Last Updated: 10/01/2024

# **ABILIFY ASIMTUFII**

### **Products Affected**

#### • Abilify Asimtufii

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

NR\_0009\_3741 09/2014

Formulary ID: 25110: version 9

# **ABILIFY MYCITE**

#### **Products Affected**

• Abilify Mycite Maintenance Kit

• Abilify Mycite Starter Kit

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ABIRATERONE**

### **Products Affected**

• Abiraterone Acetate

## • Zytiga

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Node-positive (N1), non-metastatic (M0) prostate cancer, very-high-risk prostate cancer, non-metastatic high-risk prostate cancer, non-metastatic prostate cancer with prostate-specific antigen (PSA) persistence/recurrence after radical prostatectomy |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.  |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **ACITRETIN**

#### **Products Affected**

#### • Acitretin

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Prevention of non-melanoma skin cancers in high risk individuals, Lichen planus, Keratosis follicularis (Darier Disease)                             |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For psoriasis: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate or cyclosporine. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **ACTEMRA**

#### **Products Affected**

• Actemra

### • Actemra Actpen

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ACTHAR HP**

# **Products Affected**

• Acthar

#### • Acthar Gel

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ACTIMMUNE**

#### **Products Affected**

#### • Actimmune INJ 100MCG/0.5ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses                     | Mycosis fungoides, Sezary syndrome                                 |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **ADAKVEO**

# **Products Affected**

#### • Adakveo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

#### **ADALIMUMAB AET**

#### **Products Affected**

- Abrilada
- Abrilada 1-pen Kit
- Adalimumab-aaty 1-pen Kit
- Adalimumab-aaty 2-syringe Kit
- Adalimumab-adaz
- Adalimumab-adbm
- Adalimumab-adbm Crohns/uc/hs Starter
- Adalimumab-adbm Psoriasis/uveitis Starter
- Adalimumab-adbm Starter Package For Crohns Disease/uc/hs
- Adalimumab-adbm Starter Package For Psoriasis/uveitis
- Adalimumab-fkjp
- Adalimumab-ryvk
- Adalimumab-ryvk (2 Pen)
- Amjevita
- Cyltezo
- Cyltezo Starter Package For Crohns Disease/uc/hs

- Cyltezo Starter Package For Psoriasis
- Cyltezo Starter Package For Psoriasis/uveitis
- Hadlima
- Hadlima Pushtouch
- Hulio
- Hyrimoz
- Hyrimoz Crohn's Disease And Ulcerative Colitis Starter Pack
- Hyrimoz Pediatric Crohns Disease Starter Pack
- Hyrimoz Pediatric Crohn'sdisease Starter Pack
- Hyrimoz Plaque Psoriasis/uveitis Starter Pack
- Simlandi 1-pen Kit
- Simlandi 2-pen Kit
- Yuflyma 1-pen Kit
- Yuflyma 2-syringe Kit
- Yuflyma Cd/uc/hs Starter
- Yusimry

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |

| Coverage<br>Duration | Pending CMS Review |
|----------------------|--------------------|
| Other Criteria       | Pending CMS Review |

#### **ADAPALENE**

#### **Products Affected**

- Adapalene CREA
- Adapalene GEL
- Adapalene PADS
- Adapalene SOLN
- Adapalene Pump
- Adapalene/benzoyl Peroxide

- Cabtreo
- Differin CREA
- Differin GEL 0.3%
- Differin LOTN
- Epiduo
- Epiduo Forte

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ADBRY**

#### **Products Affected**

• Adbry

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ADEMPAS**

#### **Products Affected**

### • Adempas

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ADLARITY**

#### **Products Affected**

### • Adlarity

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ADZYNMA**

### **Products Affected**

### • Adzynma

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **AGAMREE**

### **Products Affected**

### • Agamree

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **AIMOVIG**

### **Products Affected**

### • Aimovig

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For the preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants. For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Initial: 3 months, Continuation: Plan Year  |
| Other Criteria                     | N/A   |

# AJOVY AET

### **Products Affected**

• Ajovy

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **AKEEGA**

#### **Products Affected**

### • Akeega

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | The requested drug will be used in combination with a gonadotropin-<br>releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **AKLIEF**

### **Products Affected**

#### • Aklief

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ALDURAZYME**

#### **Products Affected**

### • Aldurazyme

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ALECENSA**

# **Products Affected**

#### • Alecensa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ALIQOPA**

### **Products Affected**

• Aliqopa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ALKINDI**

#### **Products Affected**

### • Alkindi Sprinkle

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ALOSETRON**

### **Products Affected**

• Lotronex

• Alosetron Hydrochloride

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For severe diarrhea-predominant irritable bowel syndrome (IBS): 1) The requested drug is being prescribed for a biological female or a person that self-identifies as a female, 2) chronic IBS symptoms lasting at least 6 months, 3) gastrointestinal tract abnormalities have been ruled out, AND 4) inadequate treatment response to one conventional therapy (e.g., antispasmodics, antidepressants, antidiarrheals). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# ALPHA1-PROTEINASE INHIBITOR

#### **Products Affected**

- Aralast Np INJ 1000MG, 500MG
- Glassia

- Prolastin-c
- Zemaira

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For alpha1-proteinase inhibitor deficiency: Patient must have 1) clinically evident emphysema, AND 2) pretreatment serum alpha1-proteinase inhibitor level less than 11 micromol/L (80 milligrams per deciliter [mg/dL] by radial immunodiffusion or 50 mg/dL by nephelometry). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **ALUNBRIG**

#### **Products Affected**

### • Alunbrig

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), brain metastases from ALK-positive NSCLC, inflammatory myofibroblastic tumors (IMT) with ALK translocation, Erdheim-Chester disease (ECD) with ALK-fusion |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic, AND 2) the disease is anaplastic lymphoma kinase (ALK)-positive.  |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **ALVAIZ**

#### **Products Affected**

#### • Alvaiz

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For chronic or persistent immune thrombocytopenia (ITP) (new starts): 1) Patient (pt) has experienced an inadequate treatment response or is intolerant to a prior therapy such as corticosteroids or immunoglobulins, AND 2) Untransfused platelet (plt) count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000-50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes pt to trauma). For ITP (continuation): plt count response to the requested drug: 1) Current plt count is less than or equal to 200,000/mcL, OR 2) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to a plt count sufficient to avoid clinically important bleeding. For thrombocytopenia associated with chronic hepatitis C (new starts): the requested drug is used for initiation and maintenance of interferon-based therapy. For thrombocytopenia associated with chronic hepatitis C (continuation): pt is receiving interferon-based therapy. For severe aplastic anemia (AA) (new starts): Pt had an insufficient response to immunosuppressive therapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | HCV: 6mo, ITP/AA initial: 6mo, ITP reauth: Plan Year, AA reauth: APR-Plan Year, IPR-16 wks   |

#### **Other Criteria**

For severe AA (continuation): 1) Current plt count is 50,000-200,000/mcL, OR 2) Current plt count is less than 50,000/mcL and pt has not received appropriately titrated therapy for at least 16 weeks, OR 3) Current plt count is less than 50,000/mcL and pt is transfusion-independent, OR 4) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to achieve and maintain an appropriate target plt count. APR: adequate platelet response (greater than 50,000/mcL), IPR: inadequate platelet response (less than 50,000/mcL).

# **ALYMSYS**

#### **Products Affected**

## • Alymsys

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **AMBRISENTAN**

#### **Products Affected**

• Ambrisentan

#### • Letairis

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **AMITIZA AET**

## **Products Affected**

• Amitiza

### • Lubiprostone

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **AMONDYS 45**

# **Products Affected**

• Amondys 45

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **AMVUTTRA**

## **Products Affected**

#### • Amvuttra

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **APOKYN**

### **Products Affected**

• Apokyn INJ 30MG/3ML

• Apomorphine Hydrochloride INJ

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **ARANESP AET**

#### **Products Affected**

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

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **ARCALYST**

#### **Products Affected**

• Arcalyst

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Prevention of gout flares in patients initiating or continuing urate-<br>lowering therapy  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For prevention of gout flares in patients initiating or continuing urate-lowering therapy (e.g., allopurinol) (new starts): 1) two or more gout flares within the previous 12 months, AND 2) inadequate response, intolerance, or contraindication to maximum tolerated doses of a non-steroidal anti-inflammatory drug (NSAID) and colchicine, AND 3) concurrent use with urate-lowering therapy. For prevention of gout flares in patients initiating or continuing urate-lowering therapy (e.g., allopurinol) (continuation): 1) patient must have achieved or maintained a clinical benefit (i.e., a fewer number of gout attacks or fewer flare days) compared to baseline, AND 2) continued use of urate-lowering therapy concurrently with the requested drug. For recurrent pericarditis: patient must have had an inadequate response, intolerance, or contraindication to maximum tolerated doses of a NSAID and colchicine. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **ARESTIN AET**

## **Products Affected**

#### • Arestin

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **ARIKAYCE**

#### **Products Affected**

## • Arikayce

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## ARMODAFINIL

#### **Products Affected**

• Armodafinil

## • Nuvigil

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For excessive sleepiness associated with narcolepsy: The diagnosis has been confirmed by sleep lab evaluation. For excessive sleepiness associated with obstructive sleep apnea (OSA): The diagnosis has been confirmed by polysomnography. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **A**RZERRA

#### **Products Affected**

#### • Arzerra

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **ASPARLAS**

#### **Products Affected**

## • Asparlas

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ASPRUZYO**

## **Products Affected**

## • Aspruzyo Sprinkle

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **AUBAGIO**

#### **Products Affected**

#### • Teriflunomide

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **A**UGTYRO

#### **Products Affected**

## • Augtyro

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **AUSTEDO**

#### **Products Affected**

• Austedo

- Austedo Xr
- Austedo Xr Patient Titration Kit

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses                     | Tourette's syndrome  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **AUVELITY**

## **Products Affected**

## • Auvelity

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For Major Depressive Disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **AVASTIN**

## **Products Affected**

#### • Avastin

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **AVONEX AET**

#### **Products Affected**

• Avonex INJ 30MCG/0.5ML

#### • Avonex Pen

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **AVSOLA**

## **Products Affected**

#### • Avsola

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **AVYCAZ**

## **Products Affected**

## • Avycaz

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **A**YVAKIT

## **Products Affected**

## • Ayvakit

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Myeloid and lymphoid neoplasms with eosinophilia, gastrointestinal stromal tumor (GIST) for residual, unresectable, tumor rupture, or recurrent/metastatic disease without platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation.   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For myeloid and lymphoid neoplasms with eosinophilia, the patient meets all of the following criteria: 1) The disease is FIP1L1- PDGFRA rearrangement-positive, AND 2) The disease harbors a PDGFRA D842V mutation, AND 3) The disease is resistant to imatinib. For GIST, the patient meets either of the following criteria: 1) The disease harbors PDGFRA exon 18 mutation, including a PDGFRA D842V mutation, OR 2) The requested drug will be used after failure on at least two Food and Drug Administration (FDA)-approved therapies in residual, unresectable, tumor rupture, or recurrent/metastatic disease without PDGFRA exon 18 mutation. For systemic mastocytosis: 1) The patient has a diagnosis of indolent systemic mastocytosis or advanced systemic mastocytosis (including aggressive systemic mastocytosis [ASM], systemic mastocytosis with associated hematological neoplasm [SM-AHN], and mast cell leukemia [MCL]) AND 2) The patient has a platelet count of greater than or equal to 50,000/microliter (mcL). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **BACLOFEN SOLN**

#### **Products Affected**

• Baclofen ORAL SOLN 10MG/5ML, 5MG/5ML

#### • Ozobax Ds

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **B**AFIERTAM

## **Products Affected**

#### • Bafiertam

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **B**ALVERSA

## **Products Affected**

#### • Balversa

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For urothelial carcinoma: 1) disease has susceptible fibroblast growth factor receptor 3 (FGFR3) genetic alterations, AND 2) the requested drug will be used as subsequent therapy for any of the following: a) locally advanced, recurrent, or metastatic urothelial carcinoma, OR b) stage II-IV, recurrent, or persistent urothelial carcinoma of the bladder. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# BANZEL

## **Products Affected**

Banzel

#### • Rufinamide

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | 1 year of age or older        |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **BAVENCIO**

## **Products Affected**

#### • Bavencio

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# BAXDELA

#### **Products Affected**

#### • Baxdela

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **BELBUCA**

#### **Products Affected**

#### • Belbuca

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# BELEODAQ

## **Products Affected**

## • Beleodaq

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **BENLYSTA**

#### **Products Affected**

## • Benlysta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | For patients new to therapy: severe active central nervous system lupus.   |
| Required<br>Medical<br>Information | For systemic lupus erythematosus (SLE): 1) patient is currently receiving a stable standard therapy regimen for SLE (for example, corticosteroid, antimalarial, or NSAIDs), OR 2) patient has experienced an intolerance or has a contraindication to standard therapy regimen for SLE. For lupus nephritis: 1) patient is currently receiving a stable standard therapy regimen for lupus nephritis (for example, corticosteroid, cyclophosphamide, mycophenolate mofetil, or azathioprine) OR 2) patient has experienced an intolerance or has a contraindication to standard therapy regimen for lupus nephritis. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## BENZNIDAZOLE

#### **Products Affected**

#### • Benznidazole

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **BEOVU**

## **Products Affected**

#### • Beovu SOSY

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **BERINERT**

#### **Products Affected**

#### • Berinert

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For treatment of acute angioedema attacks due to hereditary angioedema (HAE): 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing, OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation, b) the patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **BESPONSA**

## **Products Affected**

## • Besponsa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **BESREMI**

#### **Products Affected**

#### • Besremi

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **BETASERON**

## **Products Affected**

#### • Betaseron

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **BEXAROTENE**

#### **Products Affected**

• Bexarotene CAPS

## • Targretin CAPS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Mycosis fungoides (MF)/Sezary syndrome (SS), CD30-positive primary cutaneous anaplastic large cell lymphoma (ALCL), CD30-positive lymphomatoid papulosis (LyP) |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **BIMZELX**

## **Products Affected**

#### • Bimzelx

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **BLINCYTO**

## **Products Affected**

## • Blincyto

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **BOSENTAN**

#### **Products Affected**

• Bosentan

#### • Tracleer

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) if the request is for an adult patient, the patient meets both of the following: a) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units, and b) the patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to ambrisentan (Letairis). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **BOSULIF**

#### **Products Affected**

#### • Bosulif

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Philadelphia chromosome positive B-cell acute lymphoblastic leukemia (Ph+ B-ALL), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase.  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I, G250E, V299L, and F317L, AND 3) Patient has experienced resistance or intolerance to imatinib, dasatinib, or nilotinib. For B-ALL including patients who have received hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I, G250E, V299L, and F317L. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## Вотох

### **Products Affected**

• Botox

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **B**RAFTOVI

### **Products Affected**

#### • Braftovi CAPS 75MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Adjuvant systemic therapy for cutaneous melanoma, appendiceal adenocarcinoma, recurrent NSCLC  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For colorectal cancer (including appendiceal adenocarcinoma): 1) Tumor is positive for BRAF V600E mutation, AND 2) The requested drug will be used for either of the following: a) subsequent therapy for advanced or metastatic disease, b) primary treatment for unresectable metachronous metastases. For melanoma: 1) Tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used as a single agent or in combination with binimetinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer (NSCLC): 1) Tumor is positive for BRAF V600E mutation, AND 2) Disease is advanced, recurrent, or metastatic, AND 3) The requested drug will be used in combination with binimetinib. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## BRISDELLE

### **Products Affected**

#### • Paroxetine

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **BRIUMVI AET**

### **Products Affected**

#### • Briumvi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **BRIVIACT**

#### **Products Affected**

• Briviact ORAL SOLN

#### • Briviact TABS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom (if 4 years of age or older), Xcopri (if 18 years of age or older), Spritam (if 4 years of age or older). |
| Age Restrictions                   | 1 month of age or older   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **BRIVIACT INJ**

### **Products Affected**

#### • Briviact INJ

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### BRIXADI

### **Products Affected**

#### • Brixadi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **BROMSITE AET**

#### **Products Affected**

• Bromfenac Sodium SOLN 0.075%

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **BRONCHITOL**

### **Products Affected**

#### • Bronchitol

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | 18 years of age or older      |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **BROVANA AET**

#### **Products Affected**

• Brovana

• Arformoterol Tartrate

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **BRUKINSA**

#### **Products Affected**

### • Brukinsa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For mantle cell lymphoma and chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL): the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Calquence (acalabrutinib). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

### **BUPRENORPHINE**

#### **Products Affected**

• Buprenorphine Hcl SUBL

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | The requested drug is being prescribed for the treatment of opioid use disorder AND patient meets one of the following: 1) The patient is pregnant or breastfeeding, and the requested drug is being prescribed for induction therapy and/or subsequent maintenance therapy for treatment of opioid use disorder OR 2) The requested drug is being prescribed for induction therapy for transition from opioid use to treatment of opioid use disorder OR 3) The requested drug is being prescribed for maintenance therapy for treatment of opioid use disorder in a patient who is intolerant to naloxone. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **BUPRENORPHINE PATCH**

### **Products Affected**

• Buprenorphine PTWK

#### • Butrans

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe and persistent enough to require an extended treatment period with a daily opioid analgesic in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

#### **BUTALBITAL AET**

#### **Products Affected**

- Allzital
- Ascomp/codeine
- Bupap TABS 300MG; 50MG
- Butalbital/acetaminophen CAPS
- Butalbital/acetaminophen TABS 300MG; 50MG, 325MG; 50MG
- Butalbital/acetaminophen/caffeine CAPS
- Butalbital/acetaminophen/caffeine TABS 325MG; 50MG; 40MG

- Butalbital/acetaminophen/caffeine/code ine
- Butalbital/aspirin/caffeine CAPS
- Butalbital/aspirin/caffeine/codeine
- Esgic
- Fioricet CAPS
- Fioricet/codeine CAPS 300MG; 50MG; 40MG; 30MG
- Tencon TABS 325MG; 50MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **BYDUREON**

#### **Products Affected**

### • Bydureon Beise

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **B**YETTA

### **Products Affected**

• Byetta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **B**YLVAY

### **Products Affected**

• Bylvay

• Bylvay (pellets)

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **BYOOVIZ**

### **Products Affected**

• Byooviz

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **C**ABLIVI

#### **Products Affected**

#### • Cablivi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **CABOMETYX**

### **Products Affected**

### • Cabometyx

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Non-small cell lung cancer, Ewing sarcoma, osteosarcoma, gastrointestinal stromal tumor, endometrial carcinoma   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For renal cell carcinoma: The disease is advanced, relapsed, or stage IV (including brain metastases). For non-small cell lung cancer: 1) the disease is rearranged during transfection (RET) positive AND 2) the disease is recurrent, advanced, or metastatic. For hepatocellular carcinoma: the requested drug will be used as subsequent therapy. For gastrointestinal stromal tumor (GIST): 1) the disease is residual, unresectable, recurrent, or metastatic/tumor rupture, AND 2) the disease has progressed after at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib). For Ewing sarcoma and osteosarcoma: the requested drug will be used as subsequent therapy. For differentiated thyroid cancer (DTC) (follicular, papillary, oncocytic): 1) the disease is locally advanced or metastatic, AND 2) the disease has progressed after a vascular endothelial growth factor receptor (VEGFR)- targeted therapy, AND 3) the patient is refractory to radioactive iodine therapy (RAI) or ineligible for RAI. For endometrial carcinoma: 1) the disease is recurrent, AND 2) the requested drug will be used as subsequent therapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

### **CALCIPOTRIENE**

#### **Products Affected**

- Calcipotriene CREA
- Calcipotriene FOAM
- Calcipotriene OINT
- Calcipotriene SOLN
- Calcipotriene/betamethasone Dipropionate

- Calcitrene
- Calcitriol OINT
- Enstilar
- Sorilux
- Taclonex SUSP
- Vectical

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For psoriasis: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a topical steroid. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **CALQUENCE**

### **Products Affected**

### • Calquence

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Waldenstrom macroglobulinemia (lymphoplasmacytic lymphoma),<br>marginal zone lymphoma (including extranodal marginal zone lymphoma<br>of the stomach, extranodal marginal zone lymphoma of nongastric sites,<br>nodal marginal zone lymphoma, splenic marginal zone lymphoma)   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, and splenic marginal zone lymphoma): the requested drug is being used for the treatment of relapsed, refractory, or progressive disease. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **C**AMBIA

### **Products Affected**

• Cambia

#### • Diclofenac Potassium PACK

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **CAMZYOS**

#### **Products Affected**

#### • Camzyos

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **CAPRELSA**

#### **Products Affected**

### • Caprelsa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses                     | Thyroid carcinomas (follicular, oncocytic, papillary).             |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **C**ARAC

### **Products Affected**

• Carac

#### • Fluorouracil CREA 0.5%

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **CARBAGLU**

### **Products Affected**

• Carbaglu

### • Carglumic Acid

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For N-acetylglutamate synthase (NAGS) deficiency: Diagnosis of NAGS deficiency was confirmed by enzymatic, biochemical, or genetic testing. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **CAYSTON**

### **Products Affected**

### • Cayston

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For treatment of respiratory symptoms in cystic fibrosis patients: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) The patient has a history of pseudomonas aeruginosa infection or colonization in the airways. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **C**EQUA

### **Products Affected**

• Cequa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **CERDELGA**

#### **Products Affected**

### • Cerdelga

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For type 1 Gaucher disease (GD1): 1) Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing, and 2) Patient's CYP2D6 metabolizer status has been established using an FDA-cleared test, and 3) Patient is a CYP2D6 extensive metabolizer, an intermediate metabolizer, or a poor metabolizer. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **CEREZYME**

### **Products Affected**

### • Cerezyme

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **CHANTIX AET**

#### **Products Affected**

• Varenicline Tartrate

• Varenicline Starting Month Box

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 6 months   |
| Other Criteria                     | This Prior Authorization requirement applies after the patient has received a cumulative 24 weeks of therapy in a Plan Year. |

## CHENODAL AET

### **Products Affected**

#### • Chenodal

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **CHLORDIAZEPOXIDE - 65**

#### **Products Affected**

- Chlordiazepoxide Hcl CAPS 10MG, 5MG
- Chlordiazepoxide Hydrochloride CAPS 25MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For all indications: the prescriber must acknowledge the benefit of therapy with the prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) the requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), or b) serotonin-norepinephrine reuptake inhibitors (SNRIs). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Short-term relief anxiety-preop apprehens and anx-1 mo, Anxiety Disorder-4 mo, Alc Withdrawal-PlanYR  |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older.   |

## **CHOLBAM**

### **Products Affected**

#### • Cholbam

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **CIBINQO**

### **Products Affected**

### • Cibinqo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **CIMERLI**

## **Products Affected**

### • Cimerli

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **CIMZIA**

# **Products Affected**

• Cimzia

### • Cimzia Starter Kit

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **CINQAIR**

## **Products Affected**

• Cinqair

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **CINRYZE**

## **Products Affected**

## • Cinryze

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **CINVANTI**

## **Products Affected**

### • Cinvanti

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# CITALOPRAM CAP AET

## **Products Affected**

• Citalopram Hydrobromide CAPS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **CLOBAZAM**

### **Products Affected**

• Clobazam

- Onfi SUSP
- Onfi TABS 10MG, 20MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.              |
| Off-Label Uses                     | Seizures associated with Dravet syndrome  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | N/A   |
| Age Restrictions                   | Seizures associated with Lennox-Gastaut syndrome (LGS): 2 years of age or older |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **CLOMIPRAMINE**

### **Products Affected**

• Anafranil

## • Clomipramine Hydrochloride

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Depression, panic disorder  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For obsessive-compulsive disorder (OCD) and panic disorder: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to any of the following: a serotonin and norepinephrine reuptake inhibitor (SNRI), a selective serotonin reuptake inhibitor (SSRI). For depression: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to two of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **CLORAZEPATE**

### **Products Affected**

## • Clorazepate Dipotassium TABS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Short-term relief anxiety-1 month, Anxiety Disorders-4 months, All other Diagnoses-Plan Year  |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older.   |

# **CLOZAPINE ODT**

## **Products Affected**

• Clozapine Odt

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **COLUMVI**

## **Products Affected**

### • Columvi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **COLY-MYCIN**

### **Products Affected**

• Colistimethate Sodium INJ

• Coly-mycin M

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | The requested drug is being used intravenously (IV) or intramuscularly (IM). Administration will not be via nebulizer (Note: CMS endorsed compendia do not support inhalation/nebulization of colistimethate.). The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an infectious disease specialist  |
| Coverage<br>Duration               | Initial approval: 3 months. Renewal: Plan Year  |
| Other Criteria                     | N/A   |

# **COMETRIQ**

## **Products Affected**

## • Cometriq

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Non-small cell lung cancer (NSCLC), thyroid carcinomas (follicular, oncocytic, papillary).                           |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For non-small cell lung cancer (NSCLC): Disease is positive for rearranged during transfection (RET) rearrangements. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **C**OPIKTRA

## **Products Affected**

## • Copiktra

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Hepatosplenic T-Cell lymphoma, breast implant-associated anaplastic large cell lymphoma (ALCL), peripheral T-Cell lymphoma   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), breast implant-associated anaplastic large cell lymphoma (ALCL), and peripheral T-Cell lymphoma: the patient has relapsed or refractory disease. For hepatosplenic T-Cell lymphoma: the patient has refractory disease. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **CORTROPHIN**

### **Products Affected**

## • Cortrophin

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **COSENTYX**

## **Products Affected**

• Cosentyx

- Cosentyx Sensoready Pen
- Cosentyx Unoready

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis AND 2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Skyrizi (risankizumab-rzaa), Sotyktu (deucravacitinib), Stelara (ustekinumab), Tremfya (guselkumab). For active ankylosing spondylitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active non-radiographic axial spondyloarthritis (new starts only): patient meets any of the following: 1) patient has experienced an inadequate treatment response to a non-steroidal anti-inflammatory drug (NSAID) OR 2) patient has experienced an intolerance or has a contraindication to NSAIDs. For an adult with active psoriatic arthritis (PsA) (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab), Tremfya (guselkumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For moderate to severe hidradenitis suppurativa (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf). |
| Age Restrictions                   | N/A  |

| Prescriber<br>Restrictions | N/A       |
|----------------------------|-----------|
| Coverage<br>Duration       | Plan Year |
| Other Criteria             | N/A       |

# **C**OTELLIC

### **Products Affected**

### • Cotellic

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Central nervous system (CNS) cancer (i.e., glioma, glioblastoma), adjuvant systemic therapy for cutaneous melanoma.   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For central nervous system (CNS) cancer (i.e., glioma, glioblastoma): 1) The tumor is positive for BRAF V600E activating mutation, AND 2) The requested drug will be used in combination with vemurafenib. For melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used in combination with vemurafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **CRINONE**

## **Products Affected**

### • Crinone

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **C**RYSVITA

## **Products Affected**

## • Crysvita

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **C**UTAQUIG

## **Products Affected**

• Cutaquig

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **C**UVITRU

## **Products Affected**

### • Cuvitru

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **CUVRIOR**

## **Products Affected**

### • Cuvrior

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **CYCLOPHOSPHAMIDE ORAL**

### **Products Affected**

• Cyclophosphamide CAPS

• Cyclophosphamide TABS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# CYCLOSET AET

## **Products Affected**

• Cycloset

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **CYRAMZA**

### **Products Affected**

### • Cyramza

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **CYSTAGON**

## **Products Affected**

## • Cystagon

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For nephropathic cystinosis: Diagnosis was confirmed by ANY of the following: 1) the presence of increased cystine concentration in leukocytes, OR 2) genetic testing, OR 3) demonstration of corneal cystine crystals by slit lamp examination. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **CYSTARAN**

## **Products Affected**

• Cystadrops

### • Cystaran

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For cystinosis: 1) Diagnosis was confirmed by ANY of the following: a) the presence of increased cystine concentration in leukocytes, OR b) genetic testing, OR c) demonstration of corneal cystine crystals by slit lamp examination, AND 2) the patient has corneal cystine crystal accumulation. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **D**ALFAMPRIDINE

## **Products Affected**

• Ampyra

## • Dalfampridine Er

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For multiple sclerosis, patient must meet the following (for new starts): prior to initiating therapy, patient demonstrates sustained walking impairment. For multiple sclerosis (continuation): patient must have experienced an improvement in walking speed OR other objective measure of walking ability since starting the requested drug. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# DAPAGLIFLOZIN AET

## **Products Affected**

## • Dapagliflozin Propanediol

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **DAPAGLIFLOZIN-METFORMIN AET**

### **Products Affected**

• Dapagliflozin Propanediol/metformin Hydrochloride

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **D**ARAPRIM

## **Products Affected**

• Daraprim

## • Pyrimethamine TABS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Toxoplasmosis prophylaxis, Pneumocystis jirovecii pneumonia prophylaxis, cystoisosporiasis treatment and secondary prophylaxis   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For primary toxoplasmosis prophylaxis and Pneumocystis jirovecii pneumonia (PCP) prophylaxis: 1) The patient has experienced an intolerance or has a contraindication to trimethoprim-sulfamethoxazole (TMP-SMX) AND 2) The patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 3 months. For secondary toxoplasmosis prophylaxis: The patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 6 months. For cystoisosporiasis treatment: The patient has experienced an intolerance or has a contraindication to TMP-SMX. For secondary cystoisosporiasis prophylaxis: 1) The patient has experienced an intolerance or has a contraindication to TMP-SMX AND 2) The patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 6 months. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Congen toxo tx: Plan Yr. Acqu toxo tx, prim toxo ppx, PCP ppx: 3mo. Sec toxo ppx, cysto tx/ppx: 6mo  |
| Other Criteria                     | N/A  |

# **DARZALEX**

### **Products Affected**

### • Darzalex

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# DARZALEX FASPRO

### **Products Affected**

## • Darzalex Faspro

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **D**AURISMO

### **Products Affected**

### • Daurismo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Post-induction therapy/consolidation following response to previous therapy with the same regimen for acute myeloid leukemia (AML), relapsed/refractory AML as a component of repeating the initial successful induction regimen   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For acute myeloid leukemia (AML): 1) the requested drug must be used in combination with cytarabine, 2) the patient is 75 years of age or older OR has comorbidities that preclude intensive chemotherapy, AND 3) the requested drug will be used as treatment for induction therapy, post-induction/consolidation therapy, or relapsed or refractory disease. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **D**AYBUE

