of the disease |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | Initial: 6 months, Reauthorization: 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **SILDENAFIL**

#### **Products Affected**

• sildenafil citrate oral tablet 20 mg

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Nitrate therapy, including intermittent use  |
| Required<br>Medical<br>Information | Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist or cardiologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **SOMATULINE DEPOT**

#### **Products Affected**

• SOMATULINE DEPOT

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Acromegaly and patient is not a candidate for surgery/radiotherapy or has had an inadequate response, B.) Carcinoid syndrome, or C.) Unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **SOMAVERT**

#### **Products Affected**

SOMAVERT

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of acromegaly and patient has had an inadequate response to or is ineligible for surgery or radiation therapy |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an endocrinologist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **SPRYCEL**

#### **Products Affected**

SPRYCEL

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, B.) Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy, C.) Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy, D.) Newly diagnosed Ph+ ALL in combination with chemotherapy |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **STELARA**

#### **Products Affected**

• STELARA SUBCUTANEOUS SOLUTION• STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML PREFILLED SYRINGE

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Moderate to severely active Crohn disease and patient has trial and failure or intolerance or contraindication to Humira, B.) Moderate to severe plaque psoriasis and patient has trial and failure or intolerance or contraindication to Humira and Enbrel, C.) Active psoriatic arthritis and patient has trial and failure or intolerance or contraindication to Humira and Enbrel, or D.) Moderate to severe active ulcerative colitis and patient has trial and failure or intolerance or contraindication to Humira. |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | Screening for latent tuberculosis infection is required prior to initiation of treatment   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **STIVARGA**

#### **Products Affected**

STIVARGA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Metastatic colorectal cancer in patients previously treated with fluoropyrimidine, oxaliplatin, and irinotecan containing chemotherapy, anti-VEGF therapy, and if RAS wild type, anti-EGFR therapy, B.) Liver carcinoma in patients previously treated with sorafenib, or C.) Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) after treatment with imatinib and sunitinib |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **SUNOSI**

#### **Products Affected**

SUNOSI

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to modafinil or armodafinil, or B.) obstructive sleep apnea (OSA) with excessive daytime drowsiness and has trial of/or contraindication to modafinal or armodafinal |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **SUTENT**

#### **Products Affected**

• SUTENT

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Gastrointestinal stromal tumor after disease progression on or intolerance to imatinib, B.) Pancreatic neuroendocrine tumors in a patient with unresectable locally advanced or metastatic disease, C.) Advanced renal cell carcinoma, or D.) Renal cell carcinoma and used as adjuvant therapy following nephrectomy in patients who are at high risk for recurrence |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **SYMDEKO**

### **Products Affected**

SYMDEKO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of cystic fibrosis (CF) and must meet one of the following 1.) Patient is homozygous for the F508del mutation, or 2.) Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor verified by an FDA-cleared CF mutation test |
| Age Restrictions                   | 6 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation  |
| Coverage<br>Duration               | Initial: 6 months, Renewal: 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **SYMLIN**

### **Products Affected**

- SYMLINPEN 120 SUBCUTANEOUS SOLUTION PEN-INJECTOR
  - SYMLINPEN 60 SUBCUTANEOUS SOLUTION PEN-INJECTOR

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following: A.) Confirmed diagnosis of gastroparesis, B.) Hypoglycemia unawareness  |
| Required<br>Medical<br>Information | Diagnosis of type 1 or type 2 diabetes mellitus and patient uses mealtime insulin therapy and has failed to achieve desired glucose control |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



## **TABRECTA**

### **Products Affected**

TABRECTA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **TAFINLAR**

### **Products Affected**

TAFINLAR

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid carcinoma with BRAF V600E mutation, in combination with trametinib and no satisfactory locoregional treatment options, B.) Metastatic non-small cell lung cancer with BRAF V600E mutation, in combination with trametinib OR in patients previously treated as monotherapy, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutation |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



## **TAGRISSO**

### **Products Affected**

TAGRISSO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R mutation and used as first line therapy, or B.) Metastatic non-small cell lung cancer with T790M EGFR mutation (as confirmed by an FDA-approved test) AND whose disease has progressed on or after EGFR tyrosine kinase inhibitor therapy |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **TAKHZYRO**

### **Products Affected**

TAKHZYRO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of hereditary angioedema, used in prevention of angioedema attacks AND patient has trial of, or contraindication to Firazyr |
| Age Restrictions                   | 12 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a hematologist, immunologist, or allergist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **TALZENNA**

