**2020 PDP Enhanced Prior Authorization Document**

# Abraxane

## Products Affected

- ABRAXANE

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

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For relapsed or refractory melanoma, individual is using as a single agent and Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 following at least one prior therapy. For persistent or recurrent ovarian cancer (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer) OR Individual is using for the treatment of persistent or recurrent ovarian cancer (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer) in an individual with confirmed taxane (solvent-based paclitaxel or docetaxel) hypersensitivity. For recurrent, metastatic or high-risk uterine/endometrial cancer in individual with confirmed taxane (solvent-based paclitaxel or docetaxel) hypersensitivity OR individual using for treatment of solid tumors where treatment with taxane is medically appropriate and the individual has confirmed taxane (solvent-based paclitaxel or docetaxel) hypersensitivity. For NSCLC, individual has current ECOG performance status of 0-2 OR individual is suing for using for NSCLC with confirmed taxane (solvent-based paclitaxel or docetaxel) hypersensitivity. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Abstral

**Products Affected**

- ABSTRAL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Treatment of acute or postoperative pain OR treatment of migraine headache pain OR treatment of non-cancer related breakthrough pain. |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (provide diagnosis) AND has tried and failed fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking Abstral (fentanyl) for cancer related breakthrough pain. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Actemra

**Products Affected**

- ACTEMRA
- ACTEMRA ACTPEN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Tuberculosis, or invasive fungal infections or other active serious infections, or history if recurrent infections. Individuals who have not had a tuberculin skin test or Center for Disease Control recommended equivalent to evaluate for latent tuberculosis prior to initiating Actemra (tocilizumab). Using Actemra in combination with other TNF antagonists, IL-1R antagonists, janus kinase inhibitor, anti-cd20 monoclonal antibodies or selective co-stimulation modulators. At initiation of therapy, absolute neutrophil count (ANC) below 2000/mm3, platelet count below 100,000/mm3, or ALT or AST above 1.5 times the upper limit of normal. |
| **Required Medical Information** | |
| **Age Restrictions** | individual is 18 years of age or older, except for the diagnosis of JIA, PJIA. For JIA, PJIA patient is 2 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For rheumatoid arthritis (RA), Individual has had an inadequate response to ONE non-biological or biologic disease modifying anti-rheumatic drug (DMARD) such as methotrexate (MTX) or a tumor necrosis factor (TNF) antagonist drug AND individual has had a trial and inadequate response or intolerance to: Humira(adalimumab) OR Enbrel(etanercept). For Systemic Juvenile Idiopathic Arthritis (SJIA), agent is being used to reduce signs/symptoms or induce/maintain clinical response. Individual has failed to respond to, is tolerant of, or has a medical contraindication to ONE corticosteroid or nonsteroidal anti-inflammatory drug (NSAID). For Polyarticular Juvenile Idiopathic Arthritis (PJIA), Individual has had inadequate response to, is intolerant of, or has a medical contraindication to ONE Conventional therapy [non-biologic DMARD (such as methotrexate)] AND individual has had a trial and inadequate response or intolerance to: Humira(adalimumab) OR Enbrel(etanercept). For any of the above indications, if the TNF agent (Enbrel(etanercept)/Humira(adalimumab)) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Actemra (tocilizumab) or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction. For Multicentric Castleman Disease (MCD), agent is being used as a single agent for tx of relapsed/refractory or progressive MCD. Individual is HIV (human immunodeficiency virus) and HHV-8 (human herpes-8) negative. And individual has no concurrent clinically significant infection (for example, Hepatitis B or Hepatitis C) and has no concurrent lymphoma. For Giant Cell Arteritis, agent used in combination with a tapering course of corticosteroids (such as, prednisone) OR being used as a single agent after discontinuing corticosteroids. For chronic Antibody- |
| | mediated renal transplant rejection with the following are met (Choi 2017): mbr has chronic active antibody-mediated rejection plus donor-specific antibodies and transplant glomerulopathy AND has failed to respond to IVIG plus rituximab therapy with or without plasma exchange. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# Actimmune

**Products Affected**

- ACTIMMUNE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Actiq

**Products Affected**

- ACTIQ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Treatment of acute or postoperative pain OR treatment of migraine headache pain OR treatment of non-cancer related breakthrough pain |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 16 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (provide diagnosis) AND has tried and failed fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking Actiq (fentanyl). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Adcetris

**Products Affected**

- ADCETRIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 Year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For diagnosis of Hodgkin lymphoma with either one of the following: For relapsed or refractory disease in a single line of therapy or in combination with bendamustine OR as consolidation therapy after autologous stem cell transplant for ind at high risk of relapse or progression with any of the following: a) Primary refractory Hodgkin lymphoma or b) Relapsed Hodgkin lymphoma with an initial remission duration of less than 12 months or c) Extranodal involvement at the start of pre-transplantation salvage chemotherapy OR as maintenance therapy for 1 yr following high dose therapy and autologous stem cell rescue for relapsed or refractory dx those who are brentuximab vedotin naive and have Deauville score less than 5. For CD30+ non-Hodgkins Lymphoma with either one of the following: cutaneous anaplastic large cell lymphoma OR cutaneous T-cell lymphoma, including mycosis fungoides/Sezary syndrome which is relapsed, refractory or as first line therapy for advanced disease presentation (for example, follicultropic, large cell transformation or extracutaneous disease) OR previously untreated peripheral T-cell lymphoma in combination with cyclophosphamide, doxorubicin and prednisone OR relapsed or refractory disease after at least one prior multi-agent chemotherapy regimen for treatment of ANY if the following: a) systemic anaplastic large cell lymphoma b) T-cell lymphoma (excluding cutaneous T-cell lymphoma) c) Lymphomatoid papulosis that is symptomatic or characterized by extensive cutaneous lesions OR As a single-agent for adult T-cell leukemia/lymphoma after high dose therapy and autologous stem cell rescue OR Adjuvant systemic therapy for breast implant-associated anaplastic large cell lymphoma for either of the following: a) residual, localized disease (confined to capsule/implant/breast) following partial excision or capsuletomy OR b) extended disease (stage II-IV). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Adcirca

**Products Affected**

- ADCIRCA
- ALYQ
- *tadalafil (pah)*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use in combination with phosphodiesterase-5 (PDE5) inhibitors [such as but not limited to, Cialis (tadalafil)] or use in combination with organic nitrates [such as but not limited to, isosorbide mono/dinitrate or nitroglycerin] or guanylate cyclase stimulators [such as but not limited to, Adempas (riociguat)]. For the treatment of benign prostatic hypertension or erectile dysfunction. Diagnosis of severe hepatic impairment (Child-Pugh Class C), pulmonary veno-occlusive disease (PVOD), severe renal impairment (creatinine clearance less than or equal to 30 mL/min) or on dialysis. Individual has a known degenerative retinal disorder (such as but not limited to, retinitis pigmentosa). |
| **Required Medical Information** | Catheterization-proven diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has WHO functional class II- IV symptoms. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Addyi