## **Products Affected**

• Daybue

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **D**EFERASIROX

### **Products Affected**

- Deferasirox
- Exjade

- Jadenu
- Jadenu Sprinkle

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For chronic iron overload due to blood transfusions: pretreatment serum ferritin level is greater than 1000 mcg/L. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **DEMSER**

### **Products Affected**

• Demser

### • Metyrosine

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to an alpha-adrenergic antagonist. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **DESVENLAFAXINE**

### **Products Affected**

• Desvenlafaxine Er TB24 100MG, 50MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **DHE NASAL**

### **Products Affected**

- Trudhesa
- Dihydroergotamine Mesylate NASAL SOLN
- Migranal

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | Coverage will be denied when used in conjunction with potent CYP3A4 inhibitors (e.g., ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin). |
| Required<br>Medical<br>Information | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one triptan 5-HT1 receptor agonist.   |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **DIACOMIT**

### **Products Affected**

#### • Diacomit

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | 6 months of age or older      |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

### **DIAZEPAM AET**

#### **Products Affected**

- Diazepam CONC
- Diazepam INJ 5MG/MLDiazepam SOLN 5MG/5ML

- Diazepam TABS
- Diazepam Intensol
- Valium TABS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Short-term relief anx-1 mo, skeletal muscle spasm-3 mo, Anx Disorders-4 mo, Other Diagnoses-PlanYR  |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older.   |

## **DICLOFENAC 2% SOL**

#### **Products Affected**

• Diclofenac Sodium EXTERNAL SOLN 2%

• Pennsaid SOLN 2%

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **DICLOFENAC 3% GEL**

### **Products Affected**

• Diclofenac Sodium GEL 3%

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **DIMETHYL FUMARATE AET**

#### **Products Affected**

- Dimethyl Fumarate CPDR
- Dimethyl Fumarate Starterpack CDPK 0
- Tecfidera
- Tecfidera Starter Pack

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **D**OJOLVI

### **Products Affected**

• Dojolvi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **DOPTELET AET**

### **Products Affected**

• Doptelet

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **D**RIZALMA

### **Products Affected**

### • Drizalma Sprinkle

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **DRONABINOL**

### **Products Affected**

• Dronabinol

- Marinol
- Syndros

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For nausea and vomiting associated with cancer chemotherapy: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one oral 5-HT3 receptor antagonist. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 6 months   |
| Other Criteria                     | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.                                   |

# **DUEXIS**

### **Products Affected**

• Duexis

• Ibuprofen/famotidine

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **D**UOBRII

## **Products Affected**

• Duobrii

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **DUPIXENT**

## **Products Affected**

• Dupixent

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For atopic dermatitis (AD), initial therapy: 1) Patient has moderate-to-severe disease, AND 2) Patient has had an inadequate treatment response to either a topical corticosteroid or a topical calcineurin inhibitor, OR topical corticosteroids and topical calcineurin inhibitors are not advisable for the patient. For AD, continuation of therapy: Patient achieved or maintained positive clinical response. For oral corticosteroid dependent asthma, initial therapy: Patient has inadequate asthma control despite current treatment with both of the following medications: 1) High-dose inhaled corticosteroid AND 2) Additional controller (i.e., long acting beta2-agonist, long-acting, muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For moderate-to-severe asthma, initial therapy: Patient has a baseline blood eosinophil count of at least 150 cells per microliter and their asthma remains inadequately controlled despite current treatment with both of the following medications: 1) Medium-to-high-dose inhaled corticosteroid, AND 2) Additional controller (i.e., long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. For chronic rhinosinusitis with nasal polyposis (CRSwNP): 1) The requested drug is used as add-on maintenance treatment, AND 2) Patient has experienced an inadequate treatment response to Xhance (fluticasone). |
| Age Restrictions                   | Atopic Dermatitis: 6 months of age or older, Asthma: 6 years of age or older, Chronic Rhinosinusitis with Nasal Polyposis and Prurigo Nodularis: 18 years of age or older, Eosinophilic Esophagitis: 1 year of age or older   |

| Prescriber<br>Restrictions | N/A  |
|----------------------------|--|
| Coverage<br>Duration       | AD, initial: 4 months, PN, initial: 6 months, All others: Plan Year  |
| Other Criteria             | For eosinophilic esophagitis (EoE), initial therapy: 1) Diagnosis has been confirmed by esophageal biopsy characterized by greater than or equal to 15 intraepithelial esophageal eosinophils per high power field, AND 2) Patient is exhibiting clinical manifestations of the disease (for example, dysphagia), AND 3) Patient weighs at least 15 kilograms, AND 4) Patient experienced an inadequate treatment response, intolerance, or patient has a contraindication to a topical corticosteroid. For EoE, continuation of therapy: Patient achieved or maintained a positive clinical response. For prurigo nodularis (PN), initial therapy: Patient has had an inadequate treatment response to a topical corticosteroid OR topical corticosteroids are not advisable for the patient. For PN, continuation of therapy: Patient achieved or maintained a positive clinical response. |

# **D**URYSTA

### **Products Affected**

• Durysta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **D**UVYZAT

### **Products Affected**

• Duvyzat

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **D**YCLOPRO

### **Products Affected**

• Dyclopro

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **D**YSPORT

### **Products Affected**

• Dysport

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **EFUDEX**

## **Products Affected**

#### • Efudex CREA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **EGRIFTA**

### **Products Affected**

• Egrifta Sv

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **ELAPRASE**

## **Products Affected**

• Elaprase

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **E**LELYSO

## **Products Affected**

• Elelyso

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **E**LFABRIO

### **Products Affected**

#### • Elfabrio

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ELIGARD**

### **Products Affected**

• Eligard

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses                     | Recurrent androgen receptor positive salivary gland tumors         |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **E**LREXFIO

### **Products Affected**

### • Elrexfio

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **ELYXYB**

### **Products Affected**

• Elyxyb

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **EMFLAZA**

### **Products Affected**

• Deflazacort

#### • Emflaza

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **EMGALITY**

### **Products Affected**

• Emgality

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For the preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants. For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline. For episodic cluster headache, initial: The patient experienced an inadequate treatment response, intolerance, or contraindication to a triptan 5-HT1 receptor agonist. For episodic cluster headache, continuation: The patient received the requested drug for at least 3 weeks of treatment and had a reduction in weekly cluster headache attack frequency from baseline. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Initial: 3 months, Continuation: Plan Year  |
| Other Criteria                     | N/A   |

## **EMPAVELI**

## **Products Affected**

### • Empaveli

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **EMPLICITI**

## **Products Affected**

### • Empliciti

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **EMSAM**

### **Products Affected**

#### • Emsam

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For Major Depressive Disorder (MDD): 1) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion OR 2) The patient is unable to swallow oral formulations. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **ENDARI**

### **Products Affected**

• Endari

### • L-glutamine PACK

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | 5 years of age or older       |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **E**NHERTU

## **Products Affected**

#### • Enhertu

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ENJAYMO**

### **Products Affected**

### • Enjaymo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ENSPRYNG**

#### **Products Affected**

### • Enspryng

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ENTADFI**

## **Products Affected**

#### • Entadfi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ENTYVIO**

#### **Products Affected**

### • Entyvio

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **EOHILIA**

## **Products Affected**

#### • Eohilia

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **EPCLUSA**

### **Products Affected**

### • Epclusa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Criteria will be applied consistent with current AASLD-IDSA guidance   |
| Other Criteria                     | N/A  |

# **EPIDIOLEX**

## **Products Affected**

### • Epidiolex

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | 1 year of age or older        |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **EPKINLY**

### **Products Affected**

• Epkinly

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# ЕРО

## **Products Affected**

• Procrit

• Retacrit

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Anemia due to myelodysplastic syndromes (MDS), anemia in rheumatoid arthritis (RA), anemia due to hepatitis C treatment (ribavirin in combination with either interferon alfa or peginterferon alfa)  |
| Exclusion<br>Criteria              | Patients receiving chemotherapy with curative intent. Patients with myeloid cancer.   |
| Required<br>Medical<br>Information | Requirements regarding hemoglobin (Hgb) values exclude values due to a recent transfusion. For initial approval: 1) for all uses except anemia due to chemotherapy or myelodysplastic syndrome (MDS): patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%), AND 2) for all uses except surgery: pretreatment (no erythropoietin treatment in previous month) Hgb is less than 10 g/dL, AND 3) for MDS: pretreatment serum erythropoietin level is 500 international units/L or less. For reauthorizations (patient received erythropoietin treatment in previous month) in all uses except surgery: 1) patient has received at least 12 weeks of erythropoietin therapy, AND 2) patient responded to erythropoietin therapy, AND 3) current Hgb is less than 12 g/dL, AND 4) for all uses except anemia due to chemotherapy or MDS: patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 16 weeks  |
| Other Criteria                     | Coverage includes use in anemia in patients whose religious beliefs forbid blood transfusions. Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual (e.g., used for treatment of anemia for a patient with chronic renal failure who is undergoing dialysis, or furnished from physician's supply incident to a physician service).  |

# **EPOGEN AET**

#### **Products Affected**

• Epogen INJ 10000UNIT/ML, 20000UNIT/ML, 2000UNIT/ML, 4000UNIT/ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **EPRONTIA**

### **Products Affected**

• Eprontia

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom (if 4 years of age or older), Xcopri (if 18 years of age or older), Spritam (if 4 years of age or older). For monotherapy treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response or intolerance to a generic topiramate immediate release product, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) If the patient is 6 years of age or older, the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Spritam. For the preventative treatment of migraines: 1) The patient has experienced an inadequate treatment response or intolerance to a generic topiramate immediate release product, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). |
| Age Restrictions                   | Epilepsy: 2 years of age or older, Migraine: 12 years of age or older  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **EPSOLAY**

### **Products Affected**

• Epsolay

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ERAXIS AET**

#### **Products Affected**

• Eraxis

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ERBITUX**

#### **Products Affected**

#### • Erbitux

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **ERGOTAMINE**

#### **Products Affected**

• Migergot

• Ergotamine Tartrate/caffeine

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | Coverage will be denied when used in conjunction with potent CYP3A4 inhibitors (e.g., ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin). |
| Required<br>Medical<br>Information | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least ONE triptan 5-HT1 agonist.            |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **ERIVEDGE**

## **Products Affected**

### • Erivedge

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Adult medulloblastoma   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For adult medulloblastoma: patient has received prior systemic therapy AND has tumor(s) with mutations in the sonic hedgehog pathway. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **E**RLEADA

#### **Products Affected**

#### • Erleada

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | The requested drug will be used in combination with a gonadotropin-<br>releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **ERLOTINIB**

### **Products Affected**

• Tarceva

• Erlotinib Hydrochloride TABS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Recurrent non-small cell lung cancer (NSCLC), recurrent chordoma, relapsed or stage IV renal cell carcinoma (RCC), brain metastases from non-small cell lung cancer (NSCLC), recurrent pancreatic cancer  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For non-small cell lung cancer (NSCLC) (including brain metastases from NSCLC): 1) the disease is recurrent, advanced, or metastatic, AND 2) the patient has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease. For pancreatic cancer: the disease is locally advanced, unresectable, recurrent, or metastatic. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **ESBRIET**

### **Products Affected**

• Esbriet

#### • Pirfenidone

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For idiopathic pulmonary fibrosis (new starts only): 1) a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy reveals the usual interstitial pneumonia (UIP) pattern, OR 2) HRCT study of the chest reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported either by a lung biopsy or by a multidisciplinary discussion between at least a radiologist and pulmonologist who are experienced in idiopathic pulmonary fibrosis if a lung biopsy has not been conducted. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

### **ETANERCEPT**

#### **Products Affected**

- Enbrel INJ 25MG/0.5ML, 50MG/ML
- Enbrel Mini
- Enbrel Sureclick

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Hidradenitis suppurativa, non-radiographic axial spondyloarthritis   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For moderately to severely active rheumatoid arthritis (new starts only):  1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis AND 2) patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e. at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). For hidradenitis suppurativa (new starts only): patient has severe, refractory disease. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |

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

# **EVENITY AET**

### **Products Affected**

• Evenity

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **EVEROLIMUS**

#### **Products Affected**

- Afinitor
- Afinitor Disperz

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

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| TH CHICH                           |                    |
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **EVKEEZA**

#### **Products Affected**

#### • Evkeeza

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **EVRYSDI**

### **Products Affected**

• Evrysdi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **EXKIVITY**

#### **Products Affected**

### • Exkivity

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# EXONDYS 51

### **Products Affected**

• Exondys 51

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# EXTAVIA AET

#### **Products Affected**

#### • Extavia

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **EYLEA**

#### **Products Affected**

• Eylea

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# EYLEA HD

### **Products Affected**

• Eylea Hd

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **FABHALTA**

### **Products Affected**

#### • Fabhalta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **FABRAZYME**

#### **Products Affected**

### • Fabrazyme

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **FANAPT**

### **Products Affected**

• Fanapt

### • Fanapt Titration Pack

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For treatment of schizophrenia: 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **FASENRA**

## **Products Affected**

• Fasenra

#### • Fasenra Pen

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For severe asthma, initial therapy: 1) Either a) Patient has baseline blood eosinophil count of at least 150 cells per microliter OR b) Patient is dependent on systemic corticosteroids, AND 2) Patient has a history of severe asthma despite current treatment with both of the following medications: a) medium-to-high-dose inhaled corticosteroid AND b) additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For severe asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. |
| Age Restrictions                   | 6 years of age or older   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **FENSOLVI**

## **Products Affected**

#### • Fensolvi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# FENTANYL PATCH

#### **Products Affected**

### • Fentanyl PT72

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe and persistent enough to require an extended treatment period with a daily opioid analgesic in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **FERRIPROX**

### **Products Affected**

• Deferiprone

- FerriproxFerriprox Twice-a-day

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **FETZIMA**

#### **Products Affected**

• Fetzima

#### • Fetzima Titration Pack

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For major depressive disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **FILGRASTIM**

#### **Products Affected**

### • Nivestym

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **FILSPARI**

#### **Products Affected**

• Filspari

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **FILSUVEZ**

#### **Products Affected**

#### • Filsuvez

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **FINTEPLA**

#### **Products Affected**

### • Fintepla

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | 2 years of age or older       |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **FIRDAPSE**

#### **Products Affected**

### • Firdapse

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **FIRMAGON**

#### **Products Affected**

• Firmagon INJ 120MG/VIAL, 80MG

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## FLECTOR AET

#### **Products Affected**

• Diclofenac Epolamine

• Flector

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **FLEQSUVY**

### **Products Affected**

• Baclofen SUSP

• Fleqsuvy

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **FLUCYTOSINE**

#### **Products Affected**

• Ancobon

• Flucytosine CAPS 250MG, 500MG

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | 6 weeks                       |
| Other Criteria                     | N/A                           |

## FLUTICASONE FUROATE AND VILANTEROL AET

#### **Products Affected**

• Fluticasone Furoate/vilanterol Ellipta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# FLUTICASONE PROPIONATE HFA AET

#### **Products Affected**

• Fluticasone Propionate Diskus

• Fluticasone Propionate Hfa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## FORM ALT PA ANALGESICS

#### **Products Affected**

- Diclofenac Potassium CAPS
- Diclofenac Potassium TABS 25MG
- Lofena
- Tramadol Hydrochloride TABS 25MG
- Zipsor

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# FORM ALT PA METFORMIN

#### **Products Affected**

• Metformin Hydrochloride TABS 625MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# FORM ALT PA TOPICAL

#### **Products Affected**

• Bruselix GEL

- Lidotral GEL 3.88%
- Mycozyl Hc

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# FORM ALT PA TOPICAL STEROIDS

### **Products Affected**

### • Hydroxym CREA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# FORM ALT PA VALSARTAN SOL

#### **Products Affected**

#### • Valsartan SOLN

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **FORTEO**

### **Products Affected**

• Forteo INJ 600MCG/2.4ML

• Teriparatide

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For postmenopausal osteoporosis: patient has ONE of the following: 1) history of fragility fracture, OR 2) pre-treatment T-score of less than or equal to -2.5 or pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment Fracture Risk Assessment Tool (FRAX) fracture probability AND patient has ANY of the following: a) indicators for higher fracture risk (e.g., advanced age, frailty, glucocorticoid therapy, very low T-scores, or increased fall risk), OR b) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy OR c) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. For primary or hypogonadal osteoporosis in men: patient has ONE of the following: 1) history of osteoporotic vertebral or hip fracture, OR 2) pre-treatment T-score of less than or equal to -2.5, or pre-treatment FRAX fracture probability AND patient has ANY of the following: a) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy, OR b) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. For glucocorticoid-induced osteoporosis: patient has had an oral bisphosphonate trial of at least 1-year duration unless patient has a contraindication or intolerance to an oral bisphosphonate, AND patient meets ANY of the following: 1) patient has a history of fragility fracture, OR 2) pre-treatment T-score of less than or equal to -2.5, OR 3) pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment FRAX fracture probability. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |

| Coverage<br>Duration | Initial: 24 months, Continuation: Plan Year   |
|----------------------|---|
| Other Criteria       | Continuation of therapy: If the patient has received greater than or equal to 24 months of therapy with any parathyroid hormone analog: 1) The patient remains at or has returned to having a high risk for fracture, AND 2) The benefit of therapy with this prescribed medication outweighs the potential risks for this patient. Patient has high FRAX fracture probability if the 10-year probability is either greater than or equal to 20 percent for any major osteoporotic fracture or greater than or equal to 3 percent for hip fracture. If glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day, the estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture. |

## **FOSCAVIR**

#### **Products Affected**

• Foscarnet Sodium INJ 6000MG/250ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **FOTIVDA**

#### **Products Affected**

#### • Fotivda

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For renal cell carcinoma: 1) The disease is advanced, relapsed, refractory or Stage IV, AND 2) The patient has received two or more prior systemic therapies. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# FRUZAQLA

### **Products Affected**

### • Fruzaqla

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **FYARRO**

#### **Products Affected**

• Fyarro

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **FYCOMPA**

#### **Products Affected**

### • Fycompa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom, Xcopri, Spritam. For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Spritam. |
| Age Restrictions                   | Partial-onset seizures (i.e., focal-onset seizures): 4 years of age or older. Primary generalized tonic-clonic seizures: 12 years of age or older  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **G**ALAFOLD

## **Products Affected**

#### • Galafold

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **GATTEX**

#### **Products Affected**

#### • Gattex

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For short bowel syndrome (SBS) initial therapy: 1) for an adult patient, the patient has been dependent on parenteral support for at least 12 months OR 2) for a pediatric patient, the patient is dependent on parenteral support. For SBS continuation: requirement for parenteral support has decreased from baseline while on therapy with the requested drug. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a gastroenterologist, gastrointestinal surgeon, or nutritional support specialist.   |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **GAVRETO**

#### **Products Affected**

#### • Gavreto

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Recurrent rearranged during transfection (RET) rearrangement-positive non-small cell lung cancer, RET mutation-positive medullary carcinoma   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For non-small cell lung cancer, patient must meet all of the following: 1) The disease is recurrent, advanced, or metastatic, AND 2) The tumor is rearranged during transfection (RET) fusion-positive or RET rearrangement-positive. |
| Age Restrictions                   | Non-small cell lung cancer: 18 years of age or older, Thyroid cancer: 12 years of age or older  |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **GAZYVA**

### **Products Affected**

### • Gazyva

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **GILENYA**

### **Products Affected**

• Gilenya

• Fingolimod Hydrochloride

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **GILOTRIF**

#### **Products Affected**

#### • Gilotrif

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For non-small cell lung cancer (NSCLC), patient meets either of the following: 1) has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease AND a) has experienced an intolerable adverse event or contraindication to erlotinib, gefitinib or osimertinib, OR 2) has metastatic squamous NSCLC that progressed after platinum-based chemotherapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **G**IMOTI

#### **Products Affected**

#### • Gimoti

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **G**IVLAARI

## **Products Affected**

#### • Givlaari

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **G**LATIRAMER

#### **Products Affected**

- Copaxone INJ 20MG/ML, 40MG/ML
- Glatiramer Acetate
- Glatopa

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## GLOPERBA AET

### **Products Affected**

### • Gloperba

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **GONADOTROPIN**

#### **Products Affected**

• Chorionic Gonadotropin INJ

- Novarel INJ 5000UNIT
- Pregnyl W/diluent Benzyl Alcohol/nacl

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **GOPRELTO-NUMBRINO**

## **Products Affected**

• Goprelto

• Cocaine Hydrochloride

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **GRANIX**

# **Products Affected**

### • Granix

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **GRASTEK**

## **Products Affected**

### • Grastek

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **GROWTH HORMONE**

## **Products Affected**

• Genotropin

• Genotropin Miniquick

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | Pediatric patients with closed epiphyses  |
| Required<br>Medical<br>Information | Pediatric growth hormone deficiency (GHD): Patient (pt) is a neonate or was diagnosed with GHD as a neonate OR meets any of the following: 1) younger than 2.5 years old (yo) with pre-treatment (pre-tx) height (ht) more than 2 standard deviations (SD) below mean and slow growth velocity OR 2) 2.5 yo or older AND one of the following: a) pre-tx 1-year ht velocity more than 2 SD below mean OR b) pre-tx ht more than 2 SD below mean and 1-year ht velocity more than 1 SD below mean, AND patient meets any of the following: 1) failed 2 pre-tx growth hormone (GH) stimulation tests (peak below 10 ng/mL), OR 2) pituitary/central nervous system (CNS) disorder (e.g., genetic defects, acquired structural abnormalities, congenital structural abnormalities) and pre-tx insulin-like growth factor-1 (IGF-1) more than 2 SD below mean. Turner syndrome (TS): 1) Confirmed by karyotyping AND 2) pre-tx ht is less than the 5th percentile for age. Small for gestational age (SGA): 1) Birth weight (wt) less than 2500g at gestational age (GA) greater than 37 weeks, OR birth wt or length below 3rd percentile for GA or at least 2 SD below mean for GA, AND 2) did not manifest catch-up growth by age 2. |
| Age Restrictions                   | SGA: 2 years of age or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an endocrinologist, nephrologist, infectious disease specialist, gastroenterologist/nutritional support specialist, or geneticist.  |
| Coverage<br>Duration               | Plan Year   |

#### **Other Criteria**

Adult GHD: Pt meets any of the following: 1) failed 2 pre-tx GH stimulation tests, OR 2) pre-tx IGF-1 more than 2 SD below mean AND failed 1 pre-tx GH stimulation test, OR 3) organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with 3 or more pituitary hormone deficiencies AND pre-tx IGF-1 more than 2 SD below mean, OR 4) genetic or structural hypothalamic-pituitary defects, OR 5) childhood-onset GHD with congenital (genetic or structural) abnormality of the hypothalamus/pituitary/CNS. For pediatric GHD, TS, SGA, and adult GHD, continuation of therapy: Patient is experiencing improvement.

# HAEGARDA

## **Products Affected**

# • Haegarda

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For the prophylaxis of angioedema attacks due to hereditary angioedema (HAE): 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing, OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation, b) the patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month. |
| Age Restrictions                   | 6 years of age or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **HALAVEN**

# **Products Affected**

• Eribulin Mesylate

### • Halaven

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# HALOG SOLUTION AET

# **Products Affected**

• Halog SOLN

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **HARVONI**

## **Products Affected**

### • Harvoni

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Criteria applied consistent w/ current AASLD-IDSA guidance. Reminder for 8wk option if appropriate.  |
| Other Criteria                     | N/A  |

# **HERCEPTIN**

- Herceptin INJ 150MG
- Herzuma

- KanjintiOgivri
- Ontruzant

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# HERCEPTIN HYLECTA

## **Products Affected**

# • Herceptin Hylecta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# HETLIOZ

# **Products Affected**

• Hetlioz

### • Tasimelteon

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For Non-24-Hour Sleep-Wake Disorder: 1) For initial therapy and continuation of therapy the patient must meet both of the following: a) diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas) and b) unable to perceive light in either eye, AND 2) If currently on therapy with the requested drug, patient must meet at least one of the following: a) increased total nighttime sleep or b) decreased daytime nap duration. For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS): 1) For initial therapy and continuation therapy, the patient has a confirmed diagnosis of SMS, AND 2) If currently on therapy with the requested drug, the patient experienced improvement in the quality of sleep since starting therapy. |
| Age Restrictions                   | Non-24: 18 years of age or older, SMS: 16 years of age or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a sleep disorder specialist, neurologist, or psychiatrist  |
| Coverage<br>Duration               | Initiation: 6 months, Renewal: Plan Year   |
| Other Criteria                     | N/A  |

# HETLIOZ LQ

# **Products Affected**

# • Hetlioz Lq

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **HIGH RISK MEDICATION - 65**

- Atropine Sulfate INJ 0.25MG/5ML, 0.4MG/ML, 0.5MG/5ML, 1MG/10ML, 1MG/ML, 8MG/20ML
- Belladonna/opium SUPP 16.2MG; 60MG
- Chlordiazepoxide/amitriptyline
- Demerol INJ 100MG/ML, 25MG/ML, 50MG/ML, 75MG/ML
- Dicyclomine Hcl SOLN
- Dicyclomine Hydrochloride CAPS
- Dicyclomine Hydrochloride INJ
- Dicyclomine Hydrochloride TABS
- Dihydroergotamine Mesylate INJ
- Diphenhydramine Hcl ELIX
- Dipyridamole TABS
- Disopyramide Phosphate CAPS
- Ergoloid Mesylates TABS
- Guanfacine Hydrochloride
- Guanfacine Hydrochloride Er
- Hyoscyamine Sulfate ELIX
- Hyoscyamine Sulfate SOLN
- Hyoscyamine Sulfate SUBL
- Hyoscyamine Sulfate TABS
- Hyoscyamine Sulfate Odt
- Indocin SUPP
- Indocin SUSP
- Indomethacin CAPS 25MG, 50MG

- Indomethacin SUPP 50MG
- Indomethacin SUSP
- Indomethacin Er
- Intuniv
- Ketorolac Tromethamine TABS
- Levsin TABS
- Levsin/sl
- Meperidine Hcl INJ 100MG/ML, 25MG/ML, 50MG/ML
- Meperidine Hcl ORAL SOLN
- Meperidine Hcl TABS 50MG
- Meprobamate
- Methscopolamine Bromide TABS
- Nifedipine CAPS
- Norpace
- Nulev
- Oscimin SUBL
- Oscimin TABS
- Pentazocine/naloxone Hcl
- Perphenazine/amitriptyline
- Promethazine Vc
- Ryclora
- Thioridazine Hcl TABS 100MG, 10MG, 25MG, 50MG
- Tigan INJ
- Trimethobenzamide Hydrochloride

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. |

| Age Restrictions           | N/A   |
|----------------------------|---|
| Prescriber<br>Restrictions | N/A   |
| Coverage<br>Duration       | Plan Year   |
| Other Criteria             | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) |

# **HIZENTRA**

## **Products Affected**

#### • Hizentra

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# HRM - ANTICONVULSANTS - 65

### **Products Affected**

- Phenobarbital ELIX 20MG/5ML
- Phenobarbital TABS 100MG, 15MG, 16.2MG, 30MG, 32.4MG, 60MG, 64.8MG, 97.2MG

• Phenobarbital Sodium INJ 130MG/ML, 65MG/ML

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Epilepsy  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.   |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) |

# HRM - HYPNOTICS - 65

- Ambien
- Ambien Cr
- Edluar
- Eszopiclone

- Lunesta
- Zaleplon
- Zolpidem Tartrate SUBL
- Zolpidem Tartrate TABS
- Zolpidem Tartrate Er

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For insomnia: 1) The patient meets one of the following: a) the patient has a contraindication to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) OR b) The non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) has been tried AND the patient experienced an inadequate treatment response OR intolerance to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) AND 2) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient AND 3) If the patient is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, quetiapine, sertraline, clonazepam, escitalopram, alprazolam) with the requested drug, the prescriber has determined that taking multiple central nervous system (CNS) active medications is medically necessary for the patient [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls.]. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |

| Other Criteria | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older    |
|----------------|--|
|                | adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prior authorization applies to greater |
|                | than cumulative 90 days of therapy per year.   |

# HRM - SCOPOLAMINE - 65

# **Products Affected**

• Transderm-scop PT72 1MG/3DAYS

• Scopolamine PT72 1MG/3DAYS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Excessive salivation   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.). |

# HRM-ANTIPARKINSON - 65

## **Products Affected**

• Benztropine Mesylate TABS

- Trihexyphenidyl Hcl SOLNTrihexyphenidyl Hydrochloride

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. EPS (extrapyramidal symptoms): 1) The patient has not tried the non-HRM alternative drug amantadine AND 2) The patient has a contraindication to the non-HRM alternative drug amantadine OR 3) The patient has tried the non-HRM alternative drug amantadine AND 4) The patient experienced an inadequate treatment response OR intolerance to the non-HRM alternative drug amantadine. Parkinson's: 1) The patient has tried two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole. AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)   |

# HRM-CYPROHEPTADINE - 65

## **Products Affected**

• Cyproheptadine Hcl SYRP

• Cyproheptadine Hydrochloride TABS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Pruritus, spasticity due to spinal cord injury  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.). Prior Authorization applies to greater than cumulative 30 days of therapy per year.  |

# HRM-DOXEPIN - 65

### **Products Affected**

- Doxepin Hcl CAPS 75MG
- Doxepin Hcl CONC

• Doxepin Hydrochloride CAPS 100MG, 10MG, 150MG, 25MG, 50MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone. For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)  |

# HRM-HYDROXYZINE - 65

- Hydroxyzine Hcl TABS 50MG
- Hydroxyzine Hydrochloride SYRP
- Hydroxyzine Hydrochloride TABS 10MG, 25MG
- Hydroxyzine Pamoate CAPSVistaril CAPS 25MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release OR 3) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 4) The patient has acute anxiety. For all indications: 1) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. AND 2) If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, cyclobenzaprine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.]. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |

| Other Criteria  This Prior Authorization only applies to patients 65 years of age or (Note: The use of this medication is potentially inappropriate in old adults, meaning it is best avoided, prescribed at reduced dosage, or with caution or carefully monitored.). | er |
|--|----|
|--|----|