### **Products Affected**

TALZENNA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **TARGRETIN GEL**

### **Products Affected**

• TARGRETIN EXTERNAL

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of primary cutaneous T-cell lymphoma (CTCL Stage 1A/1B) and patient had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) indicated for cutaneous manifestations of CTCL |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or dermatologist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



## **TASIGNA**

### **Products Affected**

TASIGNA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following: A.) Long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML), B.) Chronic phase or accelerated phase Philadelphia chromosome-positive CML in a patient with resistance or intolerance to prior therapy that included imatinib, or C.) Chronic phase Philadelphia chromosome-positive CML in a patient with resistance or intolerance to prior tyrosine-kinase inhibitor therapy |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **TAZVERIK**

### **Products Affected**

TAZVERIK

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



### **TECFIDERA**

### **Products Affected**

TECFIDERA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **TEGSEDI**

### **Products Affected**

TEGSEDI

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Any of the following A.) Platelet count less than 100,000 per microliter, B.) Urinary protein to creatinine ratio (UPCR) of 1000 mg/g or higher |
| Required<br>Medical<br>Information | Diagnosis of Polyneuropathy of hereditary transthyretin-mediated amyloidosis  |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **TERIPARATIDE**

#### **Products Affected**

• teriparatide (recombinant)

| DA Cuitoria                        | Cuitouio Dotoila   |
|------------------------------------|--|
| PA Criteria                        | Criteria Details   |
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Patient has previous trial and failure, contraindication, or intolerance to a bisphosphonate AND diagnosis of one of the following A.) osteoporosis in postmenopausal female patient with high risk for fracture and patient has history of or contraindication to Tymlos, B.) primary or hypogonadal osteoporosis in male patient with high risk for fracture, or C.) osteoporosis due to associated sustained systemic glucocorticoid therapy in patient with high risk for fracture |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | Initial: 12 months, Renewal: 12 months (Maximum 24 month treatment per patient lifetime)   |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **TETRABENAZINE**

### **Products Affected**

• tetrabenazine

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| 111 Cilicila                       | Olivelia Devaia   |
| Exclusion<br>Criteria              | Any of the following A.) Actively suicidal, B.) Untreated or inadequately treated depression, C.) Impaired hepatic function, D.) Concomitant use of monoamine oxidase inhibitors, E.) Concomitant use of reserpine or within 20 days of discontinuing reserpine |
| Required<br>Medical<br>Information | Diagnosis of chorea associated with Huntington's disease  |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



## **THALOMID**

### **Products Affected**

THALOMID

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Pregnancy  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Multiple myeloma that is newly diagnosed, or B.) Erythema nodosum leprosum (ENL) |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or infectious disease specialist                                   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **TIBSOVO**

### **Products Affected**

TIBSOVO

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test), or B.) Newly diagnosed acute myeloid leukemia with susceptible isocitrate dehydrogenase-1 mutation AND meets one of the following 1.) Patient is 75 years of age or older, OR 2.) Patient has comorbidities that preclude intensive induction chemotherapy |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or hematologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **TRIENTINE**

### **Products Affected**

CLOVIQUE

• trientine hcl

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of Wilson's disease in patients that are intolerant to penicillamine |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **TRIKAFTA**

### **Products Affected**

TRIKAFTA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of cystic fibrosis (CF) and patient has at least 1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene verified by an FDA-cleared CF mutation test |
| Age Restrictions                   | 12 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **TUKYSA**

### **Products Affected**

TUKYSA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of advanced unresectable or metastatic HER2-positive breast cancer (including brain metastases) in patients who have received one or more prior anti-HER2-based regimens in the metastatic setting and drug is being used in combination with trastuzumab and capecitabine |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **TURALIO**

### **Products Affected**

TURALIO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



## **TYMLOS**

### **Products Affected**

TYMLOS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of postmenopausal osteoporosis and one of the following A.) osteoporotic fracture or multiple risk factors for fracture, or B.) previous trial of/or contraindication to bisphosphonate |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | Initial: 12 months, Renewal: 12 months (Maximum 24 month treatment per patient lifetime)  |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



## **UPTRAVI**

### **Products Affected**

UPTRAVI

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Concomitant use with strong CYP2C8 inhibitors (e.g., gemfibrozil)  |
| Required<br>Medical<br>Information | Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist or cardiologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **VENCLEXTA**