**Products Affected**

- ADDYI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use in individuals who cannot abstain from alcohol use. Treatment of HSDD in postmenopausal women OR men. Use for enhancement of sexual performance. Use in individuals with hepatic impairment OR utilizing moderate (such as but not limited to atazanavir, ciprofloxacin, diltiazem, erythromycin, fluconazole, fosamprenavir, verapamil, grapefruit juice) or strong CYP3A4 inhibitors (examples include, but not limited to ketoconazole, itraconazole, posaconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, boceprevir, telaprevir, telithromycin, conivaptan) OR concomitant use with CYP3A4 inducers (such as but not limited to, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, St. John's Wort). |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years old |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Individual has Acquired, Generalized Hypoactive Sexual Desire Disorder (HSDD)/Acquired Female Sexual Interest Arousal Disorder (FSIAD) for at least 24 weeks characterized by low sexual desire that causes marked distress or interpersonal difficulty AND it is confirmed that the diagnosis of HSDD/FSIAD is not caused by any of the following: i) A co-existing psychiatric condition, OR ii) A co-existing medical condition that could contribute to sexual dysfunction, OR iii) Problems within a relationship, OR iv) Major life stressor (such as, loss of income, death of a family member), OR v) Effects of a medication or other drug substance. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Adempas

**Products Affected**

- ADEMPAS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use in combination with nitrates (such as but not limited to, nitroglycerin) or nitric oxide donors (such as but not limited to, amyl nitrite) in any form OR Use in combination with phosphodiesterase (PDE) inhibitors [such as, PDE-5 inhibitors (sildenafil, tadalafil, vardenafil) or nonspecific PDE inhibitors (dipyridamole, theophylline)]. Individual has a diagnosis of severe hepatic impairment (Child-Pugh class C). Individual is on dialysis or has creatinine clearance less than 15 ml/min. Individual has a diagnosis of pulmonary veno-occlusive disease (PVOD), or pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP). |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Individual has catheterization-proven diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 AND has WHO functional class II-IV symptoms. Or individual has catheterization-proven diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4 AND Individual has WHO functional class II-IV symptoms AND using for one of the following: Persistent or recurrent pulmonary hypertension after at least 180 days following surgical treatment with pulmonary endarterectomey OR Inoperable (via pulmonary endarterectomey) CTEPH. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# AFINITOR

**Products Affected**

- AFINITOR
- AFINITOR DISPERZ
- *everolimus oral tablet 2.5 mg, 5 mg, 7.5 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Afrezza

**Products Affected**

- AFREZZA INHALATION POWDER 12 UNIT, 4 & 8 & 12 UNIT, 4 UNIT, 8 UNIT, 90 X 4 UNIT & 90X8 UNIT, 90 X 8 UNIT & 90X12 UNIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individuals with a diagnosis of chronic lung disease, such as asthma or chronic obstructive pulmonary disease. Individuals who smoke cigarettes or who recently (within 6 months) quit smoking. Using as a treatment for diabetic ketoacidosis. |
| **Required Medical Information** | Individual has had a physical examination including detailed medical history to identify potential lung disease. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a diagnosis of diabetes mellitus and using for one of the following: 1. For type 1 diabetes, individual will be using concurrently with long-acting insulin. OR 2. For type 2 diabetes, individual has inadequate control, intolerance, or contraindication to at least 2 oral anti-diabetic medications. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ajovy

**Products Affected**

- AJOVY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial: 3 months, Maintenance: 1 Year |
| **Other Criteria** | For Initial requests: (I) Individual has a diagnosis of one of the following: (a) Episodic migraine defined as at least 4 and fewer than 15 migraine days per month and fewer than 15 headache days per month on average during the previous 3 month period OR (b) Chronic migraine defined as headache occurring on 15 or more days per month for more than 3 months, which on at least 8 days per month, has features of a migraine headache (ICHD-3) AND (II) Individual is using for migraine prophylaxis. For Renewal requests: Individual has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month AND Individual has obtained clinical benefit deemed significant by individual or prescriber. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Aldurazyme

**Products Affected**

- ALDURAZYME

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis is confirmed by either of the following (Clarke 2016, Lehman 2011): (a) Documented (written or verbal attestation) deficiency in alpha-L-iduronidase enzyme activity as measured in fibroblasts or leukocytes or (b) Documented (written or verbal attestation) alpha-L-iduronidase gene mutation. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For dx of mucopolysaccharidosis I (MPS I) AND Individual has one of the following forms of MPS I: (1) Hurler OR (2) Hurler-Scheie OR (3) Scheie with moderate to severe symptoms manifestations including any of the following: (a) Cardiac valve abnormalities (such as aortic or mitral valve regurgitation, with or without insufficiency or stenosis) or (b) Corneal clouding, open-angle glaucoma, and retinal degeneration, progressive or (c) Craniofacial or growth retardation or (d) Frequent, moderate to severe upper respiratory infections or (e) Hepatosplenomegaly or (f) Hernias (such as hiatal, inguinal, or umbilical) or (g) Neurological symptoms resulting from cervical instability or cervical spinal cord compression or (h) Skeletal and joint involvement, progressive (such as, arthropathy, back pain, joint stiffness, lumbar spondylolisthesis, lumbar spinal compression, osteopenia, or osteoporosis). |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Alecensa

**Products Affected**

- ALECENSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Alimta

**Products Affected**

- ALIMTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Aliqopa

**Products Affected**

- ALIQOPA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 1 year. Continuation 6 months. |
| **Other Criteria** | For initial use in the treatment of follicular lymphoma, Individual has received at least two prior systemic therapies and have not had previous treatment with another PI3-kinase inhibitor previously (for example, idelalisib [Zydelig]). For continued use, there is objective evidence of continuing clinical benefit (for example, complete response, partial response, or stable disease) verified at least every 6 months that is objectively measured. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Aloxi

**Products Affected**

- ALOXI
- *palonosetron hcl*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Alpha1-Proteinase Inhibitor

**Products Affected**

- ARALAST NP
- GLASSIA
- PROLASTIN-C
- ZEMAIRA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Alpha 1 proteinase inhibitors may not be approved for individuals with IgA antibodies. |
| **Required Medical Information** | Confirmed alpha-1 antitrypsin level is less than or equal to 11micro-mol/L (approximately equivalent to 80mg/dL measured by radial immunodiffusion or 57 mg/dL measured by nephelometry) (ATS/ERS 2003, Stoller 2017). Individual has clinically evident emphysema and one of the following: Moderate airflow obstruction is evidenced by forced expiratory volume (FEV1) of 30-65 percent of predicted value, prior to initiation of therapy OR a rapid decline in lung function as measured by a change in FEV1 greater than 120 ml/year. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Alunbrig