# HRM-HYDROXYZINE INJ - 65

- Hydroxyzine Hcl INJ 25MG/ML
- Hydroxyzine Hydrochloride INJ

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# HRM-PROMETHAZINE - 65

- Phenergan INJ
- Promethazine Hcl INJ
- Promethazine Hcl SUPP 12.5MG, 25MG
- Promethazine Hcl TABS 12.5MG

- Promethazine Hydrochloride TABS 25MG, 50MG
- Promethazine Hydrochloride Plain
- Promethegan

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prior authorization applies to greater than cumulative 30 days of therapy per year.   |

# HRMS - ANTIDEPRESSANTS

- Amitriptyline Hcl TABS 100MG, 150MG, 25MG, 75MG
- Amitriptyline Hydrochloride TABS 100MG, 10MG, 50MG
- Desipramine Hydrochloride

- Imipramine Hcl TABS 25MG, 50MG
- Imipramine Hydrochloride TABS 10MG
- Imipramine Pamoate
- Norpramin TABS 10MG, 25MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Neuropathic pain  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)   |

# HRMS - CARBINOXAMINE

- Carbinoxamine Maleate SOLN
- Carbinoxamine Maleate TABS
- Ryvent

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)   |

# HRMS - CLEMASTINE- 65

## **Products Affected**

• Clemastine Fumarate SYRP

• Clemastine Fumarate TABS 2.68MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)   |

# **HRMS - DIABETES AGENTS**

## **Products Affected**

- Glyburide TABS 1.25MG, 2.5MG, 5MG
- Glyburide Micronized

• Glyburide/metformin Hydrochloride

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# HRMS - TCAS

## **Products Affected**

• Protriptyline Hcl

# • Trimipramine Maleate CAPS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 3) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)   |

# HRM-SKELETAL MUSCLE RELAXANTS - 65

- Amrix
- Carisoprodol TABS
- Chlorzoxazone TABS
- Cyclobenzaprine Hydrochloride TABS
- Cyclobenzaprine Hydrochloride Er
- Fexmid
- Metaxalone
- Methocarbamol INJ 1000MG/10ML
- Methocarbamol TABS

- Norgesic
- Norgesic Forte
- Orphenadrine Citrate INJ
- Orphenadrine Citrate Er
- Orphenadrine/aspirin/caffeine
- Orphengesic Forte
- Robaxin INJ 1000MG/10ML
- Soma
- Tanlor

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | 1) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient AND 2) If the patient is using one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, hydroxyzine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.]. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 3 months  |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prior authorization applies to greater than cumulative 90 days of therapy per year.   |

# HUMIRA

- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pen

- Humira Pen-cd/uc/hs Starter INJ 80MG/0.8ML
- Humira Pen-pediatric Uc Starter Pack
- Humira Pen-ps/uv Starter INJ 0

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |

| Coverage<br>Duration | Plan Year  |
|----------------------|--|
| Other Criteria       | For non-infectious intermediate, posterior and panuveitis (new starts only): 1) patient has experienced an inadequate treatment response or intolerance to a corticosteroid OR 2) the patient has a contraindication that would prohibit a trial of corticosteroids. |

# **HYFTOR**

## **Products Affected**

• Hyftor

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **HYPNOTIC-BENZODIAZEPINES - 65**

#### **Products Affected**

- Estazolam
- Halcion TABS 0.25MG
- Restoril CAPS 15MG, 22.5MG, 7.5MG
- Temazepam CAPS 15MG, 22.5MG, 7.5MG
- Triazolam

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For short-term treatment of insomnia: 1) Prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older. Prior authorization applies to greater than cumulative 90 days of therapy per year.   |

# HYQVIA

## **Products Affected**

• Hyqvia

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **IBRANCE**

#### **Products Affected**

#### • Ibrance

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Unresectable well-differentiated/dedifferentiated liposarcoma of the retroperitoneum, recurrent hormone receptor-positive human epidermal growth factor receptor 2 (HER2)-negative breast cancer   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For breast cancer: 1) the disease is advanced, recurrent, or metastatic, AND 2) the patient has hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative disease, AND 3) the requested drug will be used in combination with an aromatase inhibitor or fulvestrant, AND 4) the patient has experienced an intolerable adverse event to Kisqali (ribociclib) OR Verzenio (abemaciclib) or has a contraindication to Kisqali (ribociclib) AND Verzenio (abemaciclib). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **IBSRELA AET**

#### **Products Affected**

• Ibsrela

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ICATIBANT**

## **Products Affected**

• Firazyr

- Icatibant Acetate
- Sajazir

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For the treatment of acute angioedema attacks due to hereditary angioedema (HAE): 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation, b) the patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month. |
| Age Restrictions                   | 18 years of age or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **ICLUSIG**

# **Products Affected**

• Iclusig

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Myeloid and/or lymphoid neoplasms with eosinophilia and FGFR1 or ABL1 rearrangement in the chronic phase or blast phase, Gastrointestinal Stromal Tumors  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For chronic myeloid leukemia (CML), including patients who have received a hematopoietic stem cell transplant: 1) Patient has accelerated or blast phase CML and no other kinase inhibitor is indicated, OR 2) Patient has chronic phase CML and has experienced resistance or intolerance to at least 2 prior kinase inhibitors AND at least one of those was imatinib, dasatinib, or nilotinib, OR 3) Patient is positive for the T315I mutation. For acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For gastrointestinal stromal tumors (GIST): 1) Disease meets any of the following: A) residual, B) unresectable, C) recurrent, D) metastatic/tumor rupture, AND 2) Disease has progressed after use of at least two Food and Drug Administration (FDA) approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **IDACIO**

#### **Products Affected**

- Adalimumab-aacf (2 Pen)
- Adalimumab-aacf (2 Syringe)
- Idacio (2 Pen)
- Idacio (2 Syringe)

- Idacio Starter Package For Crohns Disease
- Idacio Starter Package For Plaque Psoriasis

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All Medically-accepted Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |

| Coverage<br>Duration | Plan Year  |
|----------------------|--|
| Other Criteria       | For non-infectious intermediate, posterior and panuveitis (new starts only): 1) patient has experienced an inadequate treatment response or intolerance to a corticosteroid OR 2) the patient has a contraindication that would prohibit a trial of corticosteroids. |

# **IDHIFA**

#### **Products Affected**

#### • Idhifa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Newly-diagnosed acute myeloid leukemia   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation: 1) patient has newly-diagnosed AML and is not a candidate for intensive induction therapy, OR 2) the requested drug will be used as post-induction therapy following response to induction therapy with the requested drug, OR 3) patient has relapsed or refractory AML. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **IGALMI**

## **Products Affected**

• Igalmi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ILARIS**

#### **Products Affected**

#### • Ilaris INJ 150MG/ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ILUMYA**

## **Products Affected**

• Ilumya

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **IMATINIB**

## **Products Affected**

• Gleevec TABS

• Imatinib Mesylate

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Desmoid tumors, pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT), recurrent chordoma, cutaneous melanoma, Kaposi sarcoma, chronic graft versus host disease (cGVHD), T-cell acute lymphoblastic leukemia with ABL-class translocation, aggressive systemic mastocytosis for well-differentiated systemic mastocytosis (WDSM) or when eosinophilia is present with FIP1L1-PDGFRA fusion gene, myeloid and/or lymphoid neoplasms with eosinophilia and ABL1, FIP1L1-PDGFRA, or PDGFRB rearrangement in the chronic phase or blast phase.  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), including patients who have received a hematopoietic stem cell transplant: Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML: Patient did not fail (excluding failure due to intolerance) prior therapy with a tyrosine kinase inhibitor. For cutaneous melanoma: 1) Disease is metastatic or unresectable AND 2) Disease is positive for c-KIT activating mutations AND 3) Requested medication will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **IMBRUVICA**

#### **Products Affected**

- Imbruvica CAPS
- Imbruvica SUSP

• Imbruvica TABS 140MG, 280MG, 420MG

| PA Criteria           | Criteria Details   |
|-----------------------|--|
| Indications           | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses        | Hairy cell leukemia, lymphoplasmacytic lymphoma, primary central nervous system (CNS) lymphoma, human immunodeficiency virus (HIV)-related B-cell lymphoma, diffuse large B-cell lymphoma, post-transplant lymphoproliferative disorders, high-grade B-cell lymphoma, mantle cell lymphoma, marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, splenic marginal zone lymphoma) |
| Exclusion<br>Criteria | N/A  |

| Required<br>Medical<br>Information | For mantle cell lymphoma: 1) the requested drug will be used as subsequent therapy AND the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Calquence (acalabrutinib), OR 2) the requested drug will be used in combination with rituximab as pretreatment to induction therapy with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen, OR 3) the requested drug will be used as aggressive induction therapy. For marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, and splenic marginal zone lymphoma): the requested drug will be used as second-line or subsequent therapy. For hairy cell leukemia: the requested drug will be used as a single agent for disease progression. For primary CNS lymphoma: 1) the disease is relapsed or refractory OR 2) the requested drug is used for induction therapy as a single agent. For diffuse large B-cell lymphoma, high-grade B-cell lymphoma, human immunodeficiency virus (HIV)-related B-cell lymphoma: The requested drug will be used as a single agent and as second-line or subsequent therapy for relapsed or refractory disease. For post-transplant lymphoproliferative disorders: the requested drug will be used in patients who have received prior chemoimmunotherapy. For chronic lymphocytic leukemia/small lymphocytic lymphoma: the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Calquence (acalabrutinib). |
|------------------------------------|---|
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |

N/A

**Other Criteria** 

# **IMDELLTRA**

## **Products Affected**

#### • Imdelltra

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **IMFINZI**

## **Products Affected**

• Imfinzi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **IMJUDO**

## **Products Affected**

• Imjudo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **IMLYGIC**

## **Products Affected**

• Imlygic

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **IMPAVIDO**

# **Products Affected**

## • Impavido

| PA Criteria                        | Criteria Details                     |
|------------------------------------|--------------------------------------|
| Indications                        | All FDA-approved Indications.        |
| Off-Label Uses                     | N/A                                  |
| Exclusion<br>Criteria              | Pregnancy. Sjogren-Larsson-Syndrome. |
| Required<br>Medical<br>Information | N/A                                  |
| Age Restrictions                   | 12 years of age or older             |
| Prescriber<br>Restrictions         | N/A                                  |
| Coverage<br>Duration               | 28 days                              |
| Other Criteria                     | N/A                                  |

# **IMVEXXY**

#### **Products Affected**

• Imvexxy Maintenance Pack

• Imvexxy Starter Pack

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **INBRIJA**

#### **Products Affected**

• Inbrija

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For initial treatment of off episodes in Parkinson's disease: 1) The patient is currently being treated with oral carbidopa/levodopa, AND 2) The patient does not have any of the following: asthma, chronic obstructive pulmonary disease (COPD), or other chronic underlying lung disease. For continuation treatment of off episodes in Parkinson's disease: The patient is experiencing improvement on the requested drug. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **INCRELEX**

#### **Products Affected**

#### • Increlex

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | Pediatric patients with closed epiphyses  |
| Required<br>Medical<br>Information | For growth failure due to severe primary insulin-like growth factor-1 (IGF-1) deficiency or growth hormone (GH) gene deletion in patients who have developed neutralizing antibodies to GH, patient meets all of the following prior to beginning therapy with the requested drug (new starts only): 1) height 3 or more standard deviations (SD) below the mean for children of the same age and gender AND 2) basal IGF-1 level 3 or more SD below the mean for children of the same age and gender AND 3) provocative growth hormone test showing a normal or elevated growth hormone level. For growth failure due to severe primary IGF-1 deficiency or GH gene deletion in patients who have developed neutralizing antibodies to GH, continuation of therapy: patient is experiencing improvement. |
| Age Restrictions                   | 2 years of age or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an endocrinologist  |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **INFLECTRA**

# **Products Affected**

#### • Inflectra

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **INGREZZA**

## **Products Affected**

• Ingrezza

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **INLYTA**

#### **Products Affected**

• Inlyta

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.                  |
| Off-Label Uses                     | Thyroid carcinoma (papillary, oncocytic, or follicular), alveolar soft part sarcoma |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For renal cell carcinoma: the disease is advanced, relapsed, or Stage IV.           |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **INPEFA**

#### **Products Affected**

• Inpefa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# INQOVI

## **Products Affected**

• Inqovi

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **INREBIC**

#### **Products Affected**

#### • Inrebic

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and janus kinase 2 (JAK2) rearrangement, accelerated or blast phase myeloproliferative neoplasms |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement: the disease is in chronic or blast phase.                            |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **INSULIN SUPPLIES**

#### **Products Affected**

- Alcohol Prep Pads PADS 70%
- Bd Insulin Syringe Safetyglide/1ml/29g X 1/2"
- B-d Insulin Syringe Ultrafine Ii/0.3ml/31g X 5/16"
- Bd Insulin Syringe Ultra-fine/0.5ml/30g X 12.7mm
- Bd Insulin Syringe Ultra-fine/1ml/31g X 8mm
- Bd Pen Needle/original/ultra-fine/29g X 12.7mm
- Bd Veo Insulin Syringe Ultrafine/0.3ml/31g X 6mm
- Curity Gauze Pads 2"x2" 12 Ply

| PA Criteria                        | Criteria Details                                  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.                     |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | The requested product is being used with insulin. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **INTRAROSA**

# **Products Affected**

#### • Intrarosa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **IQIRVO**

## **Products Affected**

• Iqirvo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

#### IR BEFORE ER

#### **Products Affected**

- Hydrocodone Bitartrate Er
- Hydromorphone Hcl Er TB24 12MG, 16MG, 8MG
- Hydromorphone Hydrochloride Er TB24 32MG
- Hysingla Er
- Methadone Hcl INJ
- Methadone Hcl ORAL SOLN
- Methadone Hcl TABS
- Methadone Hydrochloride CONC
- Methadose CONC 10MG/ML

- Methadose Sugar-free
- Morphine Sulfate Er TBCR 100MG, 200MG
- Ms Contin TBCR 100MG, 200MG
- Nucynta Er
- Oxymorphone Hydrochloride Er TB12 10MG, 15MG, 20MG, 30MG, 5MG, 7.5MG
- Oxymorphone Hydrochlorideer
- Xtampza Er

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe and persistent enough to require an extended treatment period with a daily opioid analgesic in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |

| Coverage<br>Duration | Plan Year |
|----------------------|-----------|
| Other Criteria       | N/A       |

# **IRESSA**

#### **Products Affected**

• Gefitinib

#### • Iressa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Sensitizing epidermal growth factor receptor (EGFR) mutation-positive recurrent non-small cell lung cancer (NSCLC)   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic, AND 2) the patient must have a sensitizing epidermal growth factor receptor (EGFR) mutation. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **ISOTRETINOIN**

#### **Products Affected**

- Absorica
- Accutane
- Amnesteem

- Claravis
- Isotretinoin CAPS
- Zenatane

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Refractory acne vulgaris, severe refractory rosacea, neuroblastoma, cutaneous T-cell lymphoma (CTCL) (e.g., mycosis fungoides, Sezary syndrome), high risk for developing skin cancer (squamous cell cancers), transient acantholytic dermatosis (Grover's Disease), keratosis follicularis (Darier Disease), lamellar ichthyosis, pityriasis rubra pilaris. |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **ISTURISA**

### **Products Affected**

• Isturisa TABS 1MG, 5MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **ITRACONAZOLE**

#### **Products Affected**

- Itraconazole CAPS
- Itraconazole SOLN

- Sporanox CAPS
- Sporanox SOLN

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Coccidioidomycosis, Coccidioidomycosis prophylaxis in HIV infection,, Cryptococcosis, Microsporidiosis, Talaromycosis (formerly Penicilliosis), Histoplasmosis prophylaxis in HIV infection, Invasive fungal infection prophylaxis in liver transplant, chronic granulomatous disease (CGD), and hematologic malignancy, Sporotrichosis, Pityriasis versicolor, Tinea versicolor, Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis, primary treatment for allergic bronchopulmonary aspergillosis, primary treatment for chronic cavitary or subacute invasive (necrotizing) pulmonary aspergillosis |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | The requested drug will be used orally. For the treatment of onychomycosis due to dermatophytes (Tinea unguium), the diagnosis has been confirmed by a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy). For primary treatment of allergic bronchopulmonary aspergillosis, the requested drug is initiated in combination with systemic corticosteroids.   |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Disseminated/CNS histo, histo/CM/CGD ppx, chronic cavitary/necrotizing PA: 12 mths. Others: 6 mths   |
| Other Criteria                     | N/A  |

# **IVERMECTIN TAB**

#### **Products Affected**

• Ivermectin TABS

#### • Stromectol TABS 3MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Ascariasis, Cutaneous larva migrans, Mansonelliasis, Scabies, Gnathostomiasis, Pediculosis                         |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | The requested drug is not being prescribed for the prevention or treatment of coronavirus disease 2019 (COVID-19). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 1 month  |
| Other Criteria                     | N/A  |

#### **IVIG**

#### **Products Affected**

- Alyglo
- Asceniv
- Bivigam INJ 10%, 5GM/50ML
- Flebogamma Dif INJ 10GM/200ML, 20GM/400ML, 5GM/100ML
- Gammagard Liquid
- Gammagard S/d Iga Less Than 1mcg/ml
- Gammaked INJ 10GM/100ML, 1GM/10ML, 20GM/200ML, 5GM/50ML

- Gammaplex INJ 10GM/100ML, 10GM/200ML, 20GM/200ML, 20GM/400ML, 5GM/100ML, 5GM/50ML
- Gamunex-c
- Octagam INJ 10GM/100ML, 10GM/200ML, 1GM/20ML, 2.5GM/50ML, 20GM/200ML, 2GM/20ML, 30GM/300ML, 5GM/100ML, 5GM/50ML
- Panzyga
- Privigen

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All Medically-accepted Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For B-cell chronic lymphocytic leukemia (CLL): 1) serum IgG less than 500 mg/dL OR 2) a history of recurrent bacterial infections. For bone marrow transplant/hematopoietic stem cell transplant (BMT/HSCT): 1) IVIG is requested within the first 100 days post-transplant OR 2) serum IgG less than 400 mg/dL. For pediatric human immunodeficiency virus (HIV) infection: 1) serum IgG less than 400 mg/dL OR 2) history of recurrent bacterial infections. For dermatomyositis and polymyositis: 1) at least one standard first-line treatment (corticosteroid or immunosuppressant) has been tried but was unsuccessful or not tolerated OR 2) patient is unable to receive standard therapy because of a contraindication or other clinical reason. For pure red cell aplasia (PRCA): PRCA is secondary to parvovirus B19 infection. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |

| Other Criteria | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |
|----------------|--|
|----------------|--|

# **IWILFIN**

### **Products Affected**

### • Iwilfin

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **IXEMPRA**

### **Products Affected**

### • Ixempra Kit

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **IZERVAY**

### **Products Affected**

• Izervay

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **J**AKAFI

## **Products Affected**

Jakafi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Lower-risk myelofibrosis, accelerated or blast phase myeloproliferative neoplasms, acute lymphoblastic leukemia (ALL), chronic myelomonocytic leukemia (CMML)-2, myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) with neutrophilia, essential thrombocythemia, myeloid, lymphoid or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement, T-cell prolymphocytic leukemia  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For polycythemia vera: 1) patient had an inadequate response or intolerance to hydroxyurea and Besremi (ropeginterferon alfa-2b-njft), OR 2) patient has high risk disease. For acute lymphoblastic leukemia: patient has a cytokine receptor-like factor 2 (CRLF2) mutation or a mutation associated with activation of the Janus kinase/signal transducers and activators of transcription (JAK/STAT) pathway. For CMML-2: the requested drug is used in combination with a hypomethylating agent. For myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) with neutrophilia: the requested drug is used as a single agent or in combination with a hypomethylating agent. For essential thrombocythemia: patient had an inadequate response or loss of response to hydroxyurea, interferon therapy, or anagrelide. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement: the disease is in chronic or blast phase. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

### **JATENZO**

### **Products Affected**

#### • Jatenzo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **JAYPIRCA**

## **Products Affected**

### • Jaypirca

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL): The patient meets both of the following: 1) The patient has received prior treatment with a Bruton Tyrosine Kinase (BTK) inhibitor, for example Calquence (acalabrutinib), AND 2) The patient has received prior treatment with a B-cell lymphoma 2 (BCL-2) inhibitor. For mantle cell lymphoma: the patient has received prior treatment for a BTK inhibitor, for example Calquence (acalabrutinib). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **JEMPERLI**

## **Products Affected**

### • Jemperli

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **JEVTANA**

### **Products Affected**

#### Jevtana

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **JOENJA**

### **Products Affected**

• Joenja

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# JUBLIA AET

### **Products Affected**

• Jublia

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **JUXTAPID**

### **Products Affected**

• Juxtapid CAPS 10MG, 20MG, 30MG, 5MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **JYNARQUE**

### **Products Affected**

### • Jynarque

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **KALBITOR**

## **Products Affected**

#### • Kalbitor

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# KALYDECO

### **Products Affected**

### • Kalydeco

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# KANUMA

### **Products Affected**

#### • Kanuma

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# KERYDIN AET

### **Products Affected**

• Kerydin

### • Tavaborole

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **KESIMPTA**

### **Products Affected**

### • Kesimpta

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **KETOCONAZOLE**

### **Products Affected**

#### • Ketoconazole TABS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Cushing's syndrome   |
| Exclusion<br>Criteria              | Acute or chronic liver disease. Concurrent use with drugs that are contraindicated with ketoconazole tablets: dofetilide, quinidine, pimozide, cisapride, methadone, disopyramide, dronedarone, ranolazine, ergot alkaloids, irinotecan, lurasidone, oral midazolam, alprazolam, triazolam, felodipine, nisoldipine, tolvaptan, eplerenone, lovastatin, simvastatin, or colchicine.                          |
| Required<br>Medical<br>Information | The potential benefits outweigh the risks of treatment with oral ketoconazole. For systemic fungal infections, the patient has any of the following diagnoses: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis. For Cushing's syndrome: the requested drug is being prescribed for a patient who cannot tolerate surgery or where surgery has not been curative. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 6 months   |
| Other Criteria                     | N/A  |

# **KEVEYIS**

### **Products Affected**

• Dichlorphenamide

- KeveyisOrmalvi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## KEVZARA

### **Products Affected**

#### • Kevzara

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# KEYTRUDA

### **Products Affected**

### • Keytruda INJ 100MG/4ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **KIMMTRAK**

## **Products Affected**

#### • Kimmtrak

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# KINERET

## **Products Affected**

#### • Kineret

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# KISQALI

### **Products Affected**

- Kisqali
- Kisqali Femara 200 Dose

- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Recurrent hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer, in combination with an aromatase inhibitor, or fulvestrant. Endometrial cancer, in combination with letrozole, for estrogen receptor positive tumors. |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# KLISYRI

### **Products Affected**

• Klisyri

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# KONVOMEP

## **Products Affected**

### • Konvomep

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **KORLYM**

### **Products Affected**

• Korlym

### • Mifepristone TABS 300MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.                            |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an endocrinologist |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **KOSELUGO**

### **Products Affected**

### • Koselugo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | BRAF fusion or BRAF V600E activating mutation-positive recurrent or progressive circumscribed glioma, Langerhans cell histiocytosis. |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | For neurofibromatosis type 1: 2 years of age or older  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# KRAZATI

### **Products Affected**

#### • Krazati

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Recurrent KRAS G12C-positive non-small cell lung cancer (NSCLC),<br>Central nervous system (CNS) brain metastases from KRAS G12C-<br>positive NSCLC, KRAS G12C-positive pancreatic adenocarcinoma |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | N/A   |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# KRINTAFEL

## **Products Affected**

#### • Krintafel

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# KRISTALOSE

### **Products Affected**

• Kristalose

#### • Lactulose PACK

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For constipation: 1) The patient has experienced an inadequate treatment response to a one month trial of generic lactulose solution, OR 2) The patient has experienced an intolerance that would prohibit a one month trial of generic lactulose solution, OR 3) the patient has a contraindication to an inactive ingredient in generic lactulose solution which is not contained in the requested drug. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# KRYSTEXXA

### **Products Affected**

### • Krystexxa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **KYPROLIS**

## **Products Affected**

• Kyprolis

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# LAGEVRIO AET

### **Products Affected**

• Lagevrio

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# LAMPIT

### **Products Affected**

• Lampit

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# LAMZEDE

### **Products Affected**

#### • Lamzede

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# LAPATINIB

### **Products Affected**

• Lapatinib Ditosylate

### • Tykerb

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Brain metastases from human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent HER2-positive breast cancer, recurrent epidermal growth factor receptor (EGFR)-positive chordoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma).  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For breast cancer, the patient meets all the following: a) the disease is recurrent, advanced, or metastatic (including brain metastases), b) the disease is human epidermal growth factor receptor 2 (HER2)-positive, c) the requested drug will be used in combination with any of the following: 1) aromatase inhibitor, 2) capecitabine, OR 3) trastuzumab. For colorectal cancer: 1) requested drug will be used in combination with trastuzumab and 2) patient has not had previous treatment with a HER2 inhibitor. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# LEDIPASVIR-SOFOSBUVIR AET

### **Products Affected**

### • Ledipasvir/sofosbuvir

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## LEMTRADA AET

### **Products Affected**

#### • Lemtrada

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **LENVIMA**

#### **Products Affected**

- Lenvima 10 Mg Daily Dose
- Lenvima 12mg Daily Dose
- Lenvima 14 Mg Daily Dose
- Lenvima 18 Mg Daily Dose

- Lenvima 20 Mg Daily Dose
- Lenvima 24 Mg Daily Dose
- Lenvima 4 Mg Daily Dose
- Lenvima 8 Mg Daily Dose

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Medullary thyroid carcinoma, recurrent endometrial carcinoma, thymic carcinoma, unresectable or metastatic cutaneous melanoma.   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For differentiated thyroid cancer (follicular, papillary, or oncocytic): disease is not amenable to radioactive iodine therapy and unresectable, locally recurrent, persistent, or metastatic. For hepatocellular carcinoma (HCC): disease is unresectable or inoperable, local, metastatic or with extensive liver tumor burden. For renal cell carcinoma (RCC): the disease is advanced, relapsed, or stage IV. For endometrial carcinoma (EC), the patient meets ALL of the following: 1) The disease is advanced, recurrent, or metastatic, 2) The requested drug will be used in combination with pembrolizumab, 3) The patient experienced disease progression following prior systemic therapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# LEQVIO

### **Products Affected**

• Leqvio

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **LEUKINE**

### **Products Affected**

#### • Leukine INJ 250MCG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **LEUPROLIDE**

### **Products Affected**

• Leuprolide Acetate INJ 1MG/0.2ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Use in combination with growth hormone for children with growth failure and advancing puberty, recurrent androgen receptor positive salivary gland tumors, central precocious puberty  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For central precocious puberty (CPP): Patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP was confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay, 2) Assessment of bone age versus chronological age supports the diagnosis of CPP, 3) The onset of secondary sexual characteristics occurred prior to 8 years of age for female patients OR prior to 9 years of age for male patients. |
| Age Restrictions                   | CPP: Patient must be less than 12 years old if female and less than 13 years old if male   |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **LIBERVANT**

### **Products Affected**

#### • Libervant

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | 2 to 5 years of age           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# LIBRAX

### **Products Affected**

• Librax

• Chlordiazepoxide Hydrochloride/clidinium Bromide

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **LIBTAYO**

### **Products Affected**

• Libtayo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# LICART AET

## **Products Affected**

• Licart

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **LIDOCAINE PATCHES**

#### **Products Affected**

- Lidocaine PTCH 5%
- Lidocan

- Lidoderm
- Tridacaine
- Tridacaine II

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Pain associated with diabetic neuropathy, pain associated with cancer-<br>related neuropathy (including treatment-related neuropathy [e.g.,<br>neuropathy associated with radiation treatment or chemotherapy]). |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# LIDOTRAL HC

### **Products Affected**

• Lidotral/hydrocortisone W/peptides & Arnica

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## LINEZOLID

# **Products Affected**

• Linezolid

### • Zyvox

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns. The patient will be using the requested drug orally or intravenously. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | Prescribed or directed by an Infectious Disease specialist when being converted from intravenous (IV) linezolid (Zyvox)   |
| Coverage<br>Duration               | 28 days   |
| Other Criteria                     | N/A   |

# Liqrev

### **Products Affected**

• Liqrev

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# LITFULO

### **Products Affected**

#### • Litfulo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# LIVMARLI

### **Products Affected**

#### • Livmarli SOLN 9.5MG/ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# LIVTENCITY

### **Products Affected**

### • Livtencity

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | N/A   |
| Age Restrictions                   | 12 years of age or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an infectious disease specialist, transplant specialist, hematologist, or oncologist. |
| Coverage<br>Duration               | 3 months  |
| Other Criteria                     | N/A   |

# Lodoco

### **Products Affected**

#### • Lodoco

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **LONSURF**

### **Products Affected**

#### • Lonsurf

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Unresectable locally advanced, recurrent, or metastatic esophageal cancer. Unresectable locally advanced or recurrent gastric cancer and gastroesophageal junction cancers. Advanced or metastatic appendiceal adenocarcinoma.   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For colorectal cancer (including appendiceal adenocarcinoma): The disease is advanced or metastatic. For gastric, esophageal, or gastroesophageal junction adenocarcinoma, ALL of the following criteria must be met: 1) The disease is unresectable locally advanced, recurrent, or metastatic, and 2) The patient has been previously treated with at least two prior lines of chemotherapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# LOQTORZI