#### **Products Affected**

VENCLEXTA

#### • VENCLEXTA STARTING PACK

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | Concomitant use with strong CYP3A inhibitor during the initial and titration phase in patients with CLL or SLL  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), or B.) Newly-diagnosed acute myeloid leukemia (AML) and used in combination with azacitidine, decitabine or low-dose cytarabine in patients 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **VERZENIO**

### **Products Affected**

VERZENIO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of advanced or metastatic, HER2-negative, hormone receptor-positive breast cancer AND one of the following: A.) For postmenopausal women must be used in combination with fulvestrant for the treatment of disease progression following endocrine therapy and patient has trial and failure or contraindication to Ibrance or Kisqali, B.) For premenopausal or perimenopausal women must be used in combination with fulvestrant for the treatment of disease progression following endocrine therapy and patient has trial and failure or contraindication to Ibrance, C.) Used as monotherapy for treatment of disease progression following endocrine therapy and patient has already received at least one prior chemotherapy regimen of Ibrance or Kisqali, D.) For postmenopausal women used as initial endocrine-based treatment in combination with an aromatase inhibitor and patient has trial and failure or contraindication to Kisqali or Ibrance, E.) For premenopausal or perimenopausal women used as initial endocrine-based treatment in combination with an aromatase inhibitor and patient has trial and failure or contraindication to Kisqali |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **VITRAKVI**

#### **Products Affected**

VITRAKVI

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of metastatic or surgically unresectable neurotrophic receptor tyrosine kinase (NTRK) gene fusion positive solid tumors and used in patients with unsatisfactory alternative treatments or who have progressed following treatment |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **VIZIMPRO**

### **Products Affected**

VIZIMPRO

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of metastatic non-small cell lung cancer with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **VORICONAZOLE**

### **Products Affected**

voriconazole oral

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Invasive aspergillosis, B.) Candidemia, C.) Esophageal Candidiasis, D.) Invasive candidiasis of the skin and abdomen, kidney, bladder wall, and wounds, or E.) Serious fungal infection due to Scedosporium apiospermum or Fusarium species |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an infectious disease specialist  |
| Coverage<br>Duration               | 6 months  |
| Other Criteria                     | B vs D determination required per CMS guidance  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



## **VOTRIENT**

#### **Products Affected**

VOTRIENT

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Advanced renal cell carcinoma, or B.) Advanced soft tissue sarcoma and patient received at least one prior chemotherapy |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **VYNDAMAX**

### **Products Affected**

VYNDAMAX

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of wild type or hereditary transthyretin related familial amyloid cardiomyopathy |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a cardiologist                                       |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **XALKORI**

### **Products Affected**

XALKORI

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive or ROS1-positive as detected by an FDA-approved test |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **XELJANZ**

### **Products Affected**

XELJANZ

#### • XELJANZ XR

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following: A.) Moderate to severe rheumatoid arthritis (RA) and patient has trial and failure or intolerance or contraindication to Humira and Enbrel, B.) Active psoriatic arthritis and patient has trial and failure or intolerance or contraindication to Humira and Enbrel, or C.) Moderate to severe ulcerative colitis (UC) and patient has trial and failure or intolerance or contraindication to Humira. |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | Screening for latent tuberculosis infection is required prior to initiation of treatment   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **XGEVA**

### **Products Affected**

XGEVA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Hypocalcemia (calcium less than 8.0 mg/dL)   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Bone metastases from a solid tumor and used for the prevention of skeletal related events, B.) Multiple myeloma and used for the prevention of skeletal related events, C.) Hypercalcemia of malignancy refractory to bisphosphonate therapy, or D.) Giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity |
| Age Restrictions                   | None   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **XOLAIR**

### **Products Affected**

XOLAIR

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Chronic idiopathic urticaria in patients who remain symptomatic despite H1 antihistamine therapy, or B.) Moderate to severe persistent asthma in patients with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms are inadequately controlled with inhaled corticosteroids |
| Age Restrictions                   | 6 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or dermatologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **XOSPATA**

### **Products Affected**

XOSPATA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or hematologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **XPOVIO**

#### **Products Affected**

- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (40 MG ONCE WEEKLY)
- XPOVIO (40 MG TWICE WEEKLY)
- XPOVIO (60 MG ONCE WEEKLY)
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY)
- XPOVIO (80 MG TWICE WEEKLY)