**Products Affected**

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLET THERAPY PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Amphetamine Line

**Products Affected**

- ADZENYS ER
- ADZENYS XR-ODT
- *amphetamine er*
- DYANAVEL XR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 6 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Amphetamine Salts

**Products Affected**

- *amphetamine-dextroamphet er*
- *amphetamine-dextroamphetamine oral tablet 10 mg, 12.5 mg, 15 mg, 20 mg, 30 mg, 5 mg, 7.5 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | For dx ADHD, 3 years of age or older for immediate release. For Narcolepsy, 6 years of age or older for immediate release |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Amphetamine Salts - B

**Products Affected**

- ADDERALL ORAL TABLET 10 MG, 12.5 MG, 15 MG, 20 MG, 30 MG, 5 MG, 7.5 MG
- ADDERALL XR
- MYDAYIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | For dx ADHD, 3 years of age or older for immediate release, 6 years of age or older for extended-release. For Narcolepsy, 6 years of age or older for immediate release |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ampyra

**Products Affected**

- AMPYRA
- *dalfampridine er*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a history of seizures, OR moderate or severe renal impairment (defined as creatinine clearance less than or equal to 50 mL/min) |
| **Required Medical Information** | For renewal, individual achieved and sustained clinically significant improvement in ambulation related functional status. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial approval 12 weeks, renewal 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Anadrol 50

**Products Affected**

- ANADROL-50

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Anadrol 50 may not be used to not replace other supportive measures for anemia such as transfusion, correction of iron, folic acid, B12 or pyridoxine deficiency, antibacterial therapy, or the appropriate use of corticosteroids. Using to enhance athletic ability. Individual has a diagnosis of Carcinoma of the prostate or breast in male individuals or Carcinoma of the breast in females with Hypercalcemia. Individual has a diagnosis of nephrosis (nephrotic phase of nephritis). Individual has a diagnosis of severe hepatic dysfunction. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Individual has a diagnosis of a deficient red cell production-associated anemia, such as but not limited to: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis, or myelotoxic drug-associated hypoplastic anemia. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Apokyn

**Products Affected**

- APOKYN
- KYNMOBI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Erectile Dysfunction (ED) use |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual is using in conjunction with an antiemetic (excluding 5ht3 antagonist agents). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Aranesp

**Products Affected**

- ARANESP (ALBUMIN FREE)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Sudden loss of response with severe anemia and low reticulocyte count. Anemia in cancer patients receiving myelosuppressive chemotherapy and anemia can be managed by transfusion. Continued use when the hemoglobin level exceeds 11.0 g/dL unless otherwise specified in the criteria. Individuals with uncontrolled HTN. Use beyond 12 weeks in the absence of response in individuals with chronic kidney disease. Use beyond 8 weeks in the absence of response in individuals with myelodysplastic syndrome (MDS). Use beyond 8-9 weeks in the absence of response or if transfusions are still required in individuals with metastatic, non-myeloid cancer being treated with myelosuppressive chemotherapy agents known to produce anemia. Continued use beyond 6 weeks after therapy with myelosuppressive chemotherapy known to produce anemia is completed. |
| **Required Medical Information** | Hemoglobin (Hgb) levels are less than 10 g/dL, prior to initiation of therapy (unless otherwise specified) AND the individual iron status reveals, transferrin saturation at least 20% or ferritin at least 80 ng/mL or bone marrow demonstrates adequate iron stores AND For individuals with hypertension. For MDS, endogenous erythropoietin level is less than 500 mU/ml. For tx of anemia due to myelosuppressive chemotherapy, chemo is planned for a minimum of 2 months and the dx is non-myeloid cancer and anticipated outcome is not cure. For anemia associated with CKD ON dialysis use is to achieve and maintain hgb levels within the range of 10.0 to 11.0 g/dL. For anemia associated with CKD NOT ON dialysis use is to achieve and maintain hgb levels of 10.0g/dL. |
| **Age Restrictions** | |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | |
| **Coverage Duration** | 8wk. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Arcalyst

**Products Affected**

- ARCALYST

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use in combination with other IL-1 inhibitors, JAK inhibitors, or other biologic drugs (such as IL-6 inhibitors, TNF antagonists, or selective co-stimulation modulators). Tuberculosis, other active serious infections or a history of recurrent infections. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis prior to initiating treatment with rilonacept. |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 12 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Arzerra

**Products Affected**

- ARZERRA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# AUBAGIO

**Products Affected**

- AUBAGIO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other immunomodulatory agents (such as Gilenya, tecfidera, Tysabri, Copaxone, Extavia, Plegridy, Rebif, Avonex or Betaseron). Individual has an active acute or chronic infection at the initiation of therapy or has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis prior to initiation of therapy. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has been on Aubagio in the past 180 days OR individual has tried therapy with ONE of the following agents: Avonex (interferon beta-1a) OR Plegridy (interferon beta-1a) OR Betaseron (interferon beta-1b) OR Tecfidera (dimethyl fumarate) OR Copaxone/Glatopa (glatiramer). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Auryxia

**Products Affected**

- AURYXIA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a diagnosis of an iron overload syndrome (for example, hemochromatosis) or has a diagnosis of iron deficiency anemia associated with chronic kidney disease (CKD) stages 3, 4, or 5 and is not on dialysis [Not Part D]. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Austedo

**Products Affected**

- AUSTEDO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is suicidal or has untreated or inadequately treated depression. Individual has hepatic impairment. Individual is currently utilizing monoamine oxidase inhibitors (MAOIs), reserpine or tetrabenazine. |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For initial requests, Individual has a diagnosis of chorea associated with Huntington's disease. Has a diagnosis of Tardive dyskinesia confirmed by the following DSM-5 AND (a.) At least 60 days of stable (drug, dose) medication exposure (either typical or first generation antipsychotic agents [such as, chlorpromazine, haloperidol, fluphenazine], atypical or second-generation antipsychotic agents [such as, clozapine, risperidone, olanzapine, quetiapine, aripiprazole], or certain dopamine receptor-blocking drugs used in treatment of nausea and gastroparesis [such as, prochlorperazine, promethazine, metoclopramide]) and (b.) Presence of involuntary athetoid or choreiform movements lasting at least 30 days. For continuation requests, Individual has experienced an improvement in symptoms deemed to be clinically significant by the provider (verbal attestation). |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# AVASTIN