### **Products Affected**

• Loqtorzi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **LORBRENA**

### **Products Affected**

#### • Lorbrena

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Anaplastic lymphoma kinase (ALK)-positive recurrent non-small cell lung cancer (NSCLC), proto-oncogene tyrosine-protein kinase ROS1 (ROS1) rearrangement-positive recurrent, advanced, or metastatic NSCLC, symptomatic or relapsed/refractory ALK-positive Erdheim-Chester Disease, inflammatory myofibroblastic tumor (IMT) with ALK translocation (including advanced, recurrent/metastatic, or inoperable uterine sarcoma for IMT with ALK translocation), central nervous system (CNS) brain metastases from ALK rearrangement-positive NSCLC, relapsed or refractory ALK-positive Diffuse Large B-Cell Lymphoma |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For recurrent, advanced, or metastatic non-small cell lung cancer: 1) Disease is ALK-positive AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following products: Alecensa (alectinib) or Alunbrig (brigatinib) OR 3) Disease is positive for ROS1 rearrangement and the requested drug is being used following disease progression on crizotinib, entrectinib, or ceritinib.   |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# LOREEV XR

## **Products Affected**

• Loreev Xr

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# LUCEMYRA

### **Products Affected**

• Lofexidine Hydrochloride

• Lucemyra

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **LUCENTIS**

## **Products Affected**

#### • Lucentis SOSY

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# LUMAKRAS

## **Products Affected**

#### • Lumakras

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses                     | Recurrent KRAS G12C-positive non-small cell lung cancer (NSCLC)    |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **LUMIZYME**

### **Products Affected**

### • Lumizyme

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# LUMRYZ

### **Products Affected**

### • Lumryz

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# LUNSUMIO

### **Products Affected**

#### • Lunsumio

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **LUPKYNIS**

### **Products Affected**

### • Lupkynis

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **LUPRON PED**

### **Products Affected**

• Lupron Depot-ped (1-month)

- Lupron Depot-ped (3-month)
- Lupron Depot-ped (6-month)

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For central precocious puberty (CPP): Patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP was confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay, AND 2) Assessment of bone age versus chronological age supports the diagnosis of CPP, AND 3) The onset of secondary sexual characteristics occurred prior to 8 years of age for female patients OR prior to 9 years of age for male patients. |
| Age Restrictions                   | CPP: Patient must be less than 12 years old if female and less than 13 years old if male   |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

### **LUPRON-ENDOMETRIOSIS**

#### **Products Affected**

• Lupron Depot (3-month) INJ 11.25MG

• Lupron Depot (1-month) INJ 3.75MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Breast cancer, ovarian cancer/fallopian tube cancer/primary peritoneal cancer, androgen receptor positive recurrent salivary gland tumor  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For retreatment of endometriosis, the requested drug is used in combination with norethindrone acetate. For uterine fibroids, patient must meet one of the following: 1) diagnosis of anemia (e.g., hematocrit less than or equal to 30 percent and/or hemoglobin less than or equal to 10g/dL), OR 2) the requested medication will be used prior to surgery for uterine fibroids. For breast cancer, the requested drug is used for hormone receptor (HR)-positive disease. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Fibroids: 3 months (mo), max 6 mo total. Endometriosis: 6 mo, max 12 mo total. Others: Plan Year  |
| Other Criteria                     | N/A   |

### **LUPRON-PROSTATE CA**

#### **Products Affected**

- Leuprolide Acetate INJ 22.5MG
- Lupron Depot (1-month) INJ 7.5MG
- Lupron Depot (3-month) INJ 22.5MG
- Lupron Depot (4-month)
- Lupron Depot (6-month)

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# Lybalvi

### **Products Affected**

• Lybalvi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## LYNPARZA

#### **Products Affected**

### • Lynparza TABS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Recurrent HER2-negative, BRCA 1/2-germline mutated breast cancer, recurrent or metastatic HER2-positive, BRCA 1/2-germline mutated breast cancer, uterine leiomyosarcoma.  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For recurrent or metastatic breast cancer: the disease is BRCA 1/2-germline mutated. For prostate cancer: 1) The patient has a BRCA mutation and the requested drug will be used in combination with abiraterone and an oral corticosteroid OR 2) The patient has progressed on prior treatment with an androgen receptor-directed therapy. For ovarian, fallopian tube, or primary peritoneal cancer: The requested drug is used for maintenance therapy for stage II-IV or recurrent disease who are in complete or partial response to chemotherapy. For uterine leiomyosarcoma: 1) the patient has had at least one prior therapy AND 2) the patient has BRCA-altered disease. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# LYRICA CR

### **Products Affected**

• Lyrica Cr

### • Pregabalin Er

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN): The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# LYTGOBI

#### **Products Affected**

### • Lytgobi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Extrahepatic cholangiocarcinoma  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For cholangiocarcinoma: 1) patient has a diagnosis of unresectable, locally advanced or metastatic cholangiocarcinoma, 2) patient has received a previous treatment, AND 3) patient has a disease that has a fibroblast growth factor receptor 2 (FGFR2) gene fusion or other rearrangement. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# LYVISPAH

## **Products Affected**

### • Lyvispah

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## MARGENZA

#### **Products Affected**

### • Margenza

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# MAVENCLAD AET

#### **Products Affected**

#### • Mavenclad

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **MAVYRET**

#### **Products Affected**

### • Mavyret

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh [CTP] class B or C).  |
| Required<br>Medical<br>Information | For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [CTP class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Criteria will be applied consistent with current AASLD-IDSA guidance   |
| Other Criteria                     | N/A  |

# **MAYZENT AET**

### **Products Affected**

• Mayzent

• Mayzent Starter Pack

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **MEKINIST**

#### **Products Affected**

#### • Mekinist

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai-Dorfman disease.  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For melanoma: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used as a single agent or in combination with dabrafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For uveal melanoma: The requested drug will be used as a single agent. For ovarian cancer, fallopian tube cancer, and primary peritoneal cancer: The requested drug will be used to treat persistent or recurrent disease. For papillary, follicular, and oncocytic thyroid carcinoma: 1) The disease is positive for BRAF V600E mutation, AND 2) The disease is not amenable to radioactive iodine (RAI) therapy, AND 3) The requested drug will be used in combination with dabrafenib. For solid tumors: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used in combination with dabrafenib. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **MEKTOVI**

### **Products Affected**

#### • Mektovi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Adjuvant systemic therapy for cutaneous melanoma, Langerhans Cell Histiocytosis, recurrent non-small cell lung cancer (NSCLC)  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used in combination with encorafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer: 1) The tumor is positive for BRAF V600E mutation, AND 2) The requested drug will be used in combination with encorafenib, AND 3) The disease is advanced, recurrent, or metastatic. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

### **MEMANTINE**

#### **Products Affected**

- Memantine Hcl Titration Pak
- Memantine Hydrochloride SOLN 2MG/ML
- Memantine Hydrochloride TABS
- Memantine Hydrochloride Er

- Namenda TABS 5MG
- Namenda Titration Pak
- Namenda Xr CP24 14MG, 21MG, 28MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | This prior authorization only applies to patients less than 30 years of age. |

# **MEPRON AET**

#### **Products Affected**

• Atovaquone SUSP

• Mepron SUSP

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Babesiosis, Toxoplasmosis, Pneumocystis jirovecii pneumonia prophylaxis in pediatric patients, mild-to-moderate Pneumocystis jirovecii pneumonia treatment in pediatric patients.   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For the treatment of mild-to-moderate Pneumocystis jiroveci pneumonia (PCP): the patient had an intolerance or has a contraindication to sulfamethoxazole/trimethoprim (SMX-TMP). For the prevention of PCP and primary toxoplasmosis prophylaxis indications: 1) the patient had an intolerance or has a contraindication to SMX-TMP, AND 2) the patient is immunocompromised. For secondary toxoplasmosis prophylaxis: the patient is immunocompromised. For babesiosis treatment: the requested drug is used concurrently with azithromycin. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Secondary toxoplasmosis prophylaxis: 6 months, All other indications: 3 months  |
| Other Criteria                     | N/A   |

# **MEPSEVII**

#### **Products Affected**

• Mepsevii

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **METFORMIN ER**

#### **Products Affected**

• Glumetza

• Metformin Hydrochloride Er TB24 1000MG, 500MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | The patient has experienced an intolerance that prohibited a 4-week trial of metformin immediate-release and generic Glucophage XR. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **METHYLTESTOSTERONE**

#### **Products Affected**

• Methitest

• Methyltestosterone CAPS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to alternative testosterone products (e.g., topical testosterone, transdermal testosterone, injectable testosterone). For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **MIACALCIN AET**

#### **Products Affected**

• Calcitonin Salmon INJ

#### • Miacalcin INJ

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# MICO-ZN-PETR OINT

#### **Products Affected**

• Vusion

• Miconazole Nitrate/zinc Oxide/white Petrolatum

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **MIGLUSTAT**

### **Products Affected**

• Miglustat

- YargesaZavesca

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## MODAFINIL

#### **Products Affected**

• Modafinil TABS

• Provigil

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Idiopathic hypersomnia  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For excessive sleepiness associated with narcolepsy: The diagnosis has been confirmed by sleep lab evaluation. For excessive sleepiness associated with obstructive sleep apnea (OSA): The diagnosis has been confirmed by polysomnography. For idiopathic hypersomnia, initial request, the diagnosis has been confirmed by ALL of the following: 1) Patient has experienced lapses into sleep or an irrepressible need to sleep during daytime, on a daily basis, for at least 3 months, AND 2) Insufficient sleep syndrome is confirmed absent, AND 3) Cataplexy is absent, AND 4) Fewer than 2 sleep onset rapid eye movement periods (SOREMPs) or no SOREMPs, if the rapid eye movement latency on an overnight sleep study was less than or equal to 15 minutes, AND 5) Average sleep latency of less than or equal to 8 minutes on Multiple Sleep Latency Test or total 24-hour sleep time is greater than or equal to 11 hours, AND 6) Another condition (sleep disorder, medical or psychiatric disorder, or drug/medication use) does not better explain the hypersomnolence and test results. For idiopathic hypersomnia, continuation of therapy: The patient has experienced a decrease in daytime sleepiness from baseline. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# Monjuvi

### **Products Affected**

### • Monjuvi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **MOTEGRITY AET**

#### **Products Affected**

### • Motegrity

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# MOTPOLY XR

#### **Products Affected**

• Motpoly Xr

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# Mounjaro

### **Products Affected**

### • Mounjaro

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# Mozobil

# **Products Affected**

• Mozobil

#### • Plerixafor

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **MULPLETA**

#### **Products Affected**

### • Mulpleta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# MVASI

#### **Products Affected**

#### • Mvasi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **MYALEPT**

#### **Products Affected**

### • Myalept

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **MYCAPSSA**

### **Products Affected**

### • Mycapssa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **M**YFEMBREE

### **Products Affected**

### • Myfembree

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **MYLOTARG**

#### **Products Affected**

### • Mylotarg

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **MYOBLOC**

### **Products Affected**

### • Myobloc

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# MYTESI AET

#### **Products Affected**

• Mytesi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **NAGLAZYME**

### **Products Affected**

### • Naglazyme

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# NAPROXEN SUSPENSION

### **Products Affected**

• Naprosyn SUSP

## • Naproxen SUSP

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ibuprofen oral suspension, AND 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 6 months  |
| Other Criteria                     | N/A   |

## NAPROXEN-ESOMEPRAZOLE

### **Products Affected**

• Vimovo

• Naproxen/esomeprazole Magnesium

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# NAYZILAM

### **Products Affected**

## • Nayzilam

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | 12 years of age or older      |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **NERLYNX**

### **Products Affected**

## • Nerlynx

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer, brain metastases from HER2-positive breast cancer. |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **NEULASTA**

## **Products Affected**

- Fulphila
- Fylnetra
- Neulasta
- Neulasta Onpro Kit

- Nyvepria
- Udenyca
- Udenyca Onbody
- Ziextenzo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# NEUPOGEN

## **Products Affected**

## • Neupogen

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **NEXAVAR**

### **Products Affected**

• Nexavar

## • Sorafenib Tosylate TABS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Acute myeloid leukemia, soft tissue sarcoma (angiosarcoma, desmoid tumors/aggressive fibromatosis, and solitary fibrous tumor subtypes), gastrointestinal stromal tumor, medullary thyroid carcinoma, osteosarcoma, recurrent chordoma, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, lymphoid and/or myeloid neoplasms with eosinophilia and FLT3 rearrangement in chronic or blast phase  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For acute myeloid leukemia: the disease is FMS-like tyrosine kinase 3-internal tandem duplication (FLT3-ITD) mutation-positive and any of the following is met:1) the requested drug will be used as maintenance therapy after hematopoietic stem cell transplant, OR 2) the requested drug is being used for low-intensity treatment induction, post-induction therapy, or consolidation therapy, OR 3) the disease is relapsed/refractory. For thyroid carcinoma: histology is follicular, papillary, oncocytic, or medullary. For gastrointestinal stromal tumor (GIST): 1) the disease is residual, unresectable, recurrent, or metastatic/tumor rupture, AND 2) the disease has progressed after use of at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **NEXIUM IV**

## **Products Affected**

#### • Nexium I.v. INJ 40MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **NEXVIAZYME**

### **Products Affected**

## • Nexviazyme

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# NGENLA AET

### **Products Affected**

## • Ngenla

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **NINLARO**

### **Products Affected**

#### • Ninlaro

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Relapsed/refractory systemic light chain amyloidosis, Waldenstrom macroglobulinemia, lymphoplasmacytic lymphoma |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | N/A   |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **NITISINONE**

### **Products Affected**

• Nitisinone

#### • Orfadin

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For hereditary tyrosinemia type 1 (HT-1): Diagnosis of HT-1 is confirmed by one of the following: 1) biochemical testing (e.g., detection of succinylacetone in urine) OR 2) DNA testing (mutation analysis). |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **NITYR**

### **Products Affected**

• Nityr

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **NORTHERA**

## **Products Affected**

• Droxidopa

#### • Northera

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For neurogenic orthostatic hypotension (nOH): For initial therapy, patient has a persistent, consistent decrease in systolic blood pressure of at least 20 mmHg OR decrease in diastolic blood pressure of at least 10 mmHg within 3 minutes of standing or head-up tilt test. For continuation of therapy, patient has experienced a sustained reduction in symptoms of nOH (i.e., decrease in dizziness, lightheadedness, or feeling faint). For both initial and continuation of therapy, the requested drug will be used for patients with neurogenic orthostatic hypotension associated with one of the following diagnoses: 1) primary autonomic failure due to Parkinson's disease, multiple system atrophy, or pure autonomic failure, OR 2) dopamine beta-hydroxylase deficiency, OR 3) non-diabetic autonomic neuropathy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 3 months  |
| Other Criteria                     | N/A   |

# **NOURIANZ AET**

### **Products Affected**

#### • Nourianz

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# NOXAFIL POWDER

### **Products Affected**

## • Noxafil PACK

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **NOXAFIL SUSP**

#### **Products Affected**

• Noxafil SUSP

#### • Posaconazole SUSP

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | The requested drug will be used orally. For treatment of oropharyngeal candidiasis: patient has experienced an inadequate treatment response, intolerance, or has a contraindication to fluconazole. |
| Age Restrictions                   | 13 years of age or older   |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Oropharyngeal candidiasis: 1 month. All other indications: 6 months  |
| Other Criteria                     | N/A  |

## **NP GROWTH HORMONE**

#### **Products Affected**

- Humatrope INJ 12MG, 24MG, 6MG
- Norditropin Flexpro
- Nutropin Aq Nuspin 10

- Nutropin Aq Nuspin 20
- Nutropin Aq Nuspin 5
- Omnitrope
- Zomacton

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# NPLATE

## **Products Affected**

• Nplate

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# NUBEQA

## **Products Affected**

## • Nubeqa

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | The requested drug will be used in combination with a gonadotropin-<br>releasing hormone (GnRH) analog or after bilateral orchiectomy. For<br>metastatic hormone-sensitive prostate cancer (mHSPC) the patient has<br>experienced an inadequate treatment response, intolerance, or has a<br>contraindication to abiraterone, Xtandi, or Erleada. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# NUCALA

## **Products Affected**

#### • Nucala

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For severe asthma, initial therapy: 1) Either a) Patient has baseline blood eosinophil count of at least 150 cells per microliter OR b) Patient is dependent on systemic corticosteroids, AND 2) Patient has a history of severe asthma despite current treatment with both of the following medications: a) medium-to-high-dose inhaled corticosteroid AND b) additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For severe asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. For eosinophilic granulomatosis with polyangiitis (EGPA), initial therapy: Patient has a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10 percent. For EGPA, continuation of therapy: Patient has a beneficial response to treatment with the requested drug, as demonstrated by any of the following: 1) a reduction in the frequency of relapses, 2) a reduction in the daily oral corticosteroid dose, OR 3) no active vasculitis. For hypereosinophilic syndrome (HES), initial therapy: 1) Patient has had HES for greater than or equal to 6 months, 2) Patient has HES without an identifiable non-hematologic secondary cause, 3) Patient does not have FIP1L1-PDGFRA kinase-positive HES, 4) Patient has a history or presence of a blood eosinophil count of at least 1000 cells per microliter, AND 5) Patient has been on a stable dose of at least one HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy). For HES, continuation of therapy: Patient has a beneficial response to treatment as demonstrated by a reduction in HES flares. |
| Age Restrictions                   | Asthma: 6 years of age or older, EGPA and CRSwNP: 18 years of age or older, HES: 12 years of age or older  |

| Prescriber<br>Restrictions | N/A   |
|----------------------------|---|
| Coverage<br>Duration       | Plan Year   |
| Other Criteria             | For chronic rhinosinusitis with nasal polyps (CRSwNP): 1) The requested drug is used as add-on maintenance treatment, AND 2) The patient has experienced inadequate treatment response to Xhance (fluticasone). |

# NUEDEXTA

## **Products Affected**

#### • Nuedexta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For pseudobulbar affect (PBA) (continuation): The patient has experienced a decrease in pseudobulbar affect (PBA) episodes since starting therapy with the requested drug. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Initial: 4 months, Continuation: Plan Year   |
| Other Criteria                     | N/A  |

# **NULIBRY**

### **Products Affected**

## • Nulibry

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# Nuplazid

## **Products Affected**

• Nuplazid CAPS

## • Nuplazid TABS 10MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For hallucinations and delusions associated with Parkinson's disease psychosis, the diagnosis of Parkinson's disease must be made prior to the onset of psychotic symptoms. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# NURTEC

## **Products Affected**

#### • Nurtec

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Acute migraine treatment: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to one triptan 5-HT1 receptor agonist. Preventive treatment of migraine, initial: The patient meets either of the following: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants. Preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Preventive treatment of migraine, initial: 3 months, All other indications: Plan Year  |
| Other Criteria                     | N/A  |

# **O**CALIVA

## **Products Affected**

#### • Ocaliva

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **O**CREVUS

## **Products Affected**

#### • Ocrevus

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **O**CTREOTIDE

#### **Products Affected**

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

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Tumor control of thymomas and thymic carcinomas   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range AND 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **O**DACTRA

## **Products Affected**

#### • Odactra

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **O**DOMZO

### **Products Affected**

#### • Odomzo

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **O**FEV

### **Products Affected**

• Ofev

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For idiopathic pulmonary fibrosis (new starts only): 1) a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy reveals the usual interstitial pneumonia (UIP) pattern, OR 2) HRCT study of the chest reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported either by a lung biopsy or by a multidisciplinary discussion between at least a radiologist and pulmonologist who are experienced in idiopathic pulmonary fibrosis if a lung biopsy has not been conducted. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **OGSIVEO**

## **Products Affected**

## • Ogsiveo

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **O**JEMDA

## **Products Affected**

## • Ojemda

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For relapsed or refractory pediatric low-grade glioma (LGG): the patient's tumor is positive for either a) BRAF fusion or rearrangement OR b) BRAF V600 mutation. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **O**JJAARA

## **Products Affected**

## • Ojjaara

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Accelerated or blast phase myeloproliferative neoplasms   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For myelofibrosis, patient meets ALL of the following: 1) the patient has a diagnosis of intermediate or high-risk primary myelofibrosis or secondary myelofibrosis (i.e., post-polycythemia vera or post-essential thrombocythemia), AND 2) the patient has anemia defined as hemoglobin less than 10 grams per deciliter (g/dL) or having transfusion-dependent anemia, AND 3) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Jakafi (ruxolitinib) OR has hemoglobin less than 8 g/dL. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **O**LUMIANT

## **Products Affected**

#### • Olumiant

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **OMEGA-3**

#### **Products Affected**

• Lovaza

• Omega-3-acid Ethyl Esters CAPS 375MG; 465MG; 1GM

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For hypertriglyceridemia: Prior to the start of treatment with a triglyceride lowering drug, the patient has/had a pretreatment triglyceride level greater than or equal to 500 milligram per deciliter (mg/dL). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## Омуон

#### **Products Affected**

#### • Omvoh

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **O**NCASPAR

### **Products Affected**

#### • Oncaspar

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **ONGENTYS AET**

#### **Products Affected**

• Ongentys

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **O**NIVYDE

#### **Products Affected**

#### • Onivyde

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **O**NUREG

#### **Products Affected**

#### • Onureg

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses                     | Peripheral T-cell lymphoma   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **O**PDIVO

#### **Products Affected**

• Opdivo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **OPDUALAG**

#### **Products Affected**

#### • Opdualag

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **O**PFOLDA

#### **Products Affected**

• Opfolda

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **O**PSUMIT

#### **Products Affected**

#### • Opsumit

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

### **O**PSYNVI

#### **Products Affected**

• Opsynvi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **OPZELURA**

### **Products Affected**

#### • Opzelura

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **ORACEA AET**

#### **Products Affected**

Oracea

• Doxycycline CPDR

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a formulary generic topical metronidazole. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

### **O**RALAIR

#### **Products Affected**

#### • Oralair

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

#### **ORAL-INTRANASAL FENTANYL**

#### **Products Affected**

- Fentanyl Citrate TABS 200MCG, 400MCG, 600MCG, 800MCG
- Fentanyl Citrate Oral Transmucosal

• Fentora TABS 100MCG, 200MCG, 400MCG, 600MCG, 800MCG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For the management of breakthrough pain in cancer patients: 1) The requested drug is indicated for the treatment of breakthrough cancer-related pain only. The requested drug is being prescribed for the management of breakthrough pain in a cancer patient with underlying cancer pain AND 2) The International Classification of Diseases (ICD) diagnosis code provided supports the cancer-related diagnosis. [Note: For drug coverage approval, ICD diagnosis code provided MUST support the cancer-related diagnosis.] AND 3) The patient is currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying cancer pain AND 4) The requested drug is intended only for use in opioid tolerant patients. The patient can safely take the requested dose based on their current opioid use history. [Note: Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 60 mg of oral hydrocodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, or an equianalgesic dose of another opioid medication daily for one week or longer.]. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

### **ORENCIA**

## **Products Affected**

• Orencia

#### • Orencia Clickject

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

#### **ORENITRAM**

#### **Products Affected**

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

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **O**RGOVYX

#### **Products Affected**

• Orgovyx

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

### **ORIAHNN**

#### **Products Affected**

#### • Oriahnn

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **O**RILISSA

### **Products Affected**

#### • Orilissa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **O**RKAMBI

### **Products Affected**

#### • Orkambi

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor. |
| Age Restrictions                   | 1 year of age or older  |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **O**RLADEYO

### **Products Affected**

#### • Orladeyo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **O**RSERDU

#### **Products Affected**

#### • Orserdu

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Recurrent hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Breast cancer: 1) the disease is estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER2)-negative, and ESR1 mutated AND 2) the patient meets either of the following: a) the disease is advanced, recurrent, or metastatic AND the patient has disease progression following at least one line of endocrine therapy OR b) the disease had no response to preoperative systemic therapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **OSPHENA**

#### **Products Affected**

#### • Osphena

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **O**TEZLA

### **Products Affected**

• Otezla

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### OXAZEPAM - 65

#### **Products Affected**

#### • Oxazepam

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders, anxiety associated with depression, and the management of anxiety, tension, agitation and irritability in older patients:  1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Short-term relief anxiety-1 month, Anxiety Disorders-4 months, Alcohol Withdrawal-Plan Year  |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older.  |

### **O**XBRYTA

#### **Products Affected**

• Oxbryta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

### **O**XERVATE

### **Products Affected**

#### • Oxervate

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **O**XLUMO

### **Products Affected**

#### • Oxlumo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# OXTELLAR XR

#### **Products Affected**

#### • Oxtellar Xr

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

#### **OXYCONTIN AET**

#### **Products Affected**

- Oxycodone Hcl Er T12A 10MG, 20MG, 40MG, 80MG
- Oxycodone Hydrochloride Er T12A 10MG, 20MG
- Oxycontin T12A

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **OZEMPIC**

#### **Products Affected**

• Ozempic INJ 2MG/3ML, 4MG/3ML, 8MG/3ML

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **PADCEV**

#### **Products Affected**

• Padcev

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

#### **PALFORZIA**

#### **Products Affected**

- Palforzia Initial Dose Escalation
- Palforzia Level 1
- Palforzia Level 10
- Palforzia Level 11 (maintenance)
- Palforzia Level 11 (titration)
- Palforzia Level 2

- Palforzia Level 3
- Palforzia Level 4
- Palforzia Level 5
- Palforzia Level 6
- Palforzia Level 7
- Palforzia Level 8
- Palforzia Level 9

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# PALYNZIQ AET

#### **Products Affected**

#### • Palynziq

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **PANRETIN**

### **Products Affected**

#### • Panretin

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.                      |
| Off-Label Uses                     | Topical treatment of cutaneous lesions in patients with non-AIDS-related Kaposi sarcoma |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | N/A   |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **PEGASYS**

### **Products Affected**

### • Pegasys

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **PEMAZYRE**

#### **Products Affected**

### • Pemazyre

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# PERFOROMIST AET

#### **Products Affected**

• Formoterol Fumarate NEBU

#### • Perforomist

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **PERJETA**

#### **Products Affected**

• Perjeta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **PHENYLBUTYRATE**

#### **Products Affected**

- Buphenyl
- OlpruvaPheburane

- Sodium Phenylbutyrate POWD 3GM/TSP
- Sodium Phenylbutyrate TABS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For urea cycle disorders (UCD): Diagnosis of UCD was confirmed by enzymatic, biochemical, or genetic testing. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **PHESGO**

### **Products Affected**

• Phesgo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **PIASKY**

#### **Products Affected**

• Piasky

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **PIQRAY**

### **Products Affected**

• Piqray 200mg Daily Dose

- Piqray 250mg Daily DosePiqray 300mg Daily Dose

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Recurrent hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated breast cancer in combination with fulvestrant. |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | N/A   |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# PLEGRIDY AET

### **Products Affected**

• Plegridy

• Plegridy Starter Pack

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **POLIVY**

### **Products Affected**

• Polivy

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **POMALYST**

## **Products Affected**

### • Pomalyst

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Relapsed/refractory systemic light chain amyloidosis, primary central nervous system (CNS) lymphoma, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For multiple myeloma, patient has previously received at least two prior therapies, including an immunomodulatory agent AND a proteasome inhibitor.  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **POMBILITI**

## **Products Affected**

#### • Pombiliti

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **PONVORY AET**

### **Products Affected**

• Ponvory

• Ponvory 14-day Starter Pack

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **PORTRAZZA**

## **Products Affected**

#### • Portrazza

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **POSACONAZOLE**

### **Products Affected**

• Noxafil TBEC

#### • Posaconazole Dr

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | The requested drug will be used orally. For prophylaxis of invasive Aspergillus and Candida infections: patient weighs greater than 40 kilograms.  |
| Age Restrictions                   | Treatment of Invasive Aspergillosis: 13 years of age or older, Prophylaxis of Invasive Aspergillus and Candida Infections: 2 years of age or older |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 6 months   |
| Other Criteria                     | N/A  |

# **POTELIGEO**

## **Products Affected**

### • Poteligeo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **PRALUENT**

## **Products Affected**

#### • Praluent

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **PREGABALIN**

### **Products Affected**

• Lyrica

- Pregabalin CAPSPregabalin SOLN

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Cancer-related neuropathic pain, cancer treatment-related neuropathic pain   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For the management of postherpetic neuralgia, the management of neuropathic pain associated with diabetic peripheral neuropathy: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# PRETOMANID AET

#### **Products Affected**

#### • Pretomanid

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For tuberculosis (TB), patient meets ALL of the following: 1) the requested drug is being used for treatment of pulmonary extensively drug resistant (XDR), treatment intolerant or nonresponsive multidrug resistant (MDR) tuberculosis, AND 2) the requested drug is used in combination with bedaquiline and linezolid. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **PREVYMIS**

#### **Products Affected**

## • Prevymis TABS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For prophylaxis of cytomegalovirus (CMV) infection or disease in hematopoietic stem cell transplant (HSCT): 1) the patient is CMV-seropositive, AND 2) the patient is a recipient of an allogeneic HSCT. For prophylaxis of CMV disease in kidney transplant: 1) the patient is CMV-seronegative, AND 2) the patient is a high risk recipient of kidney transplant. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 7 months  |
| Other Criteria                     | N/A   |

# PROAIR DIGIHALER

### **Products Affected**

## • Proair Digihaler

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **PROCYSBI**

### **Products Affected**

• Procysbi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## PROLATE AET

#### **Products Affected**

- Oxycodone And Acetaminophen
- Oxycodone Hydrochloride/acetaminophen SOLN 300MG/5ML; 10MG/5ML
- Oxycodone/acetaminophen TABS 300MG; 10MG, 300MG; 5MG
- Prolate

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# PROLENSA AET

#### **Products Affected**

• Bromfenac Sodium SOLN 0.07%

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# PROMACTA AET

### **Products Affected**

#### • Promacta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **PULMOZYME**

#### **Products Affected**

• Pulmozyme SOLN 2.5MG/2.5ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

## **PYRUKYND**

### **Products Affected**

• Pyrukynd

### • Pyrukynd Taper Pack

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **Q**BREXZA

### **Products Affected**

• Qbrexza

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **Q**ELBREE

### **Products Affected**

• Qelbree

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# QINLOCK

### **Products Affected**

### • Qinlock

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Gastrointestinal stromal tumor (GIST) for residual, unresectable, tumor rupture, recurrent, or progressive disease. Metastatic or unresectable cutaneous melanoma.  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For residual, unresectable, tumor rupture, advanced, recurrent/metastatic, or progressive gastrointestinal stromal tumor (GIST): 1) Patient has received prior treatment with 3 or more kinase inhibitors, including imatinib OR 2) Patient has experienced disease progression following treatment with avapritinib and dasatinib OR 3) Patient has received prior treatment with imatinib and is intolerant of second-line sunitinib. For cutaneous melanoma: 1) Disease is metastatic or unresectable AND 2) Disease is positive for KIT activating mutations AND 3) Requested drug will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# QUETIAPINE XR