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Relapsed or refractory multiple myeloma being used in combination with dexamethasone in patient who has received at least 4 prior therapies and is refractory to at least 2 proteasome inhibitors, at least 2 immunomodulatory agents, and an anti-CD38 monoclonal antibody, or B.) Relapsed or refractory diffuse large B-cell lymphoma (DLBCL, including from follicular lymphoma) in a patient who has received at least 2 lines of systemic therapy |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or hematologist   |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



## **XTANDI**

### **Products Affected**

XTANDI

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Castration-resistant prostate cancer, or B.) Metastatic, castration-sensitive prostate cancer |
| Age Restrictions                   | 18 years of age and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or urologist  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



### **XYREM**

### **Products Affected**

XYREM

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | Any of the following A.) Concomitant treatment with sedative hypnotic agents, B.) Succinic semialdehyde dehydrogenase deficiency   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to modafinil or armodafinil, or B.) cataplexy and narcolepsy |
| Age Restrictions                   | 7 years of age and older   |
| Prescriber<br>Restrictions         | None   |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### **ZARXIO**

### **Products Affected**

ZARXIO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) Chemotherapy induced febrile neutropenia (prophylaxis), B.) Severe chronic neutropenia, C.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, or D.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS) |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |



## **ZEJULA**

### **Products Affected**

ZEJULA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| TA CITICITA                        | Criteria Details   |
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of one of the following A.) advanced or recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer and used for maintenance therapy in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin), or B.) advanced ovarian, fallopian tube, or primary peritoneal cancer and patient has been treated with 3 or more prior chemotherapy regimens, and cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA mutation, or genomic instability, and disease has progressed more than 6 months after response to the last platinum-based chemotherapy |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist or gynecologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



## **ZIEXTENZO**

### **Products Affected**

ZIEXTENZO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Exclusion<br>Criteria              | None  |
| Required<br>Medical<br>Information | Diagnosis of chemotherapy induced febrile neutropenia (prophylaxis) |
| Age Restrictions                   | None  |
| Prescriber<br>Restrictions         | None  |
| Coverage<br>Duration               | 12 months   |
| Other Criteria                     | None  |
| Indications                        | All Medically-accepted Indications.                                 |
| Off-Label Uses                     | N/A   |



## **ZYKADIA**

### **Products Affected**

• ZYKADIA ORAL TABLET

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Exclusion<br>Criteria              | None   |
| Required<br>Medical<br>Information | Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) |
| Age Restrictions                   | 18 years of age and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     | None   |
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |



### PART B VERSUS PART D

#### **Products Affected**

- ABELCET INTRAVENOUS SUSPENSION 5 MG/ML
- acetylcysteine inhalation solution 10 %, 20 •
- acyclovir sodium intravenous solution 50 mg/ml
- albuterol sulfate inhalation nebulization solution (2.5 mg/3ml) 0.083%, 0.63 mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml
- AMBISOME INTRAVENOUS SUSPENSION RECONSTITUTED 50 MG
- AMINOSYN-PF INTRAVENOUS SOLUTION 7 %
- amphotericin b intravenous solution reconstituted 50 mg
- aprepitant oral capsule 125 mg, 40 mg, 80
   & 125 mg, 80 mg
- azathioprine oral tablet 50 mg
- budesonide inhalation suspension 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2ml
- calcitonin (salmon) nasal solution 200 unit/act
- caspofungin acetate intravenous solution reconstituted 50 mg, 70 mg
- chlorpromazine hcl oral tablet 10 mg, 25 mg
- cinacalcet hcl oral tablet 30 mg, 60 mg, 90 mg
- CLINISOL SF INTRAVENOUS SOLUTION 15 %
- colistimethate sodium (cba) injection solution reconstituted 150 mg
- cromolyn sodium inhalation nebulization solution 20 mg/2ml
- cyclophosphamide oral capsule 25 mg, 50 mg
- cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg

- cyclosporine modified oral solution 100 mg/ml
- cyclosporine oral capsule 100 mg, 25 mg
- DEPO-PROVERA INTRAMUSCULAR SUSPENSION 400 MG/ML
- dextrose intravenous solution 10 %, 5 %
- diphtheria-tetanus toxoids dt intramuscular suspension 25-5 lfu/0.5ml
- ELIGARD SUBCUTANEOUS KIT 22.5 MG, 30 MG, 45 MG, 7.5 MG
- ENGERIX-B INJECTION SUSPENSION 10 MCG/0.5ML, 20 MCG/ML
- ENVARSUS XR ORAL TABLET EXTENDED RELEASE 24 HOUR 0.75 MG, 1 MG, 4 MG
- everolimus oral tablet 0.25 mg, 0.5 mg, 0.75 mg
- FIRMAGON (240 MG DOSE)
   SUBCUTANEOUS SOLUTION
   RECONSTITUTED 120 MG/VIAL
- FIRMAGON SUBCUTANEOUS SOLUTION RECONSTITUTED 80 MG
- FREAMINE HBC INTRAVENOUS SOLUTION 6.9 %
- GENGRAF ORAL CAPSULE 100 MG, 25
   MG
- GENGRAF ORAL SOLUTION 100 MG/ML
- granisetron hcl oral tablet 1 mg
- HEPATAMINE INTRAVENOUS SOLUTION 8 %
- IMOVAX RABIES INTRAMUSCULAR INJECTABLE 2.5 UNIT/ML
- INTRALIPID INTRAVENOUS EMULSION 20 %, 30 %
- INTRON A INJECTION SOLUTION 10000000 UNIT/ML, 6000000 UNIT/ML



- INTRON A INJECTION SOLUTION RECONSTITUTED 10000000 UNIT, 18000000 UNIT, 50000000 UNIT
- ipratropium bromide inhalation solution 0.02 %
- ipratropium-albuterol inhalation solution 0.5-2.5 (3) mg/3ml
- ISOLYTE-P IN D5W INTRAVENOUS SOLUTION
- levalbuterol hcl inhalation nebulization solution 0.31 mg/3ml, 0.63 mg/3ml, 1.25 mg/0.5ml, 1.25 mg/3ml
- levocarnitine oral solution 1 gm/10ml
- levocarnitine oral tablet 330 mg
- *methotrexate oral tablet 2.5 mg*
- methotrexate sodium (pf) injection solution
   50 mg/2ml
- methotrexate sodium injection solution 50 mg/2ml
- mycophenolate mofetil oral capsule 250 mg
- mycophenolate mofetil oral suspension reconstituted 200 mg/ml
- mycophenolate mofetil oral tablet 500 mg
- mycophenolate sodium oral tablet delayed release 180 mg, 360 mg
- NEPHRAMINE INTRAVENOUS SOLUTION 5.4 %
- nutrilipid intravenous emulsion 20 %
- ondansetron hcl oral solution 4 mg/5ml
- ondansetron hcl oral tablet 24 mg, 4 mg, 8 mg
- ondansetron oral tablet dispersible 4 mg, 8 mg
- pentamidine isethionate inhalation solution reconstituted 300 mg
- PLENAMINE INTRAVENOUS SOLUTION 15 %
- PREMASOL INTRAVENOUS SOLUTION 10 %

- PROCALAMINE INTRAVENOUS SOLUTION 3 %
- PROGRAF ORAL PACKET 0.2 MG, 1 MG
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- PULMOZYME INHALATION SOLUTION 1 MG/ML
- RABAVERT INTRAMUSCULAR SUSPENSION RECONSTITUTED
- RECOMBIVAX HB INJECTION SUSPENSION 10 MCG/ML, 10 MCG/ML (1ML SYRINGE), 40 MCG/ML, 5 MCG/0.5ML
- SANDIMMUNE ORAL SOLUTION 100 MG/ML
- sirolimus oral solution 1 mg/ml
- sirolimus oral tablet 0.5 mg, 1 mg, 2 mg
- tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg
- TDVAX INTRAMUSCULAR SUSPENSION 2-2 LF/0.5ML
- TENIVAC INTRAMUSCULAR INJECTABLE 5-2 LFU
- tigecycline intravenous solution reconstituted 50 mg
- tobramycin inhalation nebulization solution 300 mg/5ml
- TPN ELECTROLYTES INTRAVENOUS CONCENTRATE
- TRAVASOL INTRAVENOUS SOLUTION 10 %
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- TREXALL ORAL TABLET 10 MG, 15 MG, 5 MG, 7.5 MG
- TROPHAMINE INTRAVENOUS SOLUTION 10 %
- XATMEP ORAL SOLUTION 2.5 MG/ML
- ZORTRESS ORAL TABLET 1 MG