**Products Affected**

- AVASTIN
- MVASI
- ZIRABEV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ayvakit

**Products Affected**

- AYVAKIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Confirmed test results (written or verbal) for individual with a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including D842V mutation. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Bafiertam

**Products Affected**

- BAFIERTAM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other MS disease modifying agents (including Tecfidera, Vumerity). |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Balversa

**Products Affected**

- BALVERSA ORAL TABLET 3 MG, 4 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has confirmed (written or verbal attestation) disease susceptible to genetic alterations. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Banzel

**Products Affected**

- BANZEL ORAL SUSPENSION
- BANZEL ORAL TABLET 200 MG, 400 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 1 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Baraclude

**Products Affected**

- BARACLUDE
- *entecavir*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has a diagnosis of Chronic Hepatitis B virus (HBV) infection and has not been previously treated with lamivudine (AASLD 2016) OR is using as prophylaxis for hepatitis B reactivation in the setting of immune suppression (AGA 2015) or in combination with hepatitis C direct-acting antiviral therapy (AASLD 2017) OR Individual is a solid organ transplant recipient and using as prophylaxis for hepatitis B reactivation post (AASLD 2018). |
| **Age Restrictions** | 2 years of age and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Bavencio

**Products Affected**

- BAVENCIO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Receiving treatment with another PD-1 agent (for example, Opdivo (nivolumab) or Keytruda (pembrolizumab)). Receiving therapy for an autoimmune disease or chronic condition requiring treatment with systemic immunosuppressant. |
| **Required Medical Information** | Current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 for metastatic merkel cell carcinoma and locally advanced or metastatic urothelial carcinoma. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For metastatic merkel cell carcinoma, Bavencio is used when individual has not received treatment with another PD-1 (programed death receptor -1) agent (for example, Opdivo or Keytruda) and is not receiving treatment with a systemic immunosuppressant. For locally advanced or metastatic urothelial carcinoma, Bavencio is used as a single agent and individual has not received treatment with another PD-1 agent (for example, Opdivo or Keytruda) and is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant and individual meets ONE of the following criteria: has demonstrated disease progression on or after platinum-containing chemotherapy or has demonstrated disease progression within 12 months of receiving neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# Beleodaq

**Products Affected**

- BELEODAQ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Benlysta

**Products Affected**

- BENLYSTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For initial treatment, individual has a Clinical diagnosis of SLE per the American College of Rheumatology [ACR] criteria AND Unequivocally positive ANA (anti-nuclear antibody) titer greater than or equal to 1:80 or anti-dsDNA (double stranded DNA antibody) greater than or equal to 30 IU/mL AND SLE is active as documented by a SELENA-SLEDAI score greater than or equal to 6 while on current treatment regimen AND There is no evidence of severe renal disease (proteinuria greater than 6 gm/day, serum creatinine greater than 2.5 mg/dl, or requiring renal dialysis) AND There is no evidence of active central nervous system lupus (e.g. psychosis and seizures) AND SLE remains active while on corticosteroid, antimalarials, and/or immunosuppressants for at least the last 30 days. For continuation of therapy, individual has a clinical diagnosis of SLE per the American College of Rheumatology [ACR] criteria AND documentation of previous improvement in disease activity following treatment with belimumab indicating a therapeutic response AND there is no evidence of severe renal disease AND there is no evidence of active central nervous system lupus. |
| **Age Restrictions** | Individual is 18 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Beovu

**Products Affected**

- BEOVU

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Berinert

**Products Affected**

- BERINERT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Prophylaxis for HAE attacks. |
| **Required Medical Information** | HAE to be confirmed by a C4 level below the lower limit of normal (as defined by the laboratory performing the test) and either a C1 inhibitor antigenic level below the lower limit of normal (as defined by the lab performing test) or a C1 inhibitor functional level below the lower limit of normal (as defined by the lab performing the test). |
| **Age Restrictions** | Individual is 5 years or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a history of moderate or severe attacks (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion) and using Berinert for acute HAE attacks. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Blincyto

**Products Affected**

- BLINCYTO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 Year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Bosulif

**Products Affected**

- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Confirmed (written or verbal attestation) BCR-ABL1 positive chronic phase disease. Individual has any of the following confirmed mutations (written or verbal attestation): E255K/V, F317L/V/I/C, F359V/C/I, T315A or Y253H. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has chronic myelogenous leukemia (CML) AND has newly-diagnosed Philadelphia-positive (Ph+) or confirmed(written or verbal attestation) BCR-ABL1 positive chronic phase disease OR is using in combination as primary treatment in lymphoid blast phase or myeloid blast phase disease OR using in post-allogenic HCT therapy for those with prior accelerated or blast phase disease with complete cytogenic response. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Botox-Myobloc-Dysport

**Products Affected**

- BOTOX
- DYSPORT
- MYOBLOC
- XEOMIN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Botulinum toxin is considered cosmetic as a treatment of skin wrinkles or other cosmetic indications and is not approvable. |
| **Required Medical Information** | For Cervical Dystonia (spasmodic torticollis) of mod or greater severity when all the following are met: Individual is requesting initial tx AND HX of recurrent clonic and/or tonic involuntary contractions of 1 or more of the following muscles: sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles AND sustained head tilt and/or abnormal posturing with limited range of motion in the neck AND duration of the condition is greater than 6 months. Subsequent injections for the tx of cervical dystonia of mod or greater severity when all the following is met: Individual is requesting subsequent injections AND there is a response to initial tx documented in medical records. An initial 6 month trial For prevention of chronic migraine, PT must have migraine on 15 or more days/month for more than 3 months which on at least 8 days per month has features of a migraine HA (ICHD-3) AND Individual has had trial of/inadequate response/intolerance to 2 agents for migraine prophylaxis (at least 1 agent in any 2 of the following classes) or has contraindication to all of the following meds (AAN/AHA 2012/2015, Level A and B evidence, ICSI 2013, high quality evidence): 1 of these antidepressants: amitriptyline, venlafaxine OR 1 of these beta blockers: metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol OR the following CCB: verapamil OR 1 of these antiepileptics: valproate sod, divalproex sod, topiramate, gabapentin. Continuing tx medically nec when individual has completed an initial 6 month trial and has a reduction in overall number of migraine days or reduction in number of severe migraine days/month AND individual has obtained clinical benefit deemed significant by individual or prescriber. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year, chronic migraine 6 months |
| **Other Criteria** | Treatment of primary hyperhidrosis. Treatment of secondary hyperhidrosis. Treatment of significant drooling in patients who are unable to tolerate scopolamine. Treatment neurogenic overactive bladder (also referred to as detrusor overactivity or detrusor sphincter dyssynergia) that is inadequately controlled with anticholinergic therapy. Treatment of idiopathic overactive bladder in adults who are unresponsive to or intolerant of a trial of anticholinergic therapy. Treatment of Hirschsprung disease and associated functional obstruction caused by the inability of the internal anal sphincter to relax after prior surgical treatment. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Braftovi