### **Products Affected**

• Quetiapine Fumarate Er

• Seroquel Xr

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Maintenance monotherapy treatment in bipolar I disorder, monotherapy treatment of generalized anxiety disorder, monotherapy treatment of major depressive disorder  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For all indications: If the patient is 65 years of age or older AND is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, sertraline, clonazepam, escitalopram, alprazolam, zolpidem) with the requested drug, the prescriber determined that taking multiple central nervous system (CNS) active medications is medically necessary. [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls]. For treatment of schizophrenia: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine immediate-release, risperidone, ziprasidone. For acute treatment of manic or mixed episodes associated with bipolar I disorder or maintenance treatment of bipolar I disorder: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine immediate-release, risperidone, ziprasidone. For acute treatment of depressive episodes associated with bipolar I disorder: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: lurasidone, olanzapine, quetiapine immediate-release. For acute treatment of depressive episodes associated with bipolar II disorder: The patient experienced an inadequate treatment response or intolerance to generic quetiapine immediate-release. For adjunctive treatment of major depressive disorder (MDD): The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, olanzapine, quetiapine immediate-release. |
| Age Restrictions                   | N/A   |

| Prescriber<br>Restrictions | N/A       |
|----------------------------|-----------|
| Coverage<br>Duration       | Plan Year |
| Other Criteria             | N/A       |

# **Q**UININE SULFATE

### **Products Affected**

• Qualaquin

• Quinine Sulfate CAPS 324MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.          |
| Off-Label Uses                     | Babesiosis, uncomplicated Plasmodium vivax malaria.                         |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For babesiosis: the requested drug is used in combination with clindamycin. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 1 month   |
| Other Criteria                     | N/A   |

# **Q**ULIPTA

### **Products Affected**

• Qulipta

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Preventive treatment of migraine, initial: 1) The patient experienced an inadequate treatment response with a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants OR 2) The patient experienced an intolerance or has a contraindication that would prohibit a 4-week trial of any one of the following: antiepileptic drugs (AEDs), beta-adrenergic blocking agents, antidepressants. Preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Initial: 3 months, Continuation: Plan Year  |
| Other Criteria                     | N/A   |

# **Q**UTENZA

### **Products Affected**

• Qutenza

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **Q**UZYTTIR

### **Products Affected**

• Quzyttir

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## RADICAVA

### **Products Affected**

- Edaravone
- Radicava

- Radicava Ors
- Radicava Ors Starter Kit

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **RAGWITEK**

### **Products Affected**

### • Ragwitek

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# RAVICTI AET

### **Products Affected**

### • Ravicti

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **REBIF OPEN**

#### **Products Affected**

- Rebif
- Rebif Rebidose

- Rebif Rebidose Titration Pack
- Rebif Titration Pack

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## REBLOZYL

### **Products Affected**

### • Reblozyl

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# REBYOTA

### **Products Affected**

• Rebyota

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **RECARBRIO**

### **Products Affected**

### • Recarbrio

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **RECORLEV**

## **Products Affected**

#### • Recorlev

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **REGRANEX**

### **Products Affected**

### • Regranex

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | 20 weeks                      |
| Other Criteria                     | N/A                           |

# RELEUKO

### **Products Affected**

• Releuko INJ 300MCG/0.5ML, 480MCG/0.8ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **RELISTOR INJ**

### **Products Affected**

#### • Relistor INJ

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For the treatment of opioid-induced constipation in a patient with chronic non-cancer pain, including chronic pain related to prior cancer or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation: 1) the patient is unable to tolerate oral medications, OR 2) the patient meets one of the following criteria: A) experienced an inadequate treatment response or intolerance to an oral drug indicated for opioid-induced constipation in a patient with chronic non-cancer pain (e.g., Movantik), OR B) the patient has a contraindication that would prohibit a trial of an oral drug indicated for opioid-induced constipation in a patient with chronic non-cancer pain (e.g., Movantik). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 4 months   |
| Other Criteria                     | N/A  |

# **RELISTOR TAB**

### **Products Affected**

#### • Relistor TABS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# RELTONE

### **Products Affected**

• Reltone

• Ursodiol CAPS 200MG, 400MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **R**ELYVRIO

## **Products Affected**

### • Relyvrio

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## REMICADE

### **Products Affected**

• Infliximab

#### • Remicade

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **RENFLEXIS**

### **Products Affected**

#### • Renflexis

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## REPATHA

### **Products Affected**

• Repatha

- Repatha Pushtronex SystemRepatha Sureclick

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **RETEVMO**

### **Products Affected**

#### • Retevmo

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Recurrent rearranged during transfection (RET)-rearrangement positive non-small cell lung cancer (NSCLC), brain metastases from RET fusion-positive NSCLC, Langerhans Cell Histiocytosis with a RET gene fusion, symptomatic or relapsed/refractory Erdheim-Chester Disease with a RET gene fusion, symptomatic or relapsed/refractory Rosai-Dorfman Disease with a RET gene fusion, occult primary cancer with RET gene fusion, solid tumors with RET-gene fusion for recurrent disease  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For non-small cell lung cancer (NSCLC), patient must meet all of the following: 1) The disease is recurrent, advanced or metastatic, AND 2) The tumor is rearranged during transfection (RET) fusion-positive or RET rearrangement positive. For solid tumors, patient must meet all of the following: 1) The disease is recurrent, persistent, progressive, unresectable, locally advanced, or metastatic, 2) The patient has progressed on or following prior systemic treatment or has no satisfactory alternative treatment options, AND 3) The tumor is RET fusion-positive. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **REVCOVI**

### **Products Affected**

#### • Revcovi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# REVLIMID

### **Products Affected**

• Lenalidomide

• Revlimid

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Systemic light chain amyloidosis, classical Hodgkin lymphoma, myelodysplastic syndrome without the 5q deletion cytogenetic abnormality, myelofibrosis-associated anemia, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome, myeloproliferative neoplasms, Kaposi Sarcoma, Langerhans cell histiocytosis, Rosai-Dorfman disease, peripheral T-Cell lymphomas not otherwise specified, angioimmunoblastic T-cell lymphoma (AITL), enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma, adult T-cell leukemia/lymphoma, hepatosplenic T-cell lymphoma, primary central nervous system (CNS) lymphoma, chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), human immunodeficiency virus (HIV)-related B-cell lymphomas, monomorphic post-transplant lymphoproliferative disorder, diffuse large B-cell lymphoma, multicentric Castlemans disease, high-grade B-cell lymphomas, histologic transformation of indolent lymphoma to diffuse large B-cell lymphoma |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For myelodysplastic syndrome (MDS): patient has lower risk MDS with symptomatic anemia per the Revised International Prognostic Scoring System (IPSS-R), International Prognostic Scoring System (IPSS), or World Health organization (WHO) classification-based Prognostic Scoring System (WPSS).   |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# REYVOW

### **Products Affected**

• Reyvow

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# REZDIFFRA

## **Products Affected**

#### • Rezdiffra

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# REZLIDHIA

### **Products Affected**

#### • Rezlidhia

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **REZUROCK**

## **Products Affected**

#### • Rezurock

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | 12 years of age or older      |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **REZZAYO**

### **Products Affected**

### • Rezzayo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# RIABNI

### **Products Affected**

• Riabni

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# RINVOQ

### **Products Affected**

### • Rinvoq

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# RINVOQ LQ

### **Products Affected**

### • Rinvoq Lq

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **RITUXAN**

## **Products Affected**

#### • Rituxan

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# RITUXAN HYCELA

### **Products Affected**

### • Rituxan Hycela

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# RIVFLOZA

### **Products Affected**

#### • Rivfloza

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ROLVEDON**

### **Products Affected**

#### • Rolvedon

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# ROZLYTREK

### **Products Affected**

### • Rozlytrek

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Recurrent ROS1-positive non-small cell lung cancer (NSCLC), Non-metastatic neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors, ROS1-gene fusion-positive cutaneous melanoma |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For all neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors: the disease is without a known acquired resistance mutation. For ROS1-positive non-small cell lung cancer: the patient has recurrent, advanced, or metastatic disease.          |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# RUBRACA

### **Products Affected**

#### • Rubraca

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Uterine leiomyosarcoma, pancreatic adenocarcinoma, advanced (stage II-IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For metastatic castration-resistant prostate cancer with a deleterious breast cancer susceptibility gene (BRCA) mutation (germline and/or somatic): 1) patient has been treated with androgen receptor-directed therapy, AND 2) patient has been treated with a taxane-based chemotherapy or the patient is not fit for chemotherapy, AND 3) the requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. For maintenance treatment of BRCA mutated ovarian, fallopian tube, primary peritoneal cancer: 1) the patient has advanced (stage II-IV) disease and is in complete or partial response to primary therapy, OR 2) the patient has recurrent disease and is in complete or partial response to platinum-based chemotherapy. For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy, AND 2) the patient has BRCA-altered disease. For pancreatic adenocarcinoma: 1) the patient has metastatic disease, AND 2) the patient has somatic or germline BRCA or PALB-2 mutations. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# RUCONEST

## **Products Affected**

#### • Ruconest

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **RUXIENCE**

### **Products Affected**

#### • Ruxience

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **RYBELSUS**

#### **Products Affected**

### • Rybelsus

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **RYBREVANT**

### **Products Affected**

### • Rybrevant

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## RYDAPT

### **Products Affected**

### • Rydapt

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Relapsed or refractory acute myeloid leukemia (AML), myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FGFR1 or FLT3 rearrangements, post-induction therapy for AML, re-induction in residual disease for AML  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For acute myeloid leukemia (AML): AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and Fibroblast growth factor receptor type 1 (FGFR1) or FLT3 rearrangements: the disease is in chronic or blast phase. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **RYLAZE**

### **Products Affected**

• Rylaze

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **RYPLAZIM**

#### **Products Affected**

### • Ryplazim

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **RYSTIGGO**

#### **Products Affected**

### • Rystiggo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# RYTELO

#### **Products Affected**

• Rytelo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SAMSCA**

#### **Products Affected**

• Samsca

### • Tolvaptan

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# SANDOSTATIN LAR

#### **Products Affected**

### • Sandostatin Lar Depot

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SAPHNELO**

#### **Products Affected**

### • Saphnelo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SAPROPTERIN**

### **Products Affected**

• Javygtor

- Kuvan
- Sapropterin Dihydrochloride

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For phenylketonuria (PKU): For patients who have not yet received a therapeutic trial of the requested drug, the patient's pretreatment (including before dietary management) phenylalanine level is greater than 6 mg/dL (360 micromol/L). For patients who completed a therapeutic trial of the requested drug, the patient must have experienced improvement (e.g., reduction in blood phenylalanine levels, improvement in neuropsychiatric symptoms). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Initial: 2 months, All others: Plan Year   |
| Other Criteria                     | N/A  |

## **SARCLISA**

## **Products Affected**

#### • Sarclisa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SAVELLA**

#### **Products Affected**

• Savella

#### • Savella Titration Pack

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SCEMBLIX**

#### **Products Affected**

#### • Scemblix

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic phase or blast phase.  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For chronic myeloid leukemia (CML) in the chronic phase: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) Patient meets either of the following: A) Patient has previously been treated with 2 or more tyrosine kinase inhibitors (TKIs) AND at least one of those was imatinib, dasatinib, or nilotinib OR B) Patient is positive for the T315I mutation, AND 3) Patient is negative for the following mutations: A337T, P465S. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **SEGLENTIS**

### **Products Affected**

• Seglentis

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SEROSTIM**

#### **Products Affected**

• Serostim INJ 4MG, 5MG, 6MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SEYSARA**

#### **Products Affected**

• Seysara

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SIGNIFOR**

### **Products Affected**

• Signifor

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.                            |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an endocrinologist |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# SIGNIFOR LAR

### **Products Affected**

• Signifor Lar

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SIKLOS**

### **Products Affected**

• Siklos

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SILDENAFIL**

### **Products Affected**

• Revatio TABS

- Sildenafil Citrate SUSR
- Sildenafil Citrate TABS 20MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) If the request is for an adult, pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## SILDENAFIL INJ

#### **Products Affected**

• Revatio INJ

### • Sildenafil INJ

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# SILIQ

### **Products Affected**

• Siliq

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SIMPONI**

### **Products Affected**

### • Simponi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# SIMPONI ARIA

### **Products Affected**

### • Simponi Aria

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SIRTURO**

### **Products Affected**

#### • Sirturo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an infectious disease specialist |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **SKYCLARYS**

## **Products Affected**

• Skyclarys

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SKYRIZI**

#### **Products Affected**

- Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML, 600MG/10ML
- Skyrizi Pen

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient meets any of the following: a) patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# SKYTROFA AET

### **Products Affected**

• Skytrofa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# SOFOSBUVIR AND VELPATASVIR AET

#### **Products Affected**

• Sofosbuvir/velpatasvir

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SOGROYA AET**

### **Products Affected**

• Sogroya

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SOHONOS**

## **Products Affected**

#### • Sohonos

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SOLIRIS**

### **Products Affected**

• Soliris

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## SOMATULINE DEPOT

#### **Products Affected**

• Lanreotide Acetate

### • Somatuline Depot

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SOMAVERT**

#### **Products Affected**

#### • Somavert

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, AND 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **SOTYKTU**

#### **Products Affected**

### • Sotyktu

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient meets any of the following: a) patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# SOVALDI AET

### **Products Affected**

### • Sovaldi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **SPEVIGO**

## **Products Affected**

• Spevigo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **SPRIX**

### **Products Affected**

• Sprix

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SPRYCEL**

## **Products Affected**

• Sprycel

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Gastrointestinal stromal tumor (GIST), metastatic and/or widespread chondrosarcoma, recurrent chordoma, T-cell acute lymphoblastic leukemia (ALL), and Philadelphia (Ph)-like B-ALL, myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase, cutaneous melanoma   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For chronic myeloid leukemia (CML), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia (Ph) chromosome or BCR-ABL gene AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L. For acute lymphoblastic leukemia (ALL), the patient has a diagnosis of one of the following: 1) Philadelphia chromosome positive ALL, including patients who have received a hematopoietic stem cell transplant: Diagnosis that has been confirmed by detection of the Ph chromosome or BCR-ABL gene AND if patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L OR 2) Ph-like B-ALL with ABL-class kinase fusion OR 3) Relapsed or refractory T-cell ALL with ABL-class translocation. For gastrointestinal stromal tumor (GIST): 1) Patient meets all of the following: A) Disease is residual, unresectable, recurrent/progressive, or metastatic/tumor rupture, B) Patient has received prior therapy with avapritinib AND C) Patient is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutations. For cutaneous melanoma: 1) Disease is metastatic or unresectable, 2) Disease is positive for c-KIT activating mutations AND 3) Requested drug will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |

| Coverage<br>Duration | Plan Year |
|----------------------|-----------|
| Other Criteria       | N/A       |

## **STELARA**

### **Products Affected**

• Stelara

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient meets any of the following: a) patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **STIMUFEND**

## **Products Affected**

### • Stimufend

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **STIVARGA**

### **Products Affected**

## • Stivarga

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Osteosarcoma, glioblastoma, angiosarcoma, retroperitoneal/intra-<br>abdominal soft tissue sarcoma, rhabdomyosarcoma, soft tissue sarcomas<br>of the extremities, body wall, head and neck, appendiceal adenocarcinoma |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For colorectal cancer: 1) The disease is advanced or metastatic, AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Lonsurf (trifluridine/tipiracil).     |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **STRENSIQ**

## **Products Affected**

## • Strensiq

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **SUBLOCADE**

## **Products Affected**

### • Sublocade

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **SUNOSI**

## **Products Affected**

• Sunosi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **SUSVIMO**

## **Products Affected**

### • Susvimo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **SUTENT**

### **Products Affected**

• Sunitinib Malate

#### • Sutent

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Thyroid carcinoma (follicular, medullary, papillary, and oncocytic), soft tissue sarcoma (angiosarcoma, solitary fibrous tumor, and alveolar soft part sarcoma subtypes), recurrent chordoma, thymic carcinoma, lymphoid and/or myeloid neoplasms with eosinophilia and FLT3 rearrangement in chronic or blast phase, pheochromocytoma, paraganglioma, well differentiated grade 3 neuroendocrine tumors |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For renal cell carcinoma (RCC): 1) The disease is relapsed, advanced, or stage IV OR 2) the requested drug is being used as adjuvant treatment for patients that are at high risk of recurrent RCC following nephrectomy.  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **SYFOVRE**

## **Products Affected**

• Syfovre

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SYLVANT**

### **Products Affected**

• Sylvant

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **SYMDEKO**

### **Products Affected**

## • Symdeko

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For cystic fibrosis: The requested medication will not be used in combination with other medications containing ivacaftor. |
| Age Restrictions                   | 6 years of age or older  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **SYMLIN**

## **Products Affected**

• Symlinpen 120

## • Symlinpen 60

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **SYMPAZAN**

### **Products Affected**

## • Sympazan

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.              |
| Off-Label Uses                     | Seizures associated with Dravet syndrome  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | N/A   |
| Age Restrictions                   | Seizures associated with Lennox-Gastaut syndrome (LGS): 2 years of age or older |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **TABRECTA**

### **Products Affected**

### • Tabrecta

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Recurrent non-small cell lung cancer (NSCLC), NSCLC with high-level mesenchymal-epithelial transition (MET) amplification, central nervous system (CNS) brain metastases from MET exon-14 mutated NSCLC |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC): Tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutation.                                     |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# TADALAFIL (BPH)

## **Products Affected**

### • Tadalafil TABS 5MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | Erectile Dysfunction.  |
| Required<br>Medical<br>Information | For benign prostatic hyperplasia (BPH): the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to both of the following: 1) alpha blocker, 2) 5-alpha reductase inhibitor (5-ARI). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 26 weeks   |
| Other Criteria                     | N/A  |

# TADALAFIL (PAH)

### **Products Affected**

- Adcirca
- Alyq

- Tadalafil TABS 20MG
- Tadliq

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **TAFINLAR**

### **Products Affected**

### • Tafinlar

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Langerhans cell histiocytosis, Erdheim-Chester disease.   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For melanoma: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used as a single agent or in combination with trametinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used as a single agent or in combination with trametinib. For papillary, follicular, and oncocytic thyroid carcinoma: 1) The tumor is BRAF V600E-positive, AND 2) The disease is not amenable to radioactive iodine (RAI) therapy, AND 3) the requested drug will be used in combination with trametinib. For Langerhans Cell Histiocytosis and Erdheim-Chester Disease: The disease is positive for a BRAF V600E mutation. For solid tumors: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used in combination with trametinib. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **TAGRISSO**

## **Products Affected**

• Tagrisso

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| ra Criteria                        | Criteria Details   |
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Sensitizing epidermal growth factor receptor (EGFR) mutation-positive recurrent non-small cell lung cancer (NSCLC), brain metastases from sensitizing EGFR mutation-positive NSCLC, leptomeningeal metastases from EGFR mutation-positive NSCLC  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For non-small cell lung cancer (NSCLC), the requested drug is used in any of the following settings: 1) The patient meets both of the following: a) patient has metastatic, advanced, or recurrent NSCLC (including brain and/or leptomeningeal metastases from NSCLC) and b) patient has a sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease, OR 2) The patient meets both of the following: a) request is for adjuvant treatment of NSCLC following tumor resection and b) patient has EGFR mutation-positive disease. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **TAKHZYRO**

## **Products Affected**

• Takhzyro

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TALTZ**

## **Products Affected**

• Taltz

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TALVEY**

## **Products Affected**

• Talvey

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TALZENNA**

### **Products Affected**

### • Talzenna

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.                |
| Off-Label Uses                     | Recurrent germline breast cancer susceptibility gene (BRCA)-mutated breast cancer |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | N/A   |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# TARGRETIN TOPICAL

### **Products Affected**

• Bexarotene GEL

• Targretin GEL

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Mycosis fungoides (MF)/Sezary syndrome (SS), chronic or smoldering adult T-cell leukemia/lymphoma (ATLL), primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **TARPEYO**

### **Products Affected**

• Tarpeyo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TASCENSO**

## **Products Affected**

#### • Tascenso Odt

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **TASIGNA**

### **Products Affected**

• Tasigna

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL), gastrointestinal stromal tumor (GIST), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase, pigmented villonodular synovitis/tenosynovial giant cell tumor, cutaneous melanoma.   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor for CML, patient is negative for T315I, Y253H, E255K/V, and F359V/C/I mutations. For acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If the patient has experienced resistance to an alternative tyrosine kinase inhibitor for ALL, patient is negative for T315I, Y253H, E255K/V, F359V/C/I and G250E mutations. For gastrointestinal stromal tumor (GIST): 1) Disease is residual, unresectable, recurrent/progressive, or metastatic/tumor rupture, AND 2) Disease has progressed on at least 2 Food and Drug Administration (FDA)-approved therapies (e.g. imatinib, sunitinib, regorafenib, ripretinib). For cutaneous melanoma: 1) Disease is metastatic or unresectable, AND 2) Disease is positive for c-KIT activating mutations, AND 3) Requested drug will be used as subsequent therapy, AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |

| Other Criteria | N/Δ |
|----------------|-----|
| Other Criteria | N/A |

# **TAVALISSE**

### **Products Affected**

## • Tavalisse

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **TAVNEOS**

### **Products Affected**

### • Tavneos

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For continuation of treatment for severe anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: the patient has experienced benefit from therapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **TAZAROTENE**

### **Products Affected**

• Tazarotene CREA 0.1%

- Tazarotene GEL
- Tazorac

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For plaque psoriasis, the patient meets the following criteria: 1) the patient has less than or equal to 20 percent of affected body surface area (BSA), AND 2) the patient experienced an inadequate treatment response or intolerance to at least one topical corticosteroid OR has a contraindication that would prohibit a trial of topical corticosteroids. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **TAZVERIK**

### **Products Affected**

### • Tazverik

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | Epithelioid sarcoma: 16 years of age or older, Follicular lymphoma: 18 years of age or older |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **TECENTRIQ**

### **Products Affected**

• Tecentriq

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TECVAYLI**

## **Products Affected**

• Tecvayli

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TEGSEDI**

## **Products Affected**

• Tegsedi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# TEMAZEPAM 30MG - 65

#### **Products Affected**

• Restoril CAPS 30MG

• Temazepam CAPS 30MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For short-term treatment of insomnia: 1) The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | This Prior Authorization only applies to patients 65 years of age or older.  |

# **TEPEZZA**

### **Products Affected**

• Tepezza

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# Терметко

# **Products Affected**

## • Tepmetko

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Recurrent non-small cell lung cancer (NSCLC), NSCLC with high level mesenchymal-epithelial transition (MET) amplification, central nervous system (CNS) cancer including brain metastases and leptomeningeal metastases from MET exon-14 mutated NSCLC |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC): Tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutation.  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# TERIFLUNOMIDE AET

## **Products Affected**

• Aubagio

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TESTOPEL**

# **Products Affected**

• Testopel

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **TESTOSTERONE AET**

#### **Products Affected**

- Androderm PT24 2MG/24HR
- Androgel Pump GEL 1.62%
- Natesto

- Testim
- Vogelxo
- Vogelxo Pump

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TESTOSTERONE CYPIONATE INJ**

### **Products Affected**

• Depo-testosterone INJ 100MG/ML, 200MG/ML

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Gender Dysphoria  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **TESTOSTERONE ENANTHATE INJ**

### **Products Affected**

• Testosterone Enanthate INJ

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Gender Dysphoria  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **TETRABENAZINE**

### **Products Affected**

• Tetrabenazine

#### • Xenazine

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Tic disorders, tardive dyskinesia, hemiballismus, chorea not associated with Huntington's disease.   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For treatment of tardive dyskinesia and treatment of chorea associated with Huntington's disease: The patient has experienced an inadequate treatment response or intolerable adverse event to deutetrabenazine. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# TETRACYCLINE TAB

### **Products Affected**

• Tetracycline Hydrochlorid

• Tetracycline Hydrochloride TABS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TEZSPIRE**

# **Products Affected**

## • Tezspire

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **THALOMID**

### **Products Affected**

#### • Thalomid

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Myelofibrosis-associated anemia, acquired immunodeficiency syndrome (AIDS)-related aphthous stomatitis, Kaposi sarcoma, multicentric Castleman's disease, Rosai-Dorfman disease, Langerhans cell histiocytosis |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **TIBSOVO**

### **Products Affected**

#### • Tibsovo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Conventional (grades 1-3) or dedifferentiated chondrosarcoma, central nervous system (CNS) cancers (astrocytoma, oligodendroglioma)  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | Patient has disease with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation. For acute myeloid leukemia (AML): 1) patient has newly-diagnosed AML and meets one of the following: a) 75 years of age or older, b) patient has comorbidities that preclude use of intensive induction chemotherapy, OR 2) the requested drug will be used as post-induction therapy following response to induction therapy with the requested drug, OR 3) patient has relapsed or refractory AML. For locally advanced, unresectable, resected gross residual, or metastatic cholangiocarcinoma: the requested drug will be used as subsequent treatment for progression on or after systemic treatment. For CNS cancers: 1) disease is recurrent or progressive, AND 2) patient has oligodendroglioma or astrocytoma. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **TIVDAK**

### **Products Affected**

#### • Tivdak

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TLANDO**

### **Products Affected**

#### • Tlando

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# TOBI INHALER

### **Products Affected**

#### • Tobi Podhaler

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Non-cystic fibrosis bronchiectasis   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For cystic fibrosis and non-cystic fibrosis bronchiectasis: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) The patient has a history of Pseudomonas aeruginosa infection or colonization in the airways. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **TOBRAMYCIN**

## **Products Affected**

- Bethkis
- Kitabis Pak

- Tobi
- Tobramycin NEBU

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Non-cystic fibrosis bronchiectasis   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For cystic fibrosis and non-cystic fibrosis bronchiectasis: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) The patient has a history of Pseudomonas aeruginosa infection or colonization in the airways. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.   |

# **TOFIDENCE**

# **Products Affected**

#### • Tofidence

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# TOLAK

## **Products Affected**

• Tolak

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TOLSURA**

# **Products Affected**

#### • Tolsura

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# TOPICAL DOXEPIN

### **Products Affected**

• Doxepin Hydrochloride CREA

- Prudoxin
- Zonalon

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a topical corticosteroid or a topical calcineurin inhibitor. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 1 month  |
| Other Criteria                     | N/A  |

# **TOPICAL LIDOCAINE**

#### **Products Affected**

- Dermacinrx Lidogel
- Glydo
- Lidocaine OINT 5%
- Lidocaine Hcl PRSY

- Lidocaine Hydrochloride EXTERNAL SOLN
- Lidorex
- Pliaglis CREA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | 1) The requested drug is being used for topical anesthesia, AND 2) If the requested drug will be used as part of a compounded product, then all the active ingredients in the compounded product are Food and Drug Administration (FDA) approved for topical use. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 3 months  |
| Other Criteria                     | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.  |

## **TOPICAL TRETINOIN**

#### **Products Affected**

- Altreno
- Atralin
- Clindamycin Phosphate/tretinoin
- Retin-a CREA
- Retin-a GEL
- Retin-a Micro
- Retin-a Micro Pump

- Tretinoin CREA
- Tretinoin GEL
- Tretinoin Microsphere
- Tretinoin Microsphere Pump
- Twyneo
- Veltin
- Ziana

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **TOREMIFENE**

## **Products Affected**

• Fareston

#### • Toremifene Citrate

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | Congenital/acquired QT prolongation (long QT syndrome), uncorrected hypokalemia, or uncorrected hypomagnesemia. |
| Required<br>Medical<br>Information | N/A   |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# TRAMADOL ORAL SOLUTION

## **Products Affected**

• Qdolo

• Tramadol Hydrochloride SOLN

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TRAZIMERA**

# **Products Affected**

#### • Trazimera

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TRELSTAR**

### **Products Affected**

## • Trelstar Mixject

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TREMFYA**

### **Products Affected**

## • Tremfya INJ 100MG/ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For moderate to severe plaque psoriasis (new starts): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis AND 2) patient meets any of the following: a) patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# TREPROSTINIL INJ

## **Products Affected**

• Remodulin

• Treprostinil

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TRIENTINE**

## **Products Affected**

• Syprine

## • Trientine Hydrochloride

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **TRIKAFTA**

### **Products Affected**

#### • Trikafta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For cystic fibrosis: The requested medication will not be used in combination with other medications containing ivacaftor. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **TRINTELLIX**

### **Products Affected**

#### • Trintellix

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For major depressive disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to ONE of the following generic products: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **TRIPTODUR**

## **Products Affected**

• Triptodur

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TRODELVY**

## **Products Affected**

• Trodelvy

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# TROKENDI XR

### **Products Affected**

• Trokendi Xr

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TRULICITY**

## **Products Affected**

### • Trulicity

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | N/A   |
| Age Restrictions                   | For glycemic control in type 2 diabetes mellitus:10 years of age or older |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# TRUQAP

### **Products Affected**

• Truqap

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **TRUXIMA**

### **Products Affected**

#### • Truxima

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TUKYSA**

## **Products Affected**

• Tukysa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For colorectal cancer (including appendiceal adenocarcinoma): 1) the patient has advanced, unresectable, or metastatic disease, AND 2) the patient has human epidermal growth factor receptor 2 (HER2)-positive disease, AND 3) the patient has RAS wild-type disease, AND 4) the requested drug will be used in combination with trastuzumab, AND 5) the patient has not previously been treated with a HER2 inhibitor. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **TURALIO**