#### **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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| HUMIRA SUBCUTANEOUS PREFILLED             | LENVIMA (10 MG DAILY DOSE) 9                | <del>)</del> 2 |
| SYRINGE KIT 69                            | LENVIMA (12 MG DAILY DOSE) 9                | €              |
| I   | LENVIMA (14 MG DAILY DOSE) 9                | <del>)</del> 2 |
| IBRANCE70                                 | LENVIMA (18 MG DAILY DOSE)9                 | <del>)</del> 2 |
| ICLUSIG71                                 | LENVIMA (20 MG DAILY DOSE) 9                | <del>)</del> 2 |
| IDHIFA72                                  | LENVIMA (24 MG DAILY DOSE) 9                | €              |
| IMBRUVICA73                               | LENVIMA (4 MG DAILY DOSE) 9                 | €              |
| IMOVAX RABIES INTRAMUSCULAR               | LENVIMA (8 MG DAILY DOSE) 9                 | €              |
| INJECTABLE 2.5 UNIT/ML 186                | leuprolide acetate injection9               | <del>)</del> 3 |
| INBRIJA74                                 | levalbuterol hcl inhalation nebulization    |                |
| INCRELEX75                                | solution 0.31 mg/3ml, 0.63 mg/3ml, 1.25     | 5              |
| INQOVI76                                  | mg/0.5ml, 1.25 mg/3ml                       |                |
| INREBIC77                                 | levocarnitine oral solution 1 gm/10ml 18    |                |
| INTRALIPID INTRAVENOUS                    | levocarnitine oral tablet 330 mg 18         |                |
| EMULSION 20 %, 30 % 186                   | lidocaine external patch 5 %                |                |
| INTRAROSA78                               | LONSURF9                                    |                |
| INTRON A INJECTION SOLUTION               | LORBRENA9                                   | <del>)</del> 6 |
| 10000000 UNIT/ML, 6000000 UNIT/ML         | LUPRON DEPOT (1-MONTH)9                     | €3             |
| 187                                       | LUPRON DEPOT (3-MONTH)9                     | €3             |
| INTRON A INJECTION SOLUTION               | LUPRON DEPOT (4-MONTH)9                     | <del>)</del> 3 |
| RECONSTITUTED 10000000 UNIT,              | LUPRON DEPOT (6-MONTH)9                     | €3             |
| 18000000 UNIT, 50000000 UNIT 187          | LYNPARZA ORAL TABLET 97, 9                  | 98             |
| ipratropium bromide inhalation solution   | M   |                |
| 0.02 % 187                                | MAVYRET6                                    | 56             |
| ipratropium-albuterol inhalation solution | MAYZENT9                                    | <del>)</del> 9 |
| 0.5-2.5 (3) mg/3ml                        | MEKINIST 10                                 | 00             |
| IRESSA79                                  | MEKTOVI 10                                  | )1             |
| ISOLYTE-P IN D5W INTRAVENOUS              | methocarbamol oral6                         | 58             |
| SOLUTION 187                              | methotrexate oral tablet 2.5 mg 18          | 37             |
| ISTURISA 80                               | methotrexate sodium (pf) injection solution | 1              |
| itraconazole oral81, 82                   | 50 mg/2ml 18                                |                |
| J   | methotrexate sodium injection solution 50   |                |
| JAKAFI 84                                 | mg/2ml18                                    | 37             |
| K   | methylphenidate hcl er oral tablet extended | l              |
| KALYDECO85                                | release 10 mg, 18 mg, 20 mg, 27 mg, 36      |                |
| KESIMPTA86                                | mg, 54 mg 10                                |                |
| KISQALI (200 MG DOSE) 87                  | methylphenidate hcl er oral tablet extended | l              |
| KISQALI (400 MG DOSE) 87                  | release 24 hour 10                          |                |
| KISQALI (600 MG DOSE) 87                  | methylphenidate hcl oral solution 10        | )2             |
| KISQALI FEMARA (400 MG DOSE) 88           | methylphenidate hcl oral tablet 10          |                |
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| 187   | SOLUTION 180 MCG/0.5ML 122                  |
| mycophenolate mofetil oral suspension       | PEGASYS SUBCUTANEOUS SOLUTION               |
| reconstituted 200 mg/ml 187                 |   |
| mycophenolate mofetil oral tablet 500 mg    | PEMAZYRE123                                 |
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