**Products Affected**

- BRAFTOVI ORAL CAPSULE 50 MG, 75 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Written or verbal attestation has been provided for either BRAF V600E or V600K genetic mutation. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Briviact

**Products Affected**

- BRIVIACT INTRAVENOUS
- BRIVIACT ORAL SOLUTION
- BRIVIACT ORAL TABLET 10 MG, 100 MG, 25 MG, 50 MG, 75 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Brukinsa

**Products Affected**

- BRUKINSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has no prior BTK inhibitor usage. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Buphenyl

**Products Affected**

- BUPHENYL
- *sodium phenylbutyrate*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Management of acute hyperammonemia |
| **Required Medical Information** | Using as adjunctive therapy for chronic management of hyperammonemia |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Cabometyx

**Products Affected**

- CABOMETYX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Calquence

**Products Affected**

- CALQUENCE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Caplyta

**Products Affected**

- CAPLYTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is currently using a CYP3A4 inducer (such as carbamazepine, phenytoin, rifampin, St. John's wort, bosentan, efavirenz, etravirine, modafinil, nafcillin, aprepitant, armodafinil, pioglitazone, prednisone) and cannot discontinue the medication OR Individual is using a moderate (such as amprenavir, ciprofloxacin, cyclosporine, diltiazem, erythromycin, fluconazole, fluvoxamine, verapamil) or strong (such as, clarithromycin, grapefruit juice, itraconazole, voriconazole, nefazodone, ritonavir, nelfinavir) CYP3A4 inhibitor and cannot discontinue the medication OR Individual has moderate (Child-Pugh Class B) or severe hepatic impairment (Child-Pugh Class C). |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Caprelsa

**Products Affected**

- CAPRELSA ORAL TABLET 100 MG, 300 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Carbaglu

**Products Affected**

- CARBAGLU

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Cayston

**Products Affected**

- CAYSTON

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a forced expiratory volume in 1 second (FEV1) of less than 25% or greater than 75% of predicted |
| **Required Medical Information** | |
| **Age Restrictions** | 7 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Celebrex

**Products Affected**

- CELEBREX
- *celecoxib*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE prescription Non-Steroidal Anti-Inflammatory Drugs (NSAID) or salicylates |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Cequa

**Products Affected**

- CEQUA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods (AAO, 2018): 1)Tear break-up time (less than 10 seconds) or 2) Ocular surface dye staining using fluorescein, rose bengal, or lissamine green dyes or 3) Schirmer test (aqueous tear production of less than or equal to 10 mm of strip wetting in 5 minutes) or 4) Fluorescein clearance test/tear function index or 5) Tear osmolarity (indicating tear film instability) or 6) Tear lactoferrin concentrations in the lacrimal gland (decreased) or 7) Matrix metalloproteinase-9 (MMP-9) test. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual using for moderate to severe dry eye AND has had a trial and inadequate response or intolerance to Xiidra OR has a known hypersensitivity to any ingredient to Xiidra (preferred agent) which is not also present in the requested non-preferred agent |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Cerdelga

**Products Affected**

- CERDELGA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use of glucosylceramide synthase inhibitor in conjunction with one another or in conjunction with a substrate reduction therapy (SRT) agent or enzyme replacement therapy (ERT) agent. Use in an ultra-rapid metabolizers of CYP2D6. Individual has moderate or severe renal impairment or end-stage renal disease (ESRD). Individual has mild, moderate or severe hepatic impairment or cirrhosis OR individual has pre-existing cardiac disease or long QT syndrome. |
| **Required Medical Information** | Presence of type 1 Gaucher disease is confirmed by either of the following: Glucocerebrosidase activity in the white blood cells or skin fibroblasts less than or equal to 30% of normal activity, OR genotype testing indicating mutation of two alleles of the glucocerebrosidase genome. And patient has clinically significant manifestations of Type 1 gauchers disease including any of the following: (A) skeletal disease (demonstrated by ANY of the following: avascular necrosis, erlenmeyer flask deformity, lytic disease, marrow infiltration, osteopenia, osteosclerosis, pathological fracture, joint deterioration or replacement) OR (B) individual presents with at least 2 of the following: clinically significant hepatomegaly as confirmed by medical imaging [such as but not limited to, volumetric magnetic resonance imaging (MRI)], clinically significant splenomegaly as confirmed by medical imaging [such as but not limited to, volumetric (MRI)], hgb less than or equal to 11.5 grams per dl for females or 12.5 grams per dl for males or 1 gram per dl below lower limit for normal for age and sex, platelet counts less than or equal to 120,000 mm3 OR (C) individual is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as confirmed by a FDA-approved genotype test. |
| **Age Restrictions** | Individual is 18 years of age or older. |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Chantix

**Products Affected**

- CHANTIX CONTINUING MONTH PAK
- CHANTIX ORAL TABLET 0.5 MG, 1 MG
- CHANTIX STARTING MONTH PAK

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

# Chenodal

**Products Affected**

- CHENODAL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has calcified (radiopaque) or radiolucent bile pigment stones OR has preexisting hepatic impairment OR has known hepatocyte dysfunction or bile ductal abnormalities (such as but not limited to intrahepatic cholestasis, primary biliary cirrhosis, or sclerosing cholangitis) OR has a gallbladder confirmed as nonvisualizing after two consecutive single doses of dye OR has gallstone complications or compelling reasons for gallbladder surgery (such as but not limited to unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary gastrointestinal fistula). |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 2 years. Requests to continue therapy beyond 24 months (2 years) should not be approved. |
| **Other Criteria** | Individual is using for gallstone dissolution AND has a well-opacifying gallbladder with radiolucent stones AND has an increased surgical risk due to systemic disease or advanced age. For continuation, Repeat imaging studies show partial dissolution of gallstone(s). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Cholbam

**Products Affected**

- CHOLBAM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Used to treat extrahepatic manifestations (such as but not limited to neurologic symptoms) of SED-associated-BASDs or PDs. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial therapy: 3 months. Continuation therapy: 1 year |
| **Other Criteria** | For initial therapy: (A) Diagnosis of bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs) including but not limited to 3 beta-hydroxy-delta 5-C27-steroid oxidotrductase defects OR (B) Diagnosis of peroximal disorders (PDs) including but not limited to Zellweger spectrum disorders AND (C) Individual has one of the following: (a) Manifestations of liver disease (for example, jaundice, hepatomegaly) (b) steatorrhea (c) Complications from decreased fat soluble vitamin (such as but not limited to vitamin D and K) absorption (for example, rickets, hypocalcemia, bleeding). For maintenance therapy: Meets the initial request criteria AND has had a clinical improvement (symptoms, lab values) in liver function and/or cholestasis AND has not developed a complete biliary obstruction. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Chorionic Gonadotropin