### **Products Affected**

#### • Turalio CAPS 125MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai-Dorfman disease   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For Langerhans cell histiocytosis: 1) disease has colony stimulating factor 1 receptor (CSF1R) mutation. For Erdheim-Chester disease and Rosai-Dorfman disease: 1) disease has CSF1R mutation AND patient has any of the following: a) symptomatic disease OR b) relapsed/refractory disease. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **TYENNE**

### **Products Affected**

• Tyenne

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TYMLOS**

### **Products Affected**

• Tymlos

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **TYSABRI**

### **Products Affected**

• Tysabri

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TYVASO**

### **Products Affected**

• Tyvaso

- Tyvaso Refill KitTyvaso Starter Kit

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# TYVASO DPI

### **Products Affected**

• Tyvaso Dpi Maintenance Kit

• Tyvaso Dpi Titration Kit

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **TZIELD**

### **Products Affected**

• Tzield

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **UBRELVY**

### **Products Affected**

• Ubrelvy

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For acute treatment of migraine: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to at least one triptan 5-HT1 receptor agonist. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **ULTOMIRIS**

### **Products Affected**

• Ultomiris INJ 1100MG/11ML, 300MG/3ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **UPLIZNA**

### **Products Affected**

### • Uplizna

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **UPTRAVI**

### **Products Affected**

• Uptravi

• Uptravi Titration Pack

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **UZEDY**

### **Products Affected**

• Uzedy

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **VABOMERE**

### **Products Affected**

#### • Vabomere

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **VABYSMO**

### **Products Affected**

• Vabysmo SOLN

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **VALCHLOR**

## **Products Affected**

#### • Valchlor

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Chronic or smoldering adult T-cell leukemia/lymphoma (ATLL), Stage 2 or higher mycosis fungoides (MF)/Sezary syndrome (SS), primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma, CD30-positive lymphomatoid papulosis (LyP), unifocal Langerhans cell histiocytosis (LCH) with isolated skin disease |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | N/A   |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# VALTOCO

### **Products Affected**

- Valtoco 10 Mg Dose
- Valtoco 15 Mg Dose

- Valtoco 20 Mg Dose
- Valtoco 5 Mg Dose

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | 6 years of age or older       |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## **VANFLYTA**

### **Products Affected**

### • Vanflyta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Relapsed or refractory acute myeloid leukemia  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For acute myeloid leukemia (AML): AML is FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (ITD)-positive. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## VECAMYL

### **Products Affected**

### • Vecamyl

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **VECTIBIX**

### **Products Affected**

• Vectibix INJ 100MG/5ML, 400MG/20ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VEGZELMA

### **Products Affected**

### • Vegzelma

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **VEKLURY**

## **Products Affected**

### • Veklury INJ 100MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **VELCADE**

### **Products Affected**

• Bortezomib INJ 1MG, 2.5MG, 3.5MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

• Velcade

## **VELSIPITY**

## **Products Affected**

• Velsipity

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## VENCLEXTA

### **Products Affected**

• Venclexta

• Venclexta Starting Pack

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Mantle cell lymphoma, blastic plasmacytoid dendritic cell neoplasm (BPDCN), multiple myeloma, relapsed or refractory acute myeloid leukemia (AML), Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, relapsed or refractory systemic light chain amyloidosis with translocation t(11:14), accelerated or blast phase myeloproliferative neoplasms, B-cell acute lymphoblastic leukemia/T-cell acute lymphoblastic leukemia (B-ALL/T-ALL), hairy cell leukemia   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For acute myeloid leukemia (AML): 1) patient has newly-diagnosed AML and meets one of the following: a) 75 years of age or older, b) patient has comorbidities that preclude use of intensive induction chemotherapy, OR 2) patient has poor/adverse risk disease and is a candidate for intensive induction therapy, OR 3) patient has relapsed or refractory AML. For blastic plasmacytoid dendritic cell neoplasm (BPDCN): 1) patient has systemic disease being treated with palliative intent, OR 2) patient has relapsed or refractory disease. For multiple myeloma: 1) the disease is relapsed or progressive, AND 2) the requested drug will be used in combination with dexamethasone, AND 3) patient has t(11:14) translocation. For Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma: 1) patient has previously treated disease that did not respond to primary therapy, OR 2) patient has progressive or relapsed disease. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **VENTAVIS**

### **Products Affected**

#### • Ventavis

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VEOPOZ

### **Products Affected**

• Veopoz

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## VEOZAH

### **Products Affected**

#### • Veozah

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

## VERKAZIA

### **Products Affected**

#### • Verkazia

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VERSACLOZ

## **Products Affected**

#### • Versacloz

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For the treatment of a severely ill patient with schizophrenia who failed to respond adequately to standard antipsychotic treatment (i.e., treatment-resistant schizophrenia): 1) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

## **VERZENIO**

### **Products Affected**

#### • Verzenio

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Recurrent hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer in combination with fulvestrant or an aromatase inhibitor, or as a single agent if progression on prior endocrine therapy and prior chemotherapy in the metastatic setting.  Endometrial cancer, in combination with letrozole for estrogen receptor positive tumor. |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | N/A   |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# VEVYE

### **Products Affected**

• Vevye

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VIBATIV AET

### **Products Affected**

#### • Vibativ INJ 750MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VIBERZI

## **Products Affected**

• Viberzi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VICTOZA AET

## **Products Affected**

• Liraglutide

• Victoza

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VIGABATRIN

### **Products Affected**

- Sabril
- Vigabatrin

- VigadroneVigpoder

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For complex partial seizures (i.e., focal impaired awareness seizures): patient has experienced an inadequate treatment response to at least two antiepileptic drugs for complex partial seizures (i.e., focal impaired awareness seizures). |
| Age Restrictions                   | Infantile Spasms: 1 month to 2 years of age. Complex partial seizures (i.e., focal impaired awareness seizures): 2 years of age or older   |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **VIGAFYDE**

## **Products Affected**

• Vigafyde

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VIJOICE

## **Products Affected**

• Vijoice

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **VILTEPSO**

## **Products Affected**

• Viltepso

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VIMIZIM

### **Products Affected**

#### • Vimizim

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VITRAKVI

## **Products Affected**

### • Vitrakvi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Non-metastatic neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors. |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For all neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, the disease is without a known acquired resistance mutation.           |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# VIVJOA

## **Products Affected**

• Vivjoa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **VIZIMPRO**

### **Products Affected**

## • Vizimpro

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Recurrent non-small cell lung cancer (NSCLC)  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic, and 2) the patient has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# Vonjo

## **Products Affected**

• Vonjo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses                     | Accelerated or blast phase myeloproliferative neoplasms            |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## VORICONAZOLE

#### **Products Affected**

- Vfend SUSR
- Vfend IV

- Voriconazole INJ
- Voriconazole SUSR

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.                                    |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | The patient will use the requested drug orally or intravenously. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 6 months   |
| Other Criteria                     | N/A  |

# Vosevi

### **Products Affected**

#### • Vosevi

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C)  |
| Required<br>Medical<br>Information | For hepatitis C: Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Criteria will be applied consistent with current AASLD-IDSA guidance.   |
| Other Criteria                     | N/A   |

# **VOTRIENT**

## **Products Affected**

• Votrient

• Pazopanib Hydrochloride

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| TA CITICITA                        | Criteria Details   |
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Thyroid carcinoma (follicular, papillary, oncocytic, or medullary), uterine sarcoma, chondrosarcoma, gastrointestinal stromal tumor  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For renal cell carcinoma: 1) the disease is advanced, relapsed, or stage IV, OR 2) the requested drug will be used for von Hippel-Lindau (VHL)-associated renal cell carcinoma. For gastrointestinal stromal tumor (GIST): 1) the disease is residual, unresectable, recurrent, or metastatic/tumor rupture AND 2) the patient meets one of the following: a) the disease has progressed after at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib), b) the disease is succinate dehydrogenase (SDH)-deficient GIST. For soft tissue sarcoma (STS): the patient does not have an adipocytic soft tissue sarcoma. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# Vowst

## **Products Affected**

• Vowst

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For the prevention of recurrence of Clostridioides difficile infection (CDI): 1) The diagnosis of CDI has been confirmed by a positive stool test for C. difficile toxin, AND 2) The requested drug will be administered at least 48 hours after the last dose of antibiotics used for the treatment of recurrent CDI. |
| Age Restrictions                   | 18 years of age or older   |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | 1 month  |
| Other Criteria                     | N/A  |

# Voxzogo

## **Products Affected**

• Voxzogo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VOYDEYA

## **Products Affected**

• Voydeya

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VPRIV

## **Products Affected**

• Vpriv

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **V**TAMA

## **Products Affected**

#### • Vtama

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VUITY

### **Products Affected**

• Vuity

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **VUMERITY**

### **Products Affected**

## • Vumerity

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **VYEPTI**

### **Products Affected**

• Vyepti

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VYJUVEK

## **Products Affected**

## • Vyjuvek

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## VYNDAMAX

### **Products Affected**

## • Vyndamax

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VYNDAQEL

## **Products Affected**

• Vyndaqel

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# VYONDYS 53

## **Products Affected**

• Vyondys 53

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **VYVGART**

### **Products Affected**

## • Vyvgart

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# Vyvgart Hytrulo

## **Products Affected**

## • Vyvgart Hytrulo

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **VYXEOS**

## **Products Affected**

• Vyxeos

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## WAINUA

## **Products Affected**

#### • Wainua

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# WAKIX

## **Products Affected**

• Wakix

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# WELIREG

### **Products Affected**

• Welireg

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# WINLEVI

## **Products Affected**

#### • Winlevi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# WINREVAIR

## **Products Affected**

#### • Winrevair

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# XALKORI

#### **Products Affected**

#### • Xalkori

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Recurrent non-small cell lung cancer (NSCLC), NSCLC with high-level MET amplification or MET exon 14 skipping mutation, symptomatic or relapsed/refractory anaplastic lymphoma kinase (ALK)-fusion positive Erdheim-Chester Disease, symptomatic or relapsed/refractory (ALK)-fusion positive Rosai-Dorfman Disease, (ALK)-fusion positive Langerhans Cell Histiocytosis, metastatic or unresectable ROS1 gene fusion positive cutaneous melanoma.   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For non-small cell lung cancer (NSCLC), the requested drug is used in any of the following settings: 1) the patient has recurrent, advanced or metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following products: Alecensa (alectinib) or Alunbrig (brigatinib), OR 3) the patient has recurrent, advanced or metastatic ROS-1 positive NSCLC, OR 4) the patient has NSCLC with high-level MET amplification or MET exon 14 skipping mutation. For inflammatory myofibroblastic tumor (IMT), the disease is ALK-positive. For anaplastic large cell lymphoma (ALCL): 1) the disease is relapsed or refractory, AND 2) the disease is ALK-positive. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **XDEMVY**

#### **Products Affected**

### • Xdemvy

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# **XELJANZ**

### **Products Affected**

• Xeljanz

• Xeljanz Xr

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **XEMBIFY**

#### **Products Affected**

### • Xembify

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **XENPOZYME**

### **Products Affected**

### • Xenpozyme

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **XEOMIN**

### **Products Affected**

#### • Xeomin

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# XERMELO

#### **Products Affected**

#### • Xermelo

| PA Criteria                        | Criteria Details              |
|------------------------------------|-------------------------------|
| Indications                        | All FDA-approved Indications. |
| Off-Label Uses                     | N/A                           |
| Exclusion<br>Criteria              | N/A                           |
| Required<br>Medical<br>Information | N/A                           |
| Age Restrictions                   | N/A                           |
| Prescriber<br>Restrictions         | N/A                           |
| Coverage<br>Duration               | Plan Year                     |
| Other Criteria                     | N/A                           |

# XGEVA

### **Products Affected**

## • Xgeva

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For hypercalcemia of malignancy: condition is refractory to intravenous (IV) bisphosphonate therapy or there is a clinical reason to avoid IV bisphosphonate therapy.  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# **XHANCE**

## **Products Affected**

#### • Xhance

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **XIAFLEX**

## **Products Affected**

#### • Xiaflex

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **XIFAXAN**

#### **Products Affected**

#### • Xifaxan TABS 550MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Small intestinal bacterial overgrowth syndrome (SIBO)  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For irritable bowel syndrome with diarrhea (IBS-D): 1) The patient has not previously received treatment with the requested drug, OR 2) The patient has previously received treatment with the requested drug, AND a) the patient is experiencing a recurrence of symptoms, AND b) the patient has not already received an initial 14-day course of treatment and two additional 14-day courses of treatment with the requested drug. For small intestinal bacterial overgrowth (SIBO): 1) the patient is experiencing a recurrence after completing a successful course of treatment with the requested drug OR 2) diagnosis has been confirmed by one of the following: a) quantitative culture of upper gut aspirate, b) breath testing (e.g., lactulose hydrogen or glucose hydrogen breath test). |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Reduction in risk of overt HE recurrence: 6 months, IBS-D and SIBO: 14 days  |
| Other Criteria                     | N/A  |

# XIFAXAN200

## **Products Affected**

#### • Xifaxan TABS 200MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **XIPERE**

#### **Products Affected**

• Xipere

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# XOLAIR

### **Products Affected**

• Xolair

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For moderate to severe persistent asthma, initial therapy (tx): 1) Patient (pt) has a positive skin test (or blood test) to at least one perennial aeroallergen, 2) Pt has baseline immunoglobulin E (IgE) level greater than or equal to 30 international units per milliliter (IU/mL), AND 3) Pt has inadequate asthma control despite current tx with both of the following medications: a) Medium-to-high-dose inhaled corticosteroid, AND b) Additional controller (i.e., long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless pt has an intolerance or contraindication to such therapies. For moderate to severe persistent asthma, continuation of tx (COT): Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms (sx) and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. For chronic spontaneous urticaria (CSU), initial tx: 1) Pt has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1 (IL-1)-associated urticarial syndromes (e.g., auto-inflammatory disorders, urticarial vasculitis), 2) Pt has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks, AND 3) Pt remains symptomatic despite H1 antihistamine treatment. For CSU, COT: Pt has experienced a benefit (e.g., improved sx) since initiation of tx. For chronic rhinosinusitis with nasal polyps (CRSwNP): 1) The requested drug is used as add-on maintenance treatment, AND 2) Pt has experienced inadequate treatment response to Xhance (fluticasone). For IgE-mediated food allergy, initial tx: Pt has baseline IgE level greater than or equal to 30 IU/mL. For IgE-mediated food allergy, COT: Pt has experienced a benefit as evidenced by a decrease in hypersensitivity (e.g., moderate to severe skin, respiratory or gastrointestinal sx) to food allergen. |
| Age Restrictions                   | CSU: 12 years of age or older. Asthma: 6 years of age or older. CRSwNP: 18 years of age or older. IgE-mediated food allergy: 1 year of age or older  |

| Prescriber<br>Restrictions | N/A  |
|----------------------------|--|
| Coverage<br>Duration       | CSU initial: 6 months, All others: Plan Year |
| Other Criteria             | N/A  |

# XOLREMDI

## **Products Affected**

#### • Xolremdi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# XOSPATA

### **Products Affected**

### • Xospata

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FMS-like tyrosine kinase 3 (FLT3) rearrangement: the disease is in chronic or blast phase. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **XPHOZAH**

## **Products Affected**

## • Xphozah

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **XPOVIO**

### **Products Affected**

• Xpovio

- Xpovio 60 Mg Twice Weekly Xpovio 80 Mg Twice Weekly

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma, Human Immunodeficiency Virus (HIV)-related B-cell lymphoma, high-grade B-cell lymphoma, post-transplant lymphoproliferative disorders |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For multiple myeloma: Patient must have been treated with at least one prior therapy. For B-cell lymphomas: Patient must have been treated with at least two lines of systemic therapy.                                 |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **XTANDI**

## **Products Affected**

#### • Xtandi

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications.  |
| Off-Label Uses                     | N/A  |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For the treatment of castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer: The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

# **XURIDEN**

## **Products Affected**

#### • Xuriden

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# XYOSTED AET

### **Products Affected**

• Xyosted

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **XYREM**

### **Products Affected**

• Sodium Oxybate

• Xyrem

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For the treatment of excessive daytime sleepiness in a patient with narcolepsy, initial request: 1) The diagnosis has been confirmed by sleep lab evaluation, AND 2) The patient meets one of the following criteria: a) if the patient is 17 years of age or younger, the patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate), OR has a contraindication that would prohibit a trial of central nervous system (CNS) stimulant drugs (e.g., amphetamine, dextroamphetamine, methylphenidate), b) If the patient is 18 years of age or older, the patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil, modafinil), OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drugs (e.g., armodafinil, modafinil). For the treatment of cataplexy in a patient with narcolepsy, initial request: The diagnosis has been confirmed by sleep lab evaluation. If the request is for a continuation of therapy, then the patient experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy. |
| Age Restrictions                   | 7 years of age or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a sleep disorder specialist or neurologist  |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# XYWAV

### **Products Affected**

• Xywav

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# YCANTH

#### **Products Affected**

#### • Ycanth

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# YERVOY

#### **Products Affected**

• Yervoy

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **YONDELIS**

## **Products Affected**

#### • Yondelis

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# YONSA

#### **Products Affected**

• Yonsa

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# YUPELRI AET

### **Products Affected**

### • Yupelri

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **Z**ALTRAP

### **Products Affected**

### • Zaltrap

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **Z**ARXIO

#### **Products Affected**

#### • Zarxio

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Neutropenia in myelodysplastic syndromes (MDS), agranulocytosis, neutropenia in aplastic anemia, human immunodeficiency virus (HIV)-related neutropenia, hematopoietic syndrome of acute radiation syndrome   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | If receiving chemotherapy, the requested drug will be administered at least 24 hours after chemotherapy. For prophylaxis or treatment of myelosuppressive chemotherapy-induced febrile neutropenia (FN) patient must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, AND 2) Patient has received, is currently receiving, or will be receiving treatment with myelosuppressive anti-cancer therapy. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | 6 months  |
| Other Criteria                     | N/A   |

## **Z**AVZPRET

#### **Products Affected**

### • Zavzpret

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# ZEGERID CAPSULE AET

#### **Products Affected**

## • Zegerid CAPS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ZEGERID SUSPENSION AET**

#### **Products Affected**

## • Zegerid PACK

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# ZEJULA

### **Products Affected**

## • Zejula TABS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses                     | Uterine leiomyosarcoma  |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy AND 2) the patient has BRCA-altered disease. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# **Z**ELBORAF

#### **Products Affected**

#### • Zelboraf

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses                     | Non-small cell lung cancer, hairy cell leukemia, central nervous system cancer (i.e., glioma, glioblastoma, pediatric diffuse high-grade glioma), adjuvant systemic therapy for cutaneous melanoma, Langerhans cell histiocytosis.   |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | For central nervous system (CNS) cancer (i.e., glioma, astrocytoma, glioblastoma, pediatric diffuse high-grade glioma): 1) The tumor is positive for BRAF V600E mutation, AND 2) The requested drug will be used in combination with cobimetinib OR the requested drug is being used for the treatment of pediatric diffuse high-grade glioma. For melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) the requested drug will be used as a single agent, or in combination with cobimetinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, or b) adjuvant systemic therapy. For Erdheim-Chester Disease and Langerhans Cell Histiocytosis: Tumor is positive for BRAF V600 mutation. For non-small cell lung cancer: 1) The tumor is positive for the BRAF V600E mutation, AND 2) The patient has recurrent, advanced, or metastatic disease. |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## ZEMDRI

### **Products Affected**

#### • Zemdri

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **ZEPATIER AET**

#### **Products Affected**

• Zepatier

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## ZEPOSIA

### **Products Affected**

• Zeposia

- Zeposia 7-day Starter Pack
- Zeposia Starter Kit

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## ZEPZELCA

### **Products Affected**

### • Zepzelca

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **Z**ILBRYSQ

### **Products Affected**

• Zilbrysq

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **ZINPLAVA**

#### **Products Affected**

### • Zinplava

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **Z**IRABEV

## **Products Affected**

#### • Zirabev

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## ZOKINVY

### **Products Affected**

### • Zokinvy

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## ZOLINZA

### **Products Affected**

#### • Zolinza

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses                     | Mycosis fungoides (MF)/Sezary syndrome (SS)                        |
| Exclusion<br>Criteria              | N/A  |
| Required<br>Medical<br>Information | N/A  |
| Age Restrictions                   | N/A  |
| Prescriber<br>Restrictions         | N/A  |
| Coverage<br>Duration               | Plan Year  |
| Other Criteria                     | N/A  |

## **Z**OLPIDEM

## **Products Affected**

### • Zolpidem Tartrate CAPS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **ZONISADE**

#### **Products Affected**

#### • Zonisade

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.   |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | For adjunctive treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom, Xcopri, Spritam OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). |
| Age Restrictions                   | 16 years of age or older  |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

# ZORYVE 0.3% CRM

### **Products Affected**

• Zoryve CREA 0.3%

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

# **ZORYVE FOAM**

### **Products Affected**

### • Zoryve FOAM

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **Z**TALMY

#### **Products Affected**

### • Ztalmy

| PA Criteria                        | Criteria Details              |  |  |
|------------------------------------|-------------------------------|--|--|
| Indications                        | All FDA-approved Indications. |  |  |
| Off-Label Uses                     | N/A                           |  |  |
| Exclusion<br>Criteria              | N/A                           |  |  |
| Required<br>Medical<br>Information | N/A                           |  |  |
| Age Restrictions                   | 2 years of age or older       |  |  |
| Prescriber<br>Restrictions         | N/A                           |  |  |
| Coverage<br>Duration               | Plan Year                     |  |  |
| Other Criteria                     | N/A                           |  |  |

## ZTLIDO AET

## **Products Affected**

#### • Ztlido

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **Z**URZUVAE

#### **Products Affected**

#### • Zurzuvae

| PA Criteria                        | Criteria Details  |  |  |  |
|------------------------------------|---|--|--|--|
| Indications                        | All FDA-approved Indications.   |  |  |  |
| Off-Label Uses                     | N/A   |  |  |  |
| Exclusion<br>Criteria              | N/A   |  |  |  |
| Required<br>Medical<br>Information | For the treatment of postpartum depression (PPD): diagnosis was confirmed using standardized rating scales that reliably measure depressive symptoms (e.g., Hamilton Depression Rating Scale [HDRS], Edinburgh Postnatal Depression Scale [EPDS], Patient Health Questionnaire 9 [PHQ9], Montgomery-Asberg Depression Rating Scale [MADRS], Beck's Depression Inventory [BDI], etc.). |  |  |  |
| Age Restrictions                   | N/A   |  |  |  |
| Prescriber<br>Restrictions         | N/A   |  |  |  |
| Coverage<br>Duration               | 1 month   |  |  |  |
| Other Criteria                     | N/A   |  |  |  |

## **Z**YDELIG

### **Products Affected**

### • Zydelig

| PA Criteria                        | Criteria Details  |  |
|------------------------------------|---|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.  |  |
| Off-Label Uses                     | Small lymphocytic lymphoma (SLL)  |  |
| Exclusion<br>Criteria              | N/A   |  |
| Required<br>Medical<br>Information | For chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL): the requested drug is used as second-line or subsequent therapy. |  |
| Age Restrictions                   | N/A   |  |
| Prescriber<br>Restrictions         | N/A   |  |
| Coverage<br>Duration               | Plan Year   |  |
| Other Criteria                     | N/A   |  |

## ZYKADIA

#### **Products Affected**

### • Zykadia TABS

| PA Criteria                        | Criteria Details   |  |  |  |
|------------------------------------|--|--|--|--|
| Indications                        | All FDA-approved Indications, Some Medically accepted Indications.   |  |  |  |
| Off-Label Uses                     | Recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), recurrent, advanced, or metastatic ROS1-positive NSCLC, Erdheim-Chester Disease (ECD) with ALK-fusion, inflammatory myofibroblastic tumor (IMT), brain metastases from NSCLC, relapsed or refractory ALK-positive anaplastic large cell lymphoma (ALCL)  |  |  |  |
| Exclusion<br>Criteria              | N/A  |  |  |  |
| Required<br>Medical<br>Information | For non-small cell lung cancer (NSCLC): 1) the patient has recurrent, advanced, or metastatic anaplastic lymphoma kinase (ALK)-positive AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following products: Alecensa (alectinib) or Alunbrig (brigatinib) OR 3) ROS1-positive disease. For inflammatory myofibroblastic tumor: the disease is ALK-positive. For brain metastases from NSCLC: the patient has ALK-positive NSCLC. For anaplastic large cell lymphoma (ALCL): the patient has relapsed or refractory ALK-positive disease. |  |  |  |
| Age Restrictions                   | N/A  |  |  |  |
| Prescriber<br>Restrictions         | N/A  |  |  |  |
| Coverage<br>Duration               | Plan Year  |  |  |  |
| Other Criteria                     | N/A  |  |  |  |

## ZYMFENTRA AET

#### **Products Affected**

• Zymfentra 2-pen

• Zymfentra 2-syringe

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **Z**YNLONTA

#### **Products Affected**

### • Zynlonta

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## **Z**YNYZ

#### **Products Affected**

• Zynyz

| PA Criteria                        | Criteria Details   |
|------------------------------------|--------------------|
| Indications                        | Pending CMS Review |
| Off-Label Uses                     | Pending CMS Review |
| Exclusion<br>Criteria              | Pending CMS Review |
| Required<br>Medical<br>Information | Pending CMS Review |
| Age Restrictions                   | Pending CMS Review |
| Prescriber<br>Restrictions         | Pending CMS Review |
| Coverage<br>Duration               | Pending CMS Review |
| Other Criteria                     | Pending CMS Review |

## ZYPREXA RELPREVV

#### **Products Affected**

### • Zyprexa Relprevv

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Indications                        | All FDA-approved Indications.                           |
| Off-Label Uses                     | N/A   |
| Exclusion<br>Criteria              | N/A   |
| Required<br>Medical<br>Information | Tolerability with oral olanzapine has been established. |
| Age Restrictions                   | N/A   |
| Prescriber<br>Restrictions         | N/A   |
| Coverage<br>Duration               | Plan Year   |
| Other Criteria                     | N/A   |

#### PART B VERSUS PART D

#### **Products Affected**

- Abelcet
- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Adriamycin INJ 50MG
- Akynzeo CAPS
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Ambisome
- Amphotericin B INJ
- Amphotericin B Liposome
- Anzemet TABS 50MG
- Aprepitant CAPS
- Astagraf XL
- Atgam
- Azasan
- Azathioprine INJ
- Azathioprine TABS
- Baclofen INJ 20000MCG/20ML, 40MG/20ML, 500MCG/ML, 50MCG/ML
- Bleomycin Sulfate INJ
- Budesonide SUSP
- Cellcept
- Cellcept Intravenous
- Cladribine
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix 6/5
- Clinimix 8/10
- Clinimix 8/14

- Clinimix E 2.75%/dextrose 5% INJ 570MG/100ML; 316MG/100ML; 33MG/100ML; 5GM/100ML; 515MG/100ML; 132MG/100ML; 165MG/100ML; 201MG/100ML; 159MG/100ML; 51MG/100ML; 110MG/100ML; 454MG/100ML; 154MG/100ML; 261MG/100ML; 187MG/100ML; 138MG/100ML; 117MG/100ML; 112MG/100ML; 116MG/100ML; 116MG/100ML; 110MG/100ML; 11MG/100ML; 110MG/100ML; 11MG/100ML; 110MG/100ML; 110MG/100ML;
- Clinimix E 4.25%/dextrose 10%
- Clinimix E 4.25%/dextrose 5%
- Clinimix E 5%/dextrose 15%
- Clinimix E 5%/dextrose 20%
- Clinimix E 8/10
- Clinimix E 8/14
- Clinisol Sf 15%
- Clinolipid
- Cromolyn Sodium NEBU
- Cyclosporine CAPS
- Cyclosporine INJ
- Cyclosporine Modified
- Cytarabine INJ 100MG/ML
- Cytarabine Aqueous
- Deferoxamine Mesylate
- Depo-medrol
- Desferal INJ 500MG
- Dextrose 25% INJ 250MG/ML
- Dextrose 50%
- Dextrose 70%
- Dilaudid INJ 0.2MG/ML, 1MG/ML, 2MG/ML
- Dobutamine Hcl INJ 250MG/20ML
- Dobutamine Hcl/d5w INJ 5%; 1MG/ML
- Dobutamine Hydrochloride/dextrose 5%
- Dopamine Hydrochloride INJ
- Dopamine Hydrochloride/dextrose
- Dopamine/d5w INJ 5%; 3.2MG/ML

- Doxorubicin Hcl INJ 50MG
- Doxorubicin Hydrochloride INJ 10MG, 200MG/100ML
- Duopa
- Duramorph
- Emend CAPS 80MG
- Emend SUSR
- Emend Tripack
- Engerix-b
- Envarsus Xr
- Epoprostenol Sodium
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Fentanyl Citrate INJ 1000MCG/20ML, 100MCG/2ML, 2500MCG/50ML, 250MCG/5ML, 500MCG/10ML, 50MCG/ML
- Fiasp Pumpcart
- Flolan
- Fluorouracil INJ 1GM/20ML, 2.5GM/50ML, 500MG/10ML, 5GM/100ML
- Gablofen
- Gamastan
- Ganciclovir INJ 500MG, 500MG/10ML
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hydrochloride TABS
- Heplisav-b
- Humulin R U-500 (concentrated)
- Hydromorphone Hcl INJ 10MG/ML, 1MG/ML, 4MG/ML
- Hydromorphone Hydrochloride INJ 0.25MG/0.5ML, 1MG/ML, 2MG/ML, 4MG/ML, 50MG/5ML
- Imovax Rabies (h.d.c.v.)
- Imuran TABS
- Infumorph 200
- Infumorph 500
- Intralipid INJ 20GM/100ML, 30GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate

- Isolyte-s INJ 27MEQ/L; 98MEQ/L; 23MEQ/L; 3MEQ/L; 5MEQ/L; 140MEQ/L
- Isolyte-s Ph 7.4
- Jynneos
- Kabiven
- Khapzory INJ 175MG
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU
- Levalbuterol Hydrochloride NEBU 0.63MG/3ML
- Medrol TABS 16MG, 2MG, 4MG, 8MG
- Methylprednisolone TABS
- Methylprednisolone Acetate INJ 40MG/ML, 80MG/ML
- Methylprednisolone Sodium Succinate
- Methylprednisolone Sodiumsuccinate INJ 40MG
- Milrinone Lactate INJ 10MG/10ML, 20MG/20ML, 50MG/50ML
- Milrinone Lactate In Dextrose
- Mitigo
- Morphine Sulfate INJ 0.5MG/ML, 10MG/ML, 1MG/ML, 2MG/ML, 4MG/ML, 50MG/ML, 5MG/ML, 8MG/ML
- Morphine Sulfate/sodium Chloride INJ 1MG/ML
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil INJ
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Myfortic
- Myhibbin
- Nebupent
- Neoral
- Nulojix
- Nutrilipid
- Omegaven
- Ondansetron Hcl SOLN
- Ondansetron Hcl TABS 24MG
- Ondansetron Hydrochloride TABS

- Ondansetron Odt
- Orapred Odt
- Pediapred SOLN
- Pentamidine Isethionate INHALATION SOLR
- Perikabiven
- Plenamine INJ 147.4MEQ/L;
  2.17GM/100ML; 1.47GM/100ML;
  434MG/100ML; 749MG/100ML;
  1.04GM/100ML; 894MG/100ML;
  749MG/100ML; 1.04GM/100ML;
  1.18GM/100ML; 749MG/100ML;
  1.04GM/100ML; 894MG/100ML;
  592MG/100ML; 749MG/100ML;
  250MG/100ML; 39MG/100ML;
  960MG/100ML
- Prednisolone SOLN
- Prednisolone TABS
- Prednisolone Sodium Phosphate ORAL SOLN 10MG/5ML, 15MG/5ML, 20MG/5ML, 25MG/5ML, 5MG/5ML
- Prednisolone Sodium Phosphate Odt
- Prednisone SOLN
- Prednisone TABS 10MG, 1MG, 2.5MG, 20MG, 50MG, 5MG
- Prednisone Intensol
- Prehevbrio
- Premasol INJ 52MEQ/L;
   1760MG/100ML; 880MG/100ML;
   34MEQ/L; 1760MG/100ML;
   372MG/100ML; 406MG/100ML;
   526MG/100ML; 492MG/100ML;
   492MG/100ML; 526MG/100ML;
   356MG/100ML; 356MG/100ML;
   390MG/100ML; 34MG/100ML;
   152MG/100ML
- Prialt
- Prograf
- Prosol
- Pulmicort
- Rabavert
- Rapamune SOLN
- Rapamune TABS 1MG, 2MG
- Rayos

- Recombivax Hb
- Sandimmune CAPS 100MG, 25MG
- Sandimmune INJ
- Sandimmune SOLN
- Simulect
- Sirolimus SOLN
- Sirolimus TABS
- Smoflipid
- Solu-medrol INJ 1000MG, 125MG, 2GM, 40MG, 500MG
- Tacrolimus CAPS
- Thymoglobulin
- Tpn Electrolytes INJ 29.5MEQ/20ML;
   4.5MEQ/20ML; 35MEQ/20ML;
   5MEQ/20ML; 20MEQ/20ML;
   35MEQ/20ML
- Travasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 492MG/100ML; 526MG/100ML; 356MG/100ML; 500MG/100ML; 356MG/100ML; 390MG/100ML; 34MG/100ML; 152MG/100ML
- Trophamine INJ 0.54GM/100ML;
  1.2GM/100ML; 0.32GM/100ML; 0; 0;
  0.5GM/100ML; 0.36GM/100ML;
  0.48GM/100ML; 0.82GM/100ML;
  1.4GM/100ML; 1.2GM/100ML;
  0.34GM/100ML; 0.48GM/100ML;
  0.68GM/100ML; 0.38GM/100ML;
  5MEQ/L; 0.025GM/100ML;
  0.42GM/100ML; 0.2GM/100ML;
  0.24GM/100ML; 0.78GM/100ML
- Varubi TBPK
- Veletri
- Vinblastine Sulfate INJ 1MG/ML
- Vincristine Sulfate INJ 1MG/ML
- Zortress
- Zulresso

#### **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.

### **INDEX**

| $\boldsymbol{A}$                            | Adalimumab-ryvk (2 Pen)     |     |
|---|-----------------------------|-----|
| Abelcet                                     | Adapalene                   | 11  |
| Abilify Asimtufii                           | Adapalene Pump              | 11  |
| Abilify Mycite                              | Adapalene/benzoyl Peroxide  | 11  |
| Abilify Mycite Maintenance Kit              | Adbry                       | 12  |
| Abilify Mycite Starter Kit                  | Adcirca                     | 633 |
| Abiraterone 3                               | Adempas                     | 13  |
| Abiraterone Acetate                         | Adlarity                    | 14  |
| Abrilada9                                   | Adriamycin                  | 815 |
| Abrilada 1-pen Kit9                         | Adzynma                     | 15  |
| Absorica                                    | Afinitor                    | 203 |
| Accutane 324                                | Afinitor Disperz            | 203 |
| Acetylcysteine                              | Agamree                     | 16  |
| Acitretin                                   | Aimovig                     | 17  |
| Actemra 5                                   | Ajovy                       | 18  |
| Actemra Actpen                              | Ajovy Aet                   | 18  |
| Acthar 6                                    | Akeega                      | 19  |
| Acthar Gel6                                 | Aklief                      |     |
| Acthar Hp6                                  | Akynzeo                     |     |
| Actimmune                                   | Albuterol Sulfate           |     |
| Acyclovir Sodium                            | Alcohol Prep Pads           |     |
| Adakveo 8                                   | Aldurazyme                  |     |
| Adalimumab Aet9                             | Alecensa                    |     |
| Adalimumab-aacf (2 Pen)295                  | Aliqopa                     |     |
| Adalimumab-aacf (2 Syringe)295              | Alkindi                     |     |
| Adalimumab-aaty 1-pen Kit9                  | Alkindi Sprinkle            |     |
| Adalimumab-aaty 2-syringe Kit9              | Allzital                    |     |
| Adalimumab-adaz9                            | Alosetron                   |     |
| Adalimumab-adbm9                            | Alosetron Hydrochloride     |     |
| Adalimumab-adbm Crohns/uc/hs Starter9       | Alpha1-proteinase Inhibitor |     |
| Adalimumab-adbm Psoriasis/uveitis Starter 9 | Altreno                     |     |
| Adalimumab-adbm Starter Package For Crohns  | Alunbrig                    |     |
| Disease/uc/hs9                              | Alvaiz                      |     |
| Adalimumab-adbm Starter Package For         | Alyglo                      |     |
| Psoriasis/uveitis9                          | Alymsys                     |     |
| Adalimumab-fkjp9                            | Alyq                        |     |
| Adalimumab-ryvk9                            | Ambien                      |     |
| •   | Ambien Cr                   | 270 |

| Ambisome                    | 815   | Austedo                               | 46           |
|-----------------------------|-------|---------------------------------------|--------------|
| Ambrisentan                 | 31    | Austedo Xr                            | 46           |
| Amitiza                     | 32    | Austedo Xr Patient Titration Kit      | 46           |
| Amitiza Aet                 | 32    | Auvelity                              | 47           |
| Amitriptyline Hcl           | 280   | Avastin                               | 48           |
| Amitriptyline Hydrochloride |       | Avonex                                | 49           |
| Amjevita                    |       | Avonex Aet                            | 49           |
| Amnesteem                   | 324   | Avonex Pen                            | 49           |
| Amondys 45                  | 33    | Avsola                                | 50           |
| Amphotericin B              | 815   | Avycaz                                | 51           |
| Amphotericin B Liposome     | 815   | Ayvakit                               | 52           |
| Ampyra                      | 137   | Azasan                                | 815          |
| Amrix                       | 285   | Azathioprine                          | 815          |
| Amvuttra                    | 34    | В                                     |              |
| Anafranil                   | 116   |                                       |              |
| Ancobon                     | 227   | Baclofen                              |              |
| Androderm                   | 657   | Baclofen Soln                         |              |
| Androgel Pump               | 657   | Bafiertam                             |              |
| Anzemet                     |       | Balversa                              | 55           |
| Apokyn                      | 35    | Banzel                                | 56           |
| Apomorphine Hydrochloride   | 35    | Bavencio                              |              |
| Aprepitant                  |       | Baxdela                               | 58           |
| Aralast Np                  | 26    | Bd Insulin Syringe Safetyglide/1ml/2  | 29g X 1/2318 |
| Aranesp Aet                 |       | B-d Insulin Syringe Ultrafine Ii/0.3m | 1/31g X 5/16 |
| Aranesp Albumin Free        |       |                                       | 318          |
| Arcalyst                    |       | Bd Insulin Syringe Ultra-fine/0.5ml/3 | 30g X        |
| Arestin                     |       | 12.7mm                                | 318          |
| Arestin Aet                 |       | Bd Insulin Syringe Ultra-fine/1ml/31  | g X 8mm.318  |
| Arformoterol Tartrate       |       | Bd Pen Needle/original/ultra-fine/29g | g X 12.7mm   |
| Arikayce                    |       |                                       | 318          |
| Armodafinil                 |       | Bd Veo Insulin Syringe Ultra-fine/0.2 | 3ml/31g X    |
| Arzerra                     |       | 6mm                                   | 318          |
| Asceniv                     | 328   | Belbuca                               | 59           |
| Ascomp/codeine              | 86    | Beleodaq                              | 60           |
| Asparlas                    |       | Belladonna/opium                      | 266          |
| Aspruzyo                    |       | Benlysta                              | 61           |
| Aspruzyo Sprinkle           | 43    | Benznidazole                          | 62           |
| Astagraf XL                 |       | Benztropine Mesylate                  | 273          |
| Atgam                       |       | Beovu                                 | 63           |
| Atovaquone                  |       | Berinert                              | 64           |
| Atralin                     |       | Besponsa                              | 65           |
| Atropine Sulfate            |       | Besremi                               | 66           |
| Aubagio                     |       | Betaseron                             | 67           |
| Augtyro                     | · ·   | Bethkis                               | 668          |
| 6 )                         | ••••• | Bexarotene                            | 68, 640      |

| Bimzelx                                   | 69     | Cabtreo                                  | 11  |
|---|--------|--|-----|
| Bivigam                                   | 328    | Calcipotriene                            | 93  |
| Bleomycin Sulfate                         | 815    | Calcipotriene/betamethasone Dipropionate | 93  |
| Blincyto                                  | 70     | Calcitonin Salmon                        | 415 |
| Bortezomib                                | 712    | Calcitrene                               | 93  |
| Bosentan                                  | 71     | Calcitriol                               | 93  |
| Bosulif                                   | 72     | Calquence                                | 94  |
| Botox                                     | 73     | Cambia                                   | 95  |
| Braftovi                                  | 74     | Camzyos                                  | 96  |
| Brisdelle                                 | 75     | Caprelsa                                 | 97  |
| Briumvi                                   | 76     | Carac                                    | 98  |
| Briumvi Aet                               | 76     | Carbaglu                                 | 99  |
| Briviact                                  | 77, 78 | Carbinoxamine Maleate                    | 281 |
| Briviact Inj                              | 78     | Carglumic Acid                           | 99  |
| Brixadi                                   | 79     | Carisoprodol                             | 285 |
| Bromfenac Sodium 80                       | 0, 528 | Cayston                                  |     |
| Bromsite Aet                              | 80     | Cellcept                                 | 815 |
| Bronchitol                                | 81     | Cellcept Intravenous                     | 815 |
| Brovana                                   | 82     | Cequa                                    |     |
| Brovana Aet                               | 82     | Cerdelga                                 | 102 |
| Brukinsa                                  | 83     | Cerezyme                                 | 103 |
| Bruselix                                  | 232    | Chantix Aet                              | 104 |
| Budesonide                                | 815    | Chenodal                                 | 105 |
| Bupap                                     | 86     | Chenodal Aet                             | 105 |
| Buphenyl                                  | 509    | Chlordiazepoxide - 65                    | 106 |
| Buprenorphine                             | 84, 85 | Chlordiazepoxide Hcl                     | 106 |
| Buprenorphine Hcl                         | 84     | Chlordiazepoxide Hydrochloride           |     |
| Buprenorphine Patch                       |        | Chlordiazepoxide Hydrochloride/clidinium |     |
| Butalbital Aet                            | 86     | Bromide                                  | 374 |
| Butalbital/acetaminophen                  | 86     | Chlordiazepoxide/amitriptyline           | 266 |
| Butalbital/acetaminophen/caffeine         | 86     | Chlorzoxazone                            |     |
| Butalbital/acetaminophen/caffeine/codeine |        | Cholbam                                  | 107 |
| Butalbital/aspirin/caffeine               |        | Chorionic Gonadotropin                   | 252 |
| Butalbital/aspirin/caffeine/codeine       | 86     | Cibingo                                  |     |
| Butrans                                   |        | Cimerli                                  | 109 |
| Bydureon                                  | 87     | Cimzia                                   | 110 |
| Bydureon Beise                            | 87     | Cimzia Starter Kit                       | 110 |
| Byetta                                    | 88     | Cinqair                                  | 111 |
| Bylvay                                    | 89     | Cinryze                                  | 112 |
| Bylvay (pellets)                          | 89     | Cinvanti                                 | 113 |
| Byooviz                                   |        | Citalopram Cap Aet                       | 114 |
| •   |        | Citalopram Hydrobromide                  |     |
| C   |        | Cladribine                               |     |
| Cablivi                                   | 91     | Claravis                                 |     |
| Cabometyx                                 | 92     |  |     |

| Clemastine Fumarate             | . 282 | Cyclobenzaprine Hydrochloride                 | 285  |
|---------------------------------|-------|---|------|
| Clindamycin Phosphate/tretinoin | . 674 | Cyclobenzaprine Hydrochloride Er              | 285  |
| Clinimix 4.25%/dextrose 10%     | . 815 | Cyclophosphamide                              | 132  |
| Clinimix 4.25%/dextrose 5%      | . 815 | Cyclophosphamide Oral                         | 132  |
| Clinimix 5%/dextrose 15%        | . 815 | Cycloset                                      | 133  |
| Clinimix 5%/dextrose 20%        | . 815 | Cycloset Aet                                  | 133  |
| Clinimix 6/5                    | . 815 | Cyclosporine                                  | 815  |
| Clinimix 8/10                   | . 815 | Cyclosporine Modified                         | 815  |
| Clinimix 8/14                   | . 815 | Cyltezo                                       | 9    |
| Clinimix E 2.75%/dextrose 5%    | . 815 | Cyltezo Starter Package For Crohns Disease/u  | c/hs |
| Clinimix E 4.25%/dextrose 10%   | . 815 |   | 9    |
| Clinimix E 4.25%/dextrose 5%    | . 815 | Cyltezo Starter Package For Psoriasis         | 9    |
| Clinimix E 5%/dextrose 15%      | . 815 | Cyltezo Starter Package For Psoriasis/uveitis |      |
| Clinimix E 5%/dextrose 20%      | . 815 | Cyproheptadine Hcl                            | 274  |
| Clinimix E 8/10                 | . 815 | Cyproheptadine Hydrochloride                  | 274  |
| Clinimix E 8/14                 | . 815 | Cyramza                                       |      |
| Clinisol Sf 15%                 | . 815 | Cystadrops                                    | 136  |
| Clinolipid                      | . 815 | Cystagon                                      | 135  |
| Clobazam                        | . 115 | Cystaran                                      | 136  |
| Clomipramine                    | . 116 | Cytarabine                                    | 815  |
| Clomipramine Hydrochloride      | . 116 | Cytarabine Aqueous                            | 815  |
| Clorazepate                     |       | D   |      |
| Clorazepate Dipotassium         | . 117 |   |      |
| Clozapine Odt                   | . 118 | Dalfampridine                                 |      |
| Cocaine Hydrochloride           | . 253 | Dalfampridine Er                              | 137  |
| Colistimethate Sodium           | . 120 | Dapagliflozin Aet                             |      |
| Columvi                         | . 119 | Dapagliflozin Propanediol                     | 138  |
| Coly-mycin                      | . 120 | Dapagliflozin Propanediol/metformin           |      |
| Coly-mycin M                    | . 120 | Hydrochloride                                 | 139  |
| Cometrig                        |       | Dapagliflozin-metformin Aet                   | 139  |
| Copaxone                        |       | Daraprim                                      | 140  |
| Copiktra                        | . 122 | Darzalex                                      | 141  |
| Cortrophin                      |       | Darzalex Faspro                               | 142  |
| Cosentyx                        |       | Daurismo                                      | 143  |
| Cosentyx Sensoready Pen         |       | Daybue  | 144  |
| Cosentyx Unoready               |       | Deferasirox                                   | 145  |
| Cotellic                        | . 126 | Deferiprone                                   | 217  |
| Crinone                         | . 127 | Deferoxamine Mesylate                         | 815  |
| Cromolyn Sodium                 | . 815 | Deflazacort                                   | 174  |
| Crysvita                        | . 128 | Demerol                                       | 266  |
| Curity Gauze Pads 2             |       | Demser  | 146  |
| Cutaquig                        |       | Depo-medrol                                   | 815  |
| Cuvitru                         |       | Depo-testosterone                             | 658  |
| Cuvrior                         |       | Dermacinrx Lidogel                            |      |
|                                 |       | Desferal                                      | 815  |

| Desipramine Hydrochloride            | 280      | Dronabinol       | 157 |
|--------------------------------------|----------|------------------|-----|
| Desvenlafaxine                       | 147      | Droxidopa        | 446 |
| Desvenlafaxine Er                    | 147      | Duexis           | 158 |
| Dextrose 25%                         | 815      | Duobrii          | 159 |
| Dextrose 50%                         | 815      | Duopa            | 816 |
| Dextrose 70%                         | 815      | Dupixent         | 160 |
| Dhe Nasal                            | 148      | Duramorph        | 816 |
| Diacomit                             | 149      | Durysta          | 162 |
| Diazepam                             | 150      | Duvyzat          | 163 |
| Diazepam Aet                         | 150      | Dyclopro         | 164 |
| Diazepam Intensol                    | 150      | Dysport          | 165 |
| Dichlorphenamide                     | 348      | E                |     |
| Diclofenac 2% Sol                    | 151      |                  |     |
| Diclofenac 3% Gel                    | 152      | Edaravone        |     |
| Diclofenac Epolamine                 | 225      | Edluar           | 270 |
| Diclofenac Potassium                 |          | Efudex           |     |
| Diclofenac Sodium                    | 151, 152 | Egrifta          | 167 |
| Dicyclomine Hcl                      | 266      | Egrifta Sv       |     |
| Dicyclomine Hydrochloride            |          | Elaprase         | 168 |
| Differin                             |          | Elelyso          | 169 |
| Dihydroergotamine Mesylate           |          | Elfabrio         | 170 |
| Dilaudid                             |          | Eligard          | 171 |
| Dimethyl Fumarate                    | 153      | Elrexfio         | 172 |
| Dimethyl Fumarate Aet                |          | Elyxyb           | 173 |
| Dimethyl Fumarate Starterpack        |          | Emend            | 816 |
| Diphenhydramine Hcl                  |          | Emend Tripack    | 816 |
| Dipyridamole                         |          | Emflaza          | 174 |
| Disopyramide Phosphate               |          | Emgality         | 175 |
| Dobutamine Hcl                       |          | Empaveli         | 176 |
| Dobutamine Hcl/d5w                   | 815      | Empliciti        | 177 |
| Dobutamine Hydrochloride/dextrose 5% | 815      | Emsam            | 178 |
| Dojolvi                              |          | Enbrel           | 200 |
| Dopamine Hydrochloride               | 815      | Enbrel Mini      | 200 |
| Dopamine Hydrochloride/dextrose      | 815      | Enbrel Sureclick | 200 |
| Dopamine/d5w                         |          | Endari           | 179 |
| Doptelet                             | 155      | Engerix-b        | 816 |
| Doptelet Aet                         | 155      | Enhertu          | 180 |
| Doxepin Hcl                          | 275      | Enjaymo          | 181 |
| Doxepin Hydrochloride                | 275, 672 | Enspryng         | 182 |
| Doxorubicin Hel                      |          | Enstilar         | 93  |
| Doxorubicin Hydrochloride            |          | Entadfi          |     |
| Doxycycline                          |          | Entyvio          | 184 |
| Drizalma                             |          | Envarsus Xr      | 816 |
| Drizalma Sprinkle                    |          | Eohilia          | 185 |
| •                                    |          | Epclusa          | 186 |

| Epidiolex                    | 187 | Fasenra                                | 214      |
|------------------------------|-----|--|----------|
| Epiduo                       | 11  | Fasenra Pen                            | 214      |
| Epiduo Forte                 | 11  | Fensolvi                               | 215      |
| Epkinly                      | 188 | Fentanyl                               | 216      |
| Еро                          | 189 | Fentanyl Citrate                       | 483, 816 |
| Epogen                       | 190 | Fentanyl Citrate Oral Transmucosal     | 483      |
| Epogen Aet                   | 190 | Fentanyl Patch                         | 216      |
| Epoprostenol Sodium          | 816 | Fentora                                | 483      |
| Eprontia                     | 191 | Ferriprox                              | 217      |
| Epsolay                      | 192 | Ferriprox Twice-a-day                  | 217      |
| Eraxis                       | 193 | Fetzima                                | 218      |
| Eraxis Aet                   | 193 | Fetzima Titration Pack                 | 218      |
| Erbitux                      | 194 | Fexmid                                 | 285      |
| Ergoloid Mesylates           | 266 | Fiasp Pumpcart                         | 816      |
| Ergotamine                   | 195 | Filgrastim                             | 219      |
| Ergotamine Tartrate/caffeine | 195 | Filspari                               | 220      |
| Eribulin Mesylate            |     | Filsuvez                               | 221      |
| Erivedge                     | 196 | Fingolimod Hydrochloride               | 246      |
| Erleada                      | 197 | Fintepla                               |          |
| Erlotinib                    | 198 | Fioricet                               | 86       |
| Erlotinib Hydrochloride      | 198 | Fioricet/codeine                       | 86       |
| Esbriet                      | 199 | Firazyr                                | 293      |
| Esgic                        | 86  | Firdapse                               |          |
| Estazolam                    | 289 | Firmagon                               |          |
| Eszopiclone                  | 270 | Flebogamma Dif                         |          |
| Etanercept                   |     | Flector                                |          |
| Evenity                      |     | Flector Aet                            | 225      |
| Evenity Aet                  |     | Fleqsuvy                               | 226      |
| Everolimus                   |     | Flolan                                 |          |
| Evkeeza                      |     | Flucytosine                            |          |
| Evrysdi                      | 205 | Fluorouracil                           |          |
| Exjade                       |     | Fluticasone Furoate And Vilanterol Aet | -        |
| Exkivity                     |     | Fluticasone Furoate/vilanterol Ellipta |          |
| Exondys 51                   |     | Fluticasone Propionate Diskus          |          |
| Extavia                      |     | Fluticasone Propionate Hfa             |          |
| Extavia Aet                  |     | Fluticasone Propionate Hfa Aet         |          |
| Eylea                        |     | Form Alt Pa Analgesics                 |          |
| Eylea Hd                     |     | Form Alt Pa Metformin                  |          |
| •                            |     | Form Alt Pa Topical                    |          |
| F                            |     | Form Alt Pa Topical Steroids           |          |
| Fabhalta                     | 211 | Form Alt Pa Valsartan Sol              |          |
| Fabrazyme                    | 212 | Formoterol Fumarate                    |          |
| Fanapt                       | 213 | Forteo                                 |          |
| Fanapt Titration Pack        | 213 | Foscarnet Sodium                       |          |
| Fareston                     | 675 |  |          |

| Foscavir                               | 7 Granix                             | 254 |
|--|--------------------------------------|-----|
| Fotivda23                              | 8 Grastek                            | 255 |
| Fruzaqla23                             | 9 Growth Hormone                     | 256 |
| Fulphila43                             | 7 Guanfacine Hydrochloride           | 266 |
| Fyarro                                 | 0 Guanfacine Hydrochloride Er        | 266 |
| Fycompa24                              | .1 <b>H</b>                          |     |
| Fylnetra43                             | 7                                    |     |
| G                                      | Hadlima                              |     |
|  | Hadlima Pushtouch                    |     |
| Gablofen                               | $\varepsilon$                        |     |
| Galafold24                             |                                      |     |
| Gamastan                               |                                      |     |
| Gammagard Liquid                       |                                      |     |
| Gammagard S/d Iga Less Than 1mcg/m1 32 | _                                    |     |
| Gammaked                               |                                      |     |
| Gammaplex                              | 1                                    |     |
| Gamunex-c 32                           | 1                                    |     |
| Ganciclovir81                          | 1 2                                  |     |
| Gattex24                               | 3 Herzuma                            | 262 |
| Gavreto                                | 4 Hetlioz                            | 264 |
| Gazyva24                               | 1                                    |     |
| Gefitinib                              | High Risk Medication - 65            | 266 |
| Gengraf81                              | 6 Hizentra                           | 268 |
| Genotropin25                           | 6 Hrm - Anticonvulsants - 65         | 269 |
| Genotropin Miniquick25                 | 6 Hrm - Hypnotics - 65               | 270 |
| Gilenya                                | 6 Hrm - Scopolamine - 65             | 272 |
| Gilotrif24                             | 7 Hrm-antiparkinson - 65             | 273 |
| Gimoti                                 | 8 Hrm-cyproheptadine - 65            | 274 |
| Givlaari24                             | .9 Hrm-doxepin - 65                  | 275 |
| Glassia                                | 6 Hrm-hydroxyzine - 65               | 276 |
| Glatiramer25                           | 0 Hrm-hydroxyzine Inj - 65           | 278 |
| Glatiramer Acetate                     | 0 Hrm-promethazine - 65              | 279 |
| Glatopa                                | Hrms - Antidepressants               | 280 |
| Gleevec 30                             |                                      |     |
| Gloperba25                             | 1 Hrms - Clemastine- 65              | 282 |
| Gloperba Aet25                         | 1 Hrms - Diabetes Agents             | 283 |
| Glumetza41                             | 3 Hrms - Tcas                        | 284 |
| Glyburide28                            | 3 Hrm-skeletal Muscle Relaxants - 65 | 285 |
| Glyburide Micronized                   | 3 Hulio                              | 9   |
| Glyburide/metformin Hydrochloride      |                                      | 450 |
| Glydo67                                |                                      | 286 |
| Gonadotropin25                         |                                      | 286 |
| Goprelto                               |                                      |     |
| Goprelto-numbrino                      |                                      | 286 |
| Granisetron Hydrochloride              | -                                    |     |
|  |                                      |     |

| Humulin R U-500 (concentrated)816               | Imipramine Hcl                        | 280 |
|---|---------------------------------------|-----|
| Hydrocodone Bitartrate Er                       | Imipramine Hydrochloride              | 280 |
| Hydromorphone Hcl816                            | Imipramine Pamoate                    | 280 |
| Hydromorphone Hcl Er321                         | Imjudo                                | 306 |
| Hydromorphone Hydrochloride                     | Imlygic                               | 307 |
| Hydromorphone Hydrochloride Er                  | Imovax Rabies (h.d.c.v.)              | 816 |
| Hydroxym  | Impavido                              |     |
| Hydroxyzine Hcl276, 278                         | Imuran                                | 816 |
| Hydroxyzine Hydrochloride276, 278               | Imvexxy                               | 309 |
| Hydroxyzine Pamoate                             | Imvexxy Maintenance Pack              | 309 |
| Hyftor288                                       | Imvexxy Starter Pack                  | 309 |
| Hyoscyamine Sulfate                             | Inbrija                               |     |
| Hyoscyamine Sulfate Odt                         | Increlex                              |     |
| Hypnotic-benzodiazepines - 65                   | Indocin                               | 266 |
| Hygvia  | Indomethacin                          | 266 |
| Hyrimoz9  | Indomethacin Er                       | 266 |
| Hyrimoz Crohn's Disease And Ulcerative Colitis  | Inflectra                             | 312 |
| Starter Pack                                    | Infliximab                            |     |
| Hyrimoz Pediatric Crohns Disease Starter Pack 9 | Infumorph 200                         | 816 |
| Hyrimoz Pediatric Crohn'sdisease Starter Pack 9 | Infumorph 500                         |     |
| Hyrimoz Plaque Psoriasis/uveitis Starter Pack 9 | Ingrezza                              |     |
| Hysingla Er                                     | Inlyta                                |     |
| , ,   | Inpefa                                |     |
| I   | Inqovi                                |     |
| Ibrance   | Inrebic                               |     |
| Ibsrela   | Insulin Supplies                      |     |
| Ibsrela Aet                                     | Intralipid                            |     |
| Ibuprofen/famotidine                            | Intrarosa                             |     |
| Icatibant                                       |                                       | 266 |
| Icatibant Acetate                               | Ipratropium Bromide                   |     |
| Iclusig   | Ipratropium Bromide/albuterol Sulfate |     |
| Idacio295                                       | Iqirvo                                |     |
| Idacio (2 Pen)                                  | Ir Before Er                          |     |
| Idacio (2 Syringe)295                           | Iressa                                |     |
| Idacio Starter Package For Crohns Disease 295   | Isolyte-s                             |     |
| Idacio Starter Package For Plaque Psoriasis 295 | Isolyte-s Ph 7.4                      |     |
| Idhifa297                                       | Isotretinoin                          |     |
| Igalmi  | Isturisa                              |     |
| Ilaris  | Itraconazole                          |     |
| Ilumya300                                       | Ivermectin                            |     |
| Imatinib  | Ivermectin Tab                        |     |
| Imatinib Mesylate301                            | Ivig                                  |     |
| Imbruvica                                       | Iwilfin                               |     |
| Imdelltra                                       | Ixempra                               |     |
| Imfinzi 305                                     | 170111p1a                             | 331 |