**Products Affected**

- *chorionic gonadotropin*
- NOVAREL
- PREGNYL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use in the following: Infertility treatments (Including use with IVF, ART), Obesity, Weight loss, Stimulation of spermatogenesis in males, Treatment of anovulation in females with infertility, Ovulation induction in females. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Individual is using for Pre-pubertal cryptorchidism not caused by anatomical obstruction in males OR Hypogonadotropic hypogonadism from pituitary deficiency in males. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Cialis BPH

**Products Affected**

- CIALIS ORAL TABLET 2.5 MG, 5 MG
- *tadalafil oral tablet 2.5 mg, 5 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Erectile dysfunction. Currently on nitrate therapy. |
| **Required Medical Information** | Individual has a diagnosis of benign prostatic hyperplasia (BPH) [with or without ED] |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Cimzia

**Products Affected**

- CIMZIA
- CIMZIA PREFILLED
- CIMZIA STARTER KIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections prior to initiating Cimzia (certolizumab pegol). Individuals who have not had a tuberculin skin test or Center for Disease Control recommended equivalent to evaluate for latent tuberculosis prior to initiating Cimzia (certolizumab pegol). Using Cimzia in combination with other TNF antagonists, non-TNF immunomodulatory drugs: abatacept, anakinra, natalizumab, tofacitinib or rituximab. |
| **Required Medical Information** | Individual has chronic moderate to severe (that is, extensive or disabling) plaque psoriasis with either of the following: Individual has greater than 5% of body surface area with plaque psoriasis OR less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For moderate to severe Crohn's Disease, Individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (e.g. 5-ASA products, systemic corticosteroids, or immunosuppressants) AND Individual has had trial and inadequate response or is intolerant to Humira (adalimumab). For moderate to severe Rheumatoid Arthritis, Individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE nonbiologic DMARD AND Individual has had a trial and an inadequate response or is intolerant to Humira (adalimumab) OR Enbrel (etanercept). For moderate to severe Psoriatic Arthritis, Individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as nonbiologic DMARDs) AND has had a trial and an inadequate response or is intolerant to Humira (adalimumab) OR Enbrel (etanercept). For moderate to severe Ankylosing Spondylitis (AS), Individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as NSAIDs or non-biologic DMARDs) AND has had a trail and an inadequate response or is intolerant to Humira (adalimumab) OR Enbrel (etanercept). For plaque psoriasis individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate) AND has had a trial of and inadequate response or intolerance to Humira (adalimumab) OR Enbrel (etanercept). For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Cimzia or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR individual has either concomitant clinical condition: (1) Demyelinating disease or |
| | (2) Heart failure with documented left ventricular dysfunction. For non-radiographic axial spondyloarthritis, individual has had an inadequate response to, or has a contraindication to conventional therapy [such as NSAID or nonbiologic such as sulfasalazine)]. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# Cinqair

**Products Affected**

- CINQAIR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has blood eosinophil counts (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease and known or suspected parasitic infection) greater than or equal to 400 cells/microliter at initiation of therapy. The individual has pretreatment forced expiratory volume in one second (FEV1) less than 80% predicted AND FEV1 reversibility of at least 12% and 200mL after albuterol administration. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial requests, individual must have a diagnosis of eosinophilic asthma AND individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting beta2-agonist, leukotriene modifiers, theophylline or oral corticosteroids) (ERS/ATS 2013) AND individual has experienced 2 or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in the individual's usual maintenance dosage of oral corticosteroids (ERS/ATS 2013). For Maintenance Therapy: Treatment has resulted in clinical improvement as confirmed one or more of the following: i) Decreased utilization of rescue medications OR ii) A decreased frequency of exacerbation (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroid) OR iii) An increase in percent predicted FEV1 from pretreatment baseline OR iv) A reduction in reported asthma-related symptoms, such as, but not limited to wheezing, shortness of breath, coughing, fatigue, sleep disturbance or asthmatic symptoms upon awakening |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Cinryze

**Products Affected**

- CINRYZE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | HAE to be confirmed by a C4 level below the lower limit of normal (as defined by the laboratory performing the test) and ANY of the following: 1. C1 inhibitor antigenic level below the lower limit of normal (as defined by the lab performing test). 2. C1 inhibitor functional level below the lower limit of normal (as defined by the lab performing the test) Or 3. The presence of a known HAE-causing C1-INH mutation. |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a history of moderate or severe attacks and is using Cinryze as prophylaxis for short-term use prior to surgery, dental procedures or intubation OR for long-term prophylaxis and member has failed, or is intolerant to, or has contraindication to 17-alpha-alkylated androgens or antifibrinolytic agents. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Cometriq

**Products Affected**

- COMETRIQ (100 MG DAILY DOSE)
- COMETRIQ (140 MG DAILY DOSE)
- COMETRIQ (60 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Copaxone

**Products Affected**

- COPAXONE SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 20 MG/ML, 40 MG/ML
- *glatiramer acetate subcutaneous solution prefilled syringe 20 mg/ml, 40 mg/ml*
- *glatopa subcutaneous solution prefilled syringe 20 mg/ml, 40 mg/ml*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual with primary progressive MS (PPMS). Individual with non-active secondary progressive MS (SPMS). Concurrent use with other MS Disease modifying agents (such as, Aubagio, Gilenya, Tecfidera, Tysabri, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy or Betaseron).. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Copiktra

**Products Affected**

- COPIKTRA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Corlanor

**Products Affected**

- CORLANOR ORAL SOLUTION
- CORLANOR ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a heart rate maintained exclusively by a pacemaker. Individual has severe hypotension (blood pressure less than 90/50 mmgHg). Individual has severe hepatic impairment (Child-Pugh Class C). |
| **Required Medical Information** | |
| **Age Restrictions** | For NYHA Class II, II, or IV due to DCM, age 6 months or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | (A) Individual is using for the treatment of New York Heart Association (NYHA) class II, III or IV heart failure symptoms AND has a left ventricular ejection fraction less than or equal to 35% AND will be utilizing in combination with a beta-blocker OR has a contraindication or intolerance to beta-blocker therapy AND is in normal sinus rhythm AND If initiating treatment with Corlanor, individual has a resting heart rate greater than or equal to 70 beats per minute. OR (B) Individual is using for the treatment of New York Heart Association (NYHA) class II, III, or IV heart failure symptoms due to dilated cardiomyopathy AND has a left ventricular ejection fraction less than or equal to 45% AND is in normal sinus rhythm AND If initiating treatment with Corlanor, individual has an elevated resting heart rate. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# Cosentyx

**Products Affected**

- COSENTYX
- COSENTYX (300 MG DOSE)
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SENSOREADY PEN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | .. |
| **Required Medical Information** | Individual has moderate to severe plaque psoriasis with either of the following: Individual has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia) OR Individual is using for the treatment of non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For moderate to severe Ankylosing Spondylitis (AS), individual had an inadequate response to/intolerant of or has a medical contraindication to ONE conventional therapy [such as, NSAIDs or nonbiologic DMARDS such as sulfasalazine or a tumor necrosis factor (TNF) antagonist] AND Individual has had a trial of/inadequate response or is intolerant to Enbrel (etanercept) OR Humira (adalimumab). For moderate to severe plaque psoriasis (Ps), individual had an inadequate response to/intolerant of or has contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine or methotrexate) AND Individual has had a trial of/inadequate response or is intolerant to Enbrel (etanercept) OR Humira (adalimumab). For moderate to severe Psoriatic Arthritis (PsA), individual has had an inadequate response to/intolerant of or has a medical contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine or leflunomide)] or TNF antagonist (AAD 2011) AND Individual has had a trial of and an inadequate response or is intolerant to Enbrel (etanercept) OR Humira (adalimumab). For any of the above indications, if the TNF agent (Enbrel(etanercept)/Humira (adalimumab)) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Cosentyx or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Cosentyx may be allowed without trial of preferred TNF agents (Enbrel/Humira). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Cotellic

**Products Affected**

- COTELLIC

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis of unresectable or metastatic melanoma with confirmed (written or verbal attestation) BRAF V600E or V600K mutation. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual is using Cotellic (cobimetinib) in combination with Zelboraf (vemurafenib). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Cresemba

**Products Affected**

- CRESEMBA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has diagnosis or history of familial short QT syndrome. Use in combination with strong CYP3A4 inhibitors (such as but not limited to ketoconazole) OR strong CYP3A4 inducers (such as but not limited to rifampin). |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual initiated treatment in an inpatient setting and requires continued treatment of invasive aspergilliosis or mucormycosis in an outpatient setting. For invasive aspergillosis individual has an inadequate response/intolerance to or contraindication to voriconazole or liposomal amphotericin B (ATS 2011, IDSA 2008). For invasive mucormycosis individual has had an inadequate response/intolerance to or contraindication to amphotericin B (ATS 2001). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Crinone

**Products Affected**

- CRINONE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Progesterone supplementation or replacement as part of an Assisted Reproductive Technology ("ART") treatment for infertile women with progesterone deficiency, Progesterone supplementation/deficiency. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Cyramza

**Products Affected**

- CYRAMZA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For urothelial cancer, an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. |
| **Age Restrictions** | For urothelial cancer, 18 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 Year |
| **Other Criteria** | For locally advanced, unresectable or metastatic urothelial cancer originating from bladder, urethra, ureter or renal pelvis and using in combination with docetaxel AND disease has progressed after platinum-containing chemotherapy (cisplatin or carboplatin) AND individual has received treatment with no more than one immune checkpoint inhibitor (such as, atezolizumab, avelumab, durvalumab, nivolumab or pembrolizumab) AND has received treatment with no more than one prior systemic chemotherapy regimen in the relapsed or metastatic setting AND individual has not received prior systemic taxane therapy in any setting (neoadjuvant, adjuvant or metastatic). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# D.H.E Inj

**Products Affected**

- D.H.E. 45
- *dihydroergotamine mesylate injection*

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

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For migraine attacks with aura in individuals meeting the following International Headache Society (IHS) diagnostic criteria (must meet criteria A-D): A) At least 2 or more headache attacks AND B) Aura consisting of at least 1 of the following fully reversible aura sx: 1. visual symptoms (such as, flickering lights, spots or lines) OR 2. Sensory symptoms (for example, pins and needles, numbness) OR 3. Speech and/or language (for example, aphasia) OR 4. Motor (for example, weakness) OR 5. Brainstem (for example, ataxia or vertigo) OR 6. Retinal (for example, blindness) AND C) At least 3 of the following characteristics: a) At least 1 aura sx develops gradually over 5 or more minutes or b) 2 or more aura sx occur in succession or c) Each individual aura lasts 5 to 60 minutes or d) At least 1 aura sx is unilateral or e) At least 1 aura sx is positive (scintillations and pins and needles are examples of positive sx of aura) or f) The aura is accompanied or followed within 60 minutes, by headache AND D) Individual's headache is not attributed to another headache disorder (for example, transient ischemic attack). For migraine attacks without aura in adults meeting the following IHS diagnostic criteria: 1) At least 5 or more headache attacks AND 2) Headaches lasting 4-72 hrs (untreated or unsuccessfully treated) AND 3) Headache has at least 2 or more of the following: i) Unilateral location ii) Pulsating quality iii)Moderate or severe pain intensity iv) Aggravation by or causing avoidance of routine physical activity (such as, walking or climbing stairs) AND 4) Individual's headache is accompanied by 1 or more of the following: i) Nausea, vomiting or both ii) Photophobia or phonophobia AND 5) Individual's headache is not attributed to another headache disorder (for example, transient ischemic attack). For cluster headache episodes in adults meeting the following IHS diagnostic criteria: A) At least 5 or more attacks B) Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes if untreated AND C) Headache is accompanied by at least 1 or both of the following: 1. |

| PA Criteria | Criteria Details |
|---|---|
| | One or more of the following sx or signs, ipsilateral to the headache: (i) conjunctival injection and/or lacrimation (ii) nasal congestion and/or rhinorrhea (iii) eyelid edema (iv) forehead and facial sweating (v) forehead and facial flushing (vi) miosis and ptosis OR 2. A sense of restlessness or agitation AND D) Attacks have a frequency from one every other day to 8 per day for more than half of the time the disorder is active AND E) Individual's headache is not attributed to another headache disorder. DHE may also be may be approved: For Status migrainosus or rebound withdrawal type of headaches OR As alternative to narcotic therapy for severe migraine or cluster headaches OR individual is unresponsive to prior use of triptans for severe migraine or cluster headache. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# DAKLINZA

**Products Affected**

- DAKLINZA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and a positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD/IDSA guidance. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, Individual has had a prior trial and inadequate response to Harvoni (sofosbuvir/ledipasvir) OR individual is currently on and completing a course of therapy with the requested regimen OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni (ledipasvir/sofosbuvir) which is not also in Daklinza OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni (sofosbuvir/ledipasvir). For GT 4, individual has had a prior trial and inadequate response to Harvoni (sofosbuvir/ledipasvir) or Epclusa (sofosbuvir/velpatasvir). OR individual is currently on and completing a course of therapy with the requested regimen OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni(sofosbuvir/ledipasvir) or Epclusa (sofosbuvir/velpatasvir) which is not also in Daklinza OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni (sofosbuvir/ledipasvir) or Epclusa (sofosbuvir/velpatasvir). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Daliresp

**Products Affected**

- DALIRESP

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is using to treat acute bronchospasm OR moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment OR using concomitantly with strong cytochrome P450 enzyme inducer (such as but not limited to phenobarbital, carbamazepine or phenytoin) |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual is currently or will be concomitantly using with a long-acting bronchodilator. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Darzalex

**Products Affected**

- DARZALEX
- DARZALEX FASPRO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Has received treatment with daratumumab or another anti-CD38 agent |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Daurismo

**Products Affected**

- DAURISMO ORAL TABLET 100 MG, 25 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 75 years old or older OR has comorbidities that preclude use of intensive induction chemotherapy. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Desoxyn

**Products Affected**

- DESOXYN
- *methamphetamine hcl*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Adjunct treatment of exogenous obesity/weight loss. |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 6 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD) AND has had an appropriate trial of one of the following: (a) methylphenidate containing agent OR (b) amphetamine containing agent (such as, amphetamine/dextroamphetamine, lisdexamfetamine, or dextroamphetamine). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Dificid

**Products Affected**

- DIFICID

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has had a trial and inadequate response or intolerance to or has a contraindication to a course of oral vancomycin. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 30 days |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Doptelet

**Products Affected**

- DOPTELET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Doptelet should not be administered to individuals with chronic liver disease in an attempt to normalize platelet counts. |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Doxil

**Products Affected**

- DOXIL
- *doxorubicin hcl liposomal*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# DPP4

**Products Affected**

- *alogliptin benzoate oral tablet 12.5 mg, 25 mg, 6.25 mg*
- *alogliptin-metformin hcl*
- *alogliptin-pioglitazone oral tablet 12.5-15 mg, 12.5-30 mg, 12.5-45 mg, 25-15 mg, 25-30 mg, 25-45 mg*
- KAZANO
- KOMBIGLYZE XR ORAL TABLET EXTENDED RELEASE 24 HOUR 2.5-1000 MG, 5-1000 MG, 5-500 MG
- NESINA ORAL TABLET 12.5 MG, 25 MG, 6.25 MG
- ONGLYZA ORAL TABLET 2.5 MG, 5 MG
- OSENI ORAL TABLET 12.5-15 MG, 12.5-30 MG, 12.5-45 MG, 25-15 MG, 25-30 MG, 25-45 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had a trial and inadequate response or intolerance to metformin OR Individual has a contraindication to metformin therapy [such as but not limited to, renal insufficiency (eGFR less than 45 mL/min/1.73 m2)] AND Individual has had a trial and inadequate response or intolerance to ONE of the following: Januvia (sitagliptin), Tradjenta (linagliptin), Janumet (sitagliptin/metformin), Janumet XR (sitagliptin/metformin), Jentadueto (linagliptin/metformin), OR Jentadueto XR (linagliptin/metformin). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Duavee

**Products Affected**

- DUAVEE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | May not be approved for the following: (1) If individual had a hysterectomy (2) Individual has undiagnosed abnormal uterine bleeding (3) Individual has known, suspected, or past history of breast cancer (4) Individual has known or suspected estrogen-dependent neoplasia (5) Individual has active or past history of venous thromboembolism (6) Individual has active or past history of arterial thromboembolism (7) Individual has known hepatic impairment or disease OR (8) Individual has known protein C, protein S, or antithrombin deficiency or other known thrombophilic disorders. |
| **Required Medical Information** | |
| **Age Restrictions** | Age 18 through age 75 |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual is using for ONE of the following: Treatment of moderate to severe vasomotor symptoms associated with menopause OR Individual is using for prevention of postmenopausal osteoporosis AND is using solely for prevention of osteoporosis and has had a trial of and inadequate response or intolerance or has a contraindication to non-estrogen agents for osteoporosis. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

Y0114_20_114079_I_012 December 2020

# Duexis

**Products Affected**

- DUEXIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has had a trial and inadequate response or intolerance to one (1) oral generic prescription Non-Steroidal Anti-Inflammatory Drugs (NSAID) AND has had a trial and inadequate response or intolerance to one (1) of the following (Lanza 2009): (a) Preferred proton pump inhibitor (PPI) OR (b) Generic misoprostol OR (c) Generic histamine-2 receptor antagonist (H2RA) AND Individual has had an adequate response (pain relief and appropriate gastro protection) with a trial of ibuprofen and famotidine used at the same time AND Documentation has been provided for why the combination agent is clinically necessary and not for convenience. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Duobrii

**Products Affected**

- DUOBRII

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has a diagnosis of plaque psoriasis AND Documentation (verbal or written) has been provided for why the combination agent is clinically necessary and not for convenience. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Duopa

**Products Affected**

- DUOPA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For advanced Parkinsons disease with complicated motor fluctuations that have not been adequately controlled with optimal medical therapy with any TWO of the following: Oral levodopa-carbidopa, a Dopamine agonist [such as, but limited to Apokyn (apomorphine), Mirapex (pramipexole), Requip (ropinirole) and Neupro (rotigotine)], a catechol-0-methyl transferase (COMT) inhibitor [such as, but not limited to Comtan (entacapone) and Tasmar (tolcapone)], or a monoamine oxidase B (MAO)-B inhibitor [such as, but not limited to Eldepryl (selegiline), and Azilect (rasagiline)]. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Dupixent

**Products Affected**

- DUPIXENT SUBCUTANEOUS SOLUTION PEN-INJECTOR 300 MG/2ML
- DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/1.14ML,

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

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | A)Chronic atopic dermatitis that has been present for 3 years or more AND B) failure of topical pharmacological therapy as indicated by one or more of the following: 1) Daily treatment of topical corticosteroids of medium to higher potency for the maximum treatment period indicated in the product prescribing information has failed to achieve and maintain remission of low or mild disease activity state OR 2) topical calcineurin inhibitors (for example, Elidel, Protopic) if topical corticosteroids are not indicated for the maximum treatment period indicated in the product prescribing information has failed to achieve and maintain remission of low or mild disease activity state OR 3) Topical treatment is medically inadvisable as defined by treatments which have side effects or safety concerns which outweigh potential treatment benefits as evidenced by any of the following: Intolerance to treatment, hypersensitivity reactions, significant skin atrophy or