| Ixempra Kit             | Krazati                   | 358 |
|-------------------------|---------------------------|-----|
| Izervay                 | Krintafel                 | 359 |
| J                       | Kristalose                | 360 |
|                         | Krystexxa                 | 361 |
| Jadenu 14               | Kuvaii                    | 587 |
| Jadenu Sprinkle         | 1 <b>L</b> y profits      | 362 |
| Jakafi                  | 33 <b>L</b>               |     |
| Jatenzo33               | 34 <b>L</b>               |     |
| Javygtor58              | Lactulose                 | 360 |
| Jaypirca33              | Lagevrio                  | 363 |
| Jemperli                | Lagevrio Aet              | 363 |
| Jevtana33               | Zampit                    | 364 |
| Joenja33                | Lamzede                   | 365 |
| Jublia                  | 9 Lanreotide Acetate      | 610 |
| Jublia Aet              | 9 Lapatinib               | 366 |
| Juxtapid34              | Lapatinib Ditosylate      | 366 |
| Jynarque                |                           |     |
| Jynneos                 | _                         |     |
| K                       | Lemtrada                  |     |
| Λ                       | Lemtrada Aet              | 368 |
| Kabiven                 | 6 Lenalidomide            | 560 |
| Kalbitor                | Lenvima                   | 369 |
| Kalydeco34              | Lenvima 10 Mg Daily Dose  | 369 |
| Kanjinti                | Lenvima 12mg Daily Dose   |     |
| Kanuma                  |                           |     |
| Kerydin34               |                           |     |
| Kerydin Aet             | Lenvima 20 Mg Daily Dose  |     |
| Kesimpta34              |                           |     |
| Ketoconazole34          |                           |     |
| Ketorolac Tromethamine  | Lenvima 8 Mg Daily Dose   |     |
| Keveyis34               |                           |     |
| Kevzara34               |                           |     |
| Keytruda35              |                           |     |
| Khapzory 81             |                           |     |
| Kimmtrak                |                           |     |
| Kineret                 |                           |     |
| Kisqali                 |                           |     |
| Kisqali Femara 200 Dose |                           |     |
| Kisqali Femara 400 Dose | Ectaloutelol Hydroemeriae |     |
| Kisqali Femara 600 Dose | Le voiii                  |     |
| Kitabis Pak             | Levilli 31                |     |
| Klisyri                 | L-giutaiiiiic             |     |
| Konvomep                | Liber vant                |     |
| Korlym                  | Liorax                    |     |
| Koselugo                | Liotayo                   |     |
|                         | L10a1 t                   |     |

| Licart Aet                                      | 6 Lupron-prostate Ca                      | 398 |
|---|---|-----|
| Lidocaine                                       | 3 Lybalvi                                 | 399 |
| Lidocaine Hcl673                                | 3 Lynparza                                | 400 |
| Lidocaine Hydrochloride673                      | 3 Lyrica                                  | 522 |
| Lidocaine Patches                               | 7 Lyrica Cr                               | 401 |
| Lidocan   | 7 Lytgobi                                 | 402 |
| Lidoderm  | 7 Lyvispah                                | 403 |
| Lidorex 673                                     | M   |     |
| Lidotral232                                     | 2   |     |
| Lidotral Hc378                                  |   |     |
| Lidotral/hydrocortisone W/peptides & Arnica 378 | 8 Marinol                                 |     |
| Linezolid379                                    |   |     |
| Liqrev 380                                      |   |     |
| Liraglutide 72 <sup>2</sup>                     |   |     |
| Litfulo383                                      |   |     |
| Livmarli382                                     |   |     |
| Livtencity                                      | Mayzent Starter Pack                      |     |
| Lodoco  | N.C. 1 1                                  | 816 |
| Lofena  | Mekinist                                  | 408 |
| Lofexidine Hydrochloride                        | N. C. 1.                                  | 409 |
| Lonsurf385                                      | 3.6                                       | 410 |
| Logtorzi  | NA A TI 1 TE A A D 1                      | 410 |
| Lorbrena  | NA 41 TT 1 11 11                          | 410 |
| Loreev Xr                                       | 3.6 II 1 11 11 D                          | 410 |
| Lotronex25                                      | N.  | 266 |
| Lovaza469                                       | ) / 1                                     | 266 |
| Lubiprostone                                    | M   | 411 |
| Lucemyra389                                     | 3.6                                       | 411 |
| Lucentis  | 3.6                                       | 412 |
| Lumakras39                                      | Mataralana                                | 285 |
| Lumizyme392                                     | M (C : E                                  | 413 |
| Lumryz  | NA 40 ' II 1 11 '1                        | 231 |
| Lunesta   | NA 40 ' II 1 11 '1 E                      | 413 |
| Lunsumio394                                     | N.C. (1 1 TT 1                            | 321 |
| Lupkynis395                                     | M-41- 1 II11111-                          | 321 |
| Lupron Depot (1-month)397, 398                  | 3.6.4.1                                   | 321 |
| Lupron Depot (3-month)                          | 36.1.1.0.0                                | 321 |
| Lupron Depot (4-month)                          | N. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. | 414 |
| Lupron Depot (6-month)                          | N 4 1 1 1                                 | 285 |
| Lupron Depot-ped (1-month)390                   | M-41                                      | 266 |
| Lupron Depot-ped (3-month)                      | N   | 816 |
| Lupron Depot-ped (6-month)390                   | 36.1.1.1.1                                | 816 |
| Lupron Ped                                      |   | 816 |
| Lupron-endometriosis                            | M 4 1 1 1 1 C 1 1 1 4                     | 816 |
| 1   | Methyltestosterone                        | 414 |

| Metyrosine                                   | 146 | Naproxen                        | 433        |
|--|-----|---------------------------------|------------|
| Miacalcin                                    | 415 | Naproxen Suspension             | 433        |
| Miacalcin Aet                                | 415 | Naproxen/esomeprazole Magnesium | 434        |
| Miconazole Nitrate/zinc Oxide/white Petrolat | tum | Naproxen-esomeprazole           | 434        |
|  | 416 | Natesto                         | 657        |
| Mico-zn-petr Oint                            | 416 | Nayzilam                        | 435        |
| Mifepristone                                 | 356 | Nebupent                        | 816        |
| Migergot                                     | 195 | Neoral                          | 816        |
| Miglustat                                    | 417 | Nerlynx                         | 436        |
| Migranal                                     | 148 | Neulasta                        | 437        |
| Milrinone Lactate                            | 816 | Neulasta Onpro Kit              | 437        |
| Milrinone Lactate In Dextrose                | 816 | Neupogen                        |            |
| Mitigo                                       | 816 | Nexavar                         | 439        |
| Modafinil                                    | 418 | Nexium I.v.                     | 440        |
| Monjuvi                                      | 419 | Nexium IV                       | 440        |
| Morphine Sulfate                             | 816 | Nexviazyme                      | 441        |
| Morphine Sulfate Er                          | 321 | Ngenla                          | 442        |
| Morphine Sulfate/sodium Chloride             | 816 | Ngenla Aet                      | 442        |
| Motegrity                                    | 420 | Nifedipine                      | 266        |
| Motegrity Aet                                | 420 | Ninlaro                         | 443        |
| Motpoly Xr                                   | 421 | Nitisinone                      | 444        |
| Mounjaro                                     | 422 | Nityr                           | 445        |
| Mozobil                                      | 423 | Nivestym                        | 219        |
| Ms Contin                                    | 321 | Norditropin Flexpro             | 450        |
| Mulpleta                                     | 424 | Norgesic                        | 285        |
| Mvasi  | 425 | Norgesic Forte                  | 285        |
| Myalept                                      | 426 | Norpace                         | 266        |
| Mycapssa                                     | 427 | Norpramin                       | 280        |
| Mycophenolate Mofetil                        | 816 | Northera                        | 446        |
| Mycophenolic Acid Dr                         | 816 | Nourianz                        | 447        |
| Mycozyl Hc                                   | 232 | Nourianz Aet                    | 447        |
| Myfembree                                    | 428 | Novarel                         | 252        |
| Myfortic                                     | 816 | Noxafil448,                     | , 449, 519 |
| Myhibbin                                     | 816 | Noxafil Powder                  | 448        |
| Mylotarg                                     | 429 | Noxafil Susp                    | 449        |
| Myobloc                                      | 430 | Np Growth Hormone               | 450        |
| Mytesi                                       | 431 | Nplate                          | 451        |
| Mytesi Aet                                   | 431 | Nubeqa                          | 452        |
| N  |     | Nucala                          | 453        |
|  |     | Nucynta Er                      | 321        |
| Naglazyme                                    |     | Nuedexta                        | 455        |
| Namenda                                      |     | Nulev                           | 266        |
| Namenda Titration Pak                        |     | Nulibry                         | 456        |
| Namenda Xr                                   | 410 | Nulojix                         |            |
| Naprosyn                                     | 433 | -                               |            |

| Nuplazid                  | 457 | Oracea                                | 481 |
|---------------------------|-----|---------------------------------------|-----|
| Nurtec                    | 458 | Oracea Aet                            | 481 |
| Nutrilipid                | 816 | Oralair                               | 482 |
| Nutropin Aq Nuspin 10     | 450 | Oral-intranasal Fentanyl              | 483 |
| Nutropin Aq Nuspin 20     | 450 | Orapred Odt                           |     |
| Nutropin Aq Nuspin 5      |     | Orencia                               | 484 |
| Nuvigil                   |     | Orencia Clickject                     | 484 |
| Nyvepria                  | 437 | Orenitram                             |     |
| 0                         |     | Orenitram Titration Kit Month 1       | 485 |
| O                         |     | Orenitram Titration Kit Month 2       | 485 |
| Ocaliva                   | 459 | Orenitram Titration Kit Month 3       | 485 |
| Ocrevus                   |     | Orfadin                               | 444 |
| Octagam                   | 328 | Orgovyx                               | 486 |
| Octreotide                | 461 | Oriahnn                               |     |
| Octreotide Acetate        | 461 | Orilissa                              | 488 |
| Odactra                   | 462 | Orkambi                               | 489 |
| Odomzo                    | 463 | Orladeyo                              | 490 |
| Ofev                      | 464 | Ormalvi                               |     |
| Ogivri                    | 262 | Orphenadrine Citrate                  |     |
| Ogsiveo                   | 465 | Orphenadrine Citrate Er               |     |
| Ojemda                    | 466 | Orphenadrine/aspirin/caffeine         |     |
| Ojjaara                   | 467 | Orphengesic Forte                     |     |
| Olpruva                   | 509 | Orserdu                               |     |
| Olumiant                  | 468 | Oscimin                               |     |
| Omega-3                   | 469 | Osphena                               |     |
| Omega-3-acid Ethyl Esters | 469 | Otezla                                |     |
| Omegaven                  | 816 | Oxazepam                              |     |
| Omnitrope                 | 450 | Oxazepam - 65                         |     |
| Omvoh                     | 470 | Oxbryta                               |     |
| Oncaspar                  | 471 | Oxervate                              |     |
| Ondansetron Hcl           | 816 | Oxlumo                                |     |
| Ondansetron Hydrochloride | 816 | Oxtellar Xr                           |     |
| Ondansetron Odt           | 817 | Oxycodone And Acetaminophen           |     |
| Onfi                      | 115 | Oxycodone Hcl Er                      |     |
| Ongentys                  | 472 | Oxycodone Hydrochloride Er            |     |
| Ongentys Aet              | 472 | Oxycodone Hydrochloride/acetaminophen |     |
| Onivyde                   | 473 | Oxycodone/acetaminophen               |     |
| Ontruzant                 | 262 | Oxycontin                             |     |
| Onureg                    | 474 | Oxycontin Aet                         |     |
| Opdivo                    |     | Oxymorphone Hydrochloride Er          |     |
| Opdualag                  |     | Oxymorphone Hydrochlorideer           |     |
| Opfolda                   |     | Ozempic                               |     |
| Opsumit                   |     | Ozobax Ds                             |     |
| Opsynvi                   |     | O2000A D3                             | 3   |
| Onzelura                  | 480 |                                       |     |

| P                                 | Piqray 300mg Daily Dose512                |
|-----------------------------------|---|
| Padcev 50                         | Pirfenidone199                            |
| Palforzia 50                      | Dlaquidy 512                              |
| Palforzia Initial Dose Escalation | Dlaggidy A at 512                         |
| Palforzia Level 1                 | Dlagridy Starter Dack 513                 |
| Palforzia Level 10                | D1  |
| Palforzia Level 11 (maintenance)  | Pleriva for A22                           |
| Palforzia Level 11 (titration)    | Dligglic 673                              |
| Palforzia Level 2                 | Doling 514                                |
| Palforzia Level 3                 | Domalyst 515                              |
| Palforzia Level 4                 | Domahiliti 516                            |
| Palforzia Level 5                 | Donyony 517                               |
| Palforzia Level 6                 | Panyary 14 day Starter Pools 517          |
| Palforzia Level 7                 | Danisary A at 517                         |
| Palforzia Level 8                 | Dortro 770 519                            |
|                                   | Possoonezolo 440 510                      |
| Palforzia Level 9                 | Doggoonezolo Dr. 510                      |
| Palynziq                          | Poteligeo 520                             |
| Palynziq Aet                      | Draluent 501                              |
| Panretin                          | T Produicolona 917                        |
| Panzyga                           | Dradnicalana Sadium Phaenhata 917         |
| Paroxetine 7.                     | Duadwigalama Cadiyum Dhaamhata Odt 917    |
| Part B Versus Part D              | Dradnicana 917                            |
| Pazopanib Hydrochloride           | Dradnicana Intencal 917                   |
| Pediapred81                       | Progabalin 522                            |
| Pegasys50                         | Dragabalin Er 401                         |
| Pemazyre 50                       | Drognyl W/dilyont Dongyl Alcohol/nool 252 |
| Pennsaid                          | Drohovbrio 917                            |
| Pentamidine Isethionate           | 1   |
| Pentazocine/naloxone Hcl          | 6 Premasol                                |
| Perforomist                       | 7 Pretomanid                              |
| Perforomist Aet                   | Pretomanid Aet                            |
| Perikabiven81                     | 7 Prevymis                                |
| Perjeta50                         | 8 Prialt                                  |
| Perphenazine/amitriptyline        | Privigen 328                              |
| Pheburane                         |   |
| Phenergan                         | Procrit                                   |
| Phenobarbital26                   | Procysbi                                  |
| Phenobarbital Sodium              | Prograf                                   |
| Phenylbutyrate50                  | Prolastin-c26                             |
| Phesgo                            | 9 Prolate527                              |
| Piasky51                          | Prolate Aet527                            |
| Piqray                            | Prolensa Aet528                           |
| Piqray 200mg Daily Dose           | Promacta529                               |
| Piqray 250mg Daily Dose           | Promocto Act 520                          |

| Promethazine Hcl                   | Recarbrio                 | 34/      |
|------------------------------------|---------------------------|----------|
| Promethazine Hydrochloride279      | Recombivax Hb             | 817      |
| Promethazine Hydrochloride Plain   | Recorlev                  | 548      |
| Promethazine Vc                    | Regranex                  | 549      |
| Promethegan                        | Releuko                   | 550      |
| Prosol                             | Relistor                  | 551, 552 |
| Protriptyline Hcl                  | Relistor Inj              | 551      |
| Provigil                           | Relistor Tab              | 552      |
| Prudoxin                           | Reltone                   | 553      |
| Pulmicort                          | Relyvrio                  | 554      |
| Pulmozyme530                       | Remicade                  | 555      |
| Pyrimethamine                      | Remodulin                 | 680      |
| Pyrukynd 531                       | Renflexis                 | 556      |
| Pyrukynd Taper Pack531             | Repatha                   | 557      |
|                                    | Repatha Pushtronex System | 557      |
| $\varrho$                          | Repatha Sureclick         | 557      |
| Qbrexza                            | Restoril                  |          |
| Qdolo                              | Retacrit                  | 189      |
| Qelbree                            | Retevmo                   | 558      |
| Qinlock                            | Retin-a                   | 674      |
| Qualaquin                          | Retin-a Micro             | 674      |
| Quetiapine Fumarate Er 535         | Retin-a Micro Pump        | 674      |
| Quetiapine Xr 535                  | Revatio                   |          |
| Quinine Sulfate                    | Revcovi                   | 559      |
| Qulipta                            | Revlimid                  |          |
| Qutenza                            | Reyvow                    |          |
| Quzyttir                           | Rezdiffra                 |          |
| R                                  | Rezlidhia                 |          |
| Rabayert817                        | Rezurock                  | 564      |
| Radicava 541                       | Rezzayo                   | 565      |
| Radicava Ors 541                   | Riabni                    | 566      |
| Radicava Ors Starter Kit           | Rinvoq                    | 567      |
| Ragwitek                           | Rinvoq Lq                 | 568      |
|                                    | Rituxan                   | 569      |
| Rapamune                           | Rituxan Hycela            | 570      |
| Ravicti Aet                        | Rivfloza                  | 571      |
|                                    | Robaxin                   | 285      |
| Rayos 817                          | Rolvedon                  | 572      |
| Rebif S44                          | Rozlytrek                 | 573      |
| Rebif Open 544  Rebif Pohidosa 544 | Rubraca                   | 574      |
| Rebif Rebidose                     | Ruconest                  | 575      |
| Rebif Rebidose Titration Pack      | Rufinamide                | 56       |
| Rebif Titration Pack               | Ruxience                  | 576      |
| Reblozyl                           | Rybelsus                  | 577      |
| Rebyota546                         | •                         |          |

| Rybrevant                   | 578      | Skyrizi Pen                    | 604 |
|-----------------------------|----------|--------------------------------|-----|
| Ryclora                     | 266      | Skytrofa                       | 605 |
| Rydapt                      | 579      | Skytrofa Aet                   | 605 |
| Rylaze                      | 580      | Smoflipid                      | 817 |
| Ryplazim                    | 581      | Sodium Oxybate                 | 779 |
| Rystiggo                    | 582      | Sodium Phenylbutyrate          | 509 |
| Rytelo                      | 583      | Sofosbuvir And Velpatasvir Aet |     |
| Ryvent                      | 281      | Sofosbuvir/velpatasvir         |     |
| S                           |          | Sogroya                        | 607 |
|                             |          | Sogroya Aet                    | 607 |
| Sabril                      |          | Sohonos                        | 608 |
| Sajazir                     |          | Soliris                        | 609 |
| Samsca                      |          | Solu-medrol                    | 817 |
| Sandimmune                  |          | Soma                           | 285 |
| Sandostatin                 |          | Somatuline Depot               | 610 |
| Sandostatin Lar             | 585      | Somavert                       | 611 |
| Sandostatin Lar Depot       | 585      | Sorafenib Tosylate             | 439 |
| Saphnelo                    | 586      | Sorilux                        |     |
| Sapropterin                 | 587      | Sotyktu                        | 612 |
| Sapropterin Dihydrochloride | 587      | Sovaldi                        |     |
| Sarclisa                    | 588      | Sovaldi Aet                    | 613 |
| Savella                     | 589      | Spevigo                        | 614 |
| Savella Titration Pack      | 589      | Sporanox                       |     |
| Scemblix                    | 590      | Sprix                          |     |
| Scopolamine                 | 272      | Sprycel                        |     |
| Seglentis                   | 591      | Stelara                        |     |
| Seroquel Xr                 | 535      | Stimufend                      |     |
| Serostim                    | 592      | Stivarga                       |     |
| Seysara                     | 593      | Strensiq                       |     |
| Signifor                    | 594      | Stromectol                     |     |
| Signifor Lar                | 595      | Sublocade                      |     |
| Siklos                      | 596      | Sunitinib Malate               |     |
| Sildenafil                  | 597, 598 | Sunosi                         |     |
| Sildenafil Citrate          | 597      | Susvimo                        |     |
| Sildenafil Inj              | 598      | Sutent                         |     |
| Siliq                       | 599      | Syfovre                        |     |
| Simlandi 1-pen Kit          | 9        | Sylvant                        |     |
| Simlandi 2-pen Kit          | 9        | Symdeko                        |     |
| Simponi                     | 600      | Symlin                         |     |
| Simponi Aria                | 601      | Symlinpen 120                  |     |
| Simulect                    | 817      | Symlinpen 60                   |     |
| Sirolimus                   | 817      | Sympazan                       |     |
| Sirturo                     |          | Syndros                        |     |
| Skyclarys                   | 603      | Syprine                        |     |
| Skyrizi                     |          | 5, printe                      | 001 |

| T                      |     | Testosterone Aet           | 657      |
|------------------------|-----|----------------------------|----------|
| Tabrecta               | 631 | Testosterone Cypionate Inj | 658      |
| Taclonex               |     | Testosterone Enanthate     | 659      |
| Tacrolimus             |     | Testosterone Enanthate Inj | 659      |
| Tadalafil              |     | Tetrabenazine              | 660      |
| Tadalafil (bph)        | *   | Tetracycline Hydrochlorid  | 661      |
| Tadalafil (pph)        |     | Tetracycline Hydrochloride | 661      |
| <b>u</b> ,             |     | Tetracycline Tab           | 661      |
| Tadliq                 |     | Tezspire                   | 662      |
| Tafinlar               |     | Thalomid                   |          |
| Tagrisso               |     | Thioridazine Hcl           |          |
| Takhzyro               |     | Thymoglobulin              |          |
| Taltz                  |     | Tibsovo                    |          |
| Talvey                 |     | Tigan                      |          |
| Talzenna               |     | Tivdak                     |          |
| Tanlor                 | 285 | Tlando                     |          |
| Tarceva                | 198 | Tobi                       |          |
| Targretin              |     | Tobi Inhaler               |          |
| Targretin Topical      | 640 |                            |          |
| Tarpeyo                | 641 | Tobi Podhaler              |          |
| Tascenso               | 642 | Tobramycin                 |          |
| Tascenso Odt           | 642 | Tofidence                  |          |
| Tasigna                | 643 | Tolak                      |          |
| Tasimelteon            | 264 | Tolsura                    |          |
| Tavaborole             | 345 | Tolvaptan                  |          |
| Tavalisse              | 645 | Topical Doxepin            |          |
| Tavneos                | 646 | Topical Lidocaine          |          |
| Tazarotene             | 647 | Topical Tretinoin          | 674      |
| Tazorac                |     | Toremifene                 | 675      |
| Tazverik               |     | Toremifene Citrate         | 675      |
| Tecentriq              |     | Torpenz                    | 203      |
| Tecfidera              |     | Tpn Electrolytes           | 817      |
| Tecfidera Starter Pack |     | Tracleer                   | 71       |
| Tecvayli               |     | Tramadol Hydrochloride     | 230, 676 |
| Tegsedi                |     | Tramadol Oral Solution     | 676      |
| Temazepam              |     | Transderm-scop             | 272      |
| _                      |     | Travasol                   | 817      |
| Temazepam 30mg - 65    |     | Trazimera                  | 677      |
| Tencon                 |     | Trelstar                   | 678      |
| Tepezza                |     | Trelstar Mixject           |          |
| Tepmetko               |     | Tremfya                    |          |
| Teriflunomide          |     | Treprostinil               |          |
| Teriflunomide Aet      |     | Treprostinil Inj           |          |
| Teriparatide           |     | Tretinoin                  |          |
| Testim                 |     |                            |          |
| Testopel               | 656 | Tretinoin Microsphere      | 0/4      |

| Tretinoin Microsphere Pump      | 674 | V                              |     |
|---------------------------------|-----|--------------------------------|-----|
| Triazolam                       | 289 | Vabomere                       | 703 |
| Tridacaine                      | 377 | Vabysmo                        |     |
| Tridacaine II                   | 377 | Valchlor                       |     |
| Trientine                       | 681 | Valium                         |     |
| Trientine Hydrochloride         | 681 | Valsartan                      |     |
| Trihexyphenidyl Hcl             | 273 | Valtoco                        |     |
| Trihexyphenidyl Hydrochloride   | 273 | Valtoco 10 Mg Dose             |     |
| Trikafta                        | 682 | Valtoco 15 Mg Dose             |     |
| Trimethobenzamide Hydrochloride | 266 | Valtoco 20 Mg Dose             |     |
| Trimipramine Maleate            | 284 | Valtoco 5 Mg Dose              |     |
| Trintellix                      | 683 | Vanflyta                       |     |
| Triptodur                       | 684 | Varenicline Starting Month Box |     |
| Trodelvy                        | 685 | Varenicline Tartrate           |     |
| Trokendi Xr                     | 686 | Varubi                         |     |
| Trophamine                      | 817 | Vecamyl                        |     |
| Trudhesa                        | 148 | Vectibix                       |     |
| Trulicity                       | 687 | Vectical                       |     |
| Truqap                          | 688 | Vegzelma                       |     |
| Truxima                         | 689 | Veklury                        |     |
| Tukysa                          | 690 | Velcade                        |     |
| Turalio                         | 691 | Veletri                        |     |
| Twyneo                          | 674 | Velsipity                      |     |
| Tyenne                          | 692 | Veltin                         |     |
| Tykerb                          | 366 | Venclexta                      |     |
| Tymlos                          | 693 | Venclexta Starting Pack        |     |
| Tysabri                         | 694 | Ventavis                       |     |
| Tyvaso                          | 695 | Veopoz                         |     |
| Tyvaso Dpi                      | 696 | Veozah                         |     |
| Tyvaso Dpi Maintenance Kit      | 696 | Verkazia                       |     |
| Tyvaso Dpi Titration Kit        | 696 | Versacloz                      |     |
| Tyvaso Refill Kit               | 695 | Verzenio                       |     |
| Tyvaso Starter Kit              | 695 | Vevye                          |     |
| Tzield                          | 697 | Vfend                          |     |
| $oldsymbol{U}$                  |     | V fend IV                      |     |
| Ubrelvy                         | 698 | Vibativ                        |     |
| Udenyca                         |     | Vibativ Aet                    |     |
| Udenyca Onbody                  |     | Viberzi                        |     |
| Ultomiris                       |     | Victoza                        |     |
| Uplizna                         | 700 | Victoza Aet                    |     |
| Uptravi                         |     | Vigabatrin                     |     |
| Uptravi Titration Pack          |     | Vigadrone                      |     |
| Ursodiol                        |     | Vigafyde                       |     |
| Uzedy                           | 702 | Vigpoder                       | 725 |

| Vijoice             | Xembify                   | 760      |
|---------------------|---------------------------|----------|
| Viltepso            | Xenazine                  | 660      |
| Vimizim             | Xenpozyme                 | 761      |
| Vimovo              | Xeomin                    | 762      |
| Vinblastine Sulfate | Xermelo                   | 763      |
| Vincristine Sulfate | Xgeva                     | 764      |
| Vistaril            | Xhance                    | 765      |
| Vitrakvi            | Xiaflex                   | 766      |
| Vivjoa731           | Xifaxan                   | 767, 768 |
| Vizimpro            | Xifaxan200                | 768      |
| Vogelxo657          | Xipere                    | 769      |
| Vogelxo Pump657     | Xolair                    | 770      |
| Vonjo733            | Xolremdi                  | 772      |
| Voriconazole        | Xospata                   | 773      |
| Vosevi              | Xphozah                   | 774      |
| Votrient            | Xpovio                    |          |
| Vowst               | Xpovio 60 Mg Twice Weekly |          |
| Voxzogo             | Xpovio 80 Mg Twice Weekly |          |
| Voydeya             | Xtampza Er                |          |
| Vpriv               | Xtandi                    |          |
| Vtama               | Xuriden                   |          |
| Vuity               | Xyosted                   | 778      |
| Vumerity            | Xyosted Aet               |          |
| Vusion416           | Xyrem                     |          |
| Vyepti              | Xywav                     |          |
| Vyjuvek             | ,                         |          |
| Vyndamax            | Y                         |          |
| Vyndagel            | Yargesa                   | 417      |
| Vyondys 53          | Ycanth                    | 781      |
| Vyvgart             | Yervoy                    | 782      |
| Vyvgart Hytrulo750  | Yondelis                  | 783      |
| Vyxeos              | Yonsa                     | 784      |
| •                   | Yuflyma 1-pen Kit         | 9        |
| W                   | Yuflyma 2-syringe Kit     | 9        |
| Wainua              | Yuflyma Cd/uc/hs Starter  | 9        |
| Wakix               | Yupelri                   | 785      |
| Welireg754          | Yupelri Aet               | 785      |
| Winlevi             | Yusimry                   | 9        |
| Winrevair756        | $\boldsymbol{Z}$          |          |
| X                   | Zaleplon                  | 270      |
| Xalkori757          | Zaltrap                   |          |
| Xdemvy              | Zarxio                    |          |
| Xeljanz             | Zavesca                   |          |
| Xeljanz Xr759       | Zavzpret                  |          |
| =                   | <u> -</u>                 |          |

| Zegerid                    | 789, 790 | Zolpidem Tartrate Er | 270      |
|----------------------------|----------|----------------------|----------|
| Zegerid Capsule Aet        | 789      | Zomacton             | 450      |
| Zegerid Suspension Aet     | 790      | Zonalon              | 672      |
| Zejula                     | 791      | Zonisade             | 803      |
| Zelboraf                   | 792      | Zortress             | 817      |
| Zemaira                    | 26       | Zoryve               | 804, 805 |
| Zemdri                     | 793      | Zoryve 0.3% Crm      | 804      |
| Zenatane                   | 324      | Zoryve Foam          | 805      |
| Zepatier                   | 794      | Ztalmy               | 806      |
| Zepatier Aet               | 794      | Ztlido               | 807      |
| Zeposia                    | 795      | Ztlido Aet           | 807      |
| Zeposia 7-day Starter Pack | 795      | Zulresso             | 817      |
| Zeposia Starter Kit        | 795      | Zurzuvae             | 808      |
| Zepzelca                   | 796      | Zydelig              | 809      |
| Ziana                      | 674      | Zykadia              | 810      |
| Ziextenzo                  | 437      | Zymfentra 2-pen      | 811      |
| Zilbrysq                   | 797      | Zymfentra 2-syringe  | 811      |
| Zinplava                   | 798      | Zymfentra Aet        | 811      |
| Zipsor                     | 230      | Zynlonta             | 812      |
| Zirabev                    | 799      | Zynyz                | 813      |
| Zokinvy                    | 800      | Zyprexa Relprevv     | 814      |
| Zolinza                    | 801      | Zytiga               | 3        |
| Zolpidem                   | 802      | Zyvox                | 379      |
| Zolpidem Tartrate          | 270, 802 |                      |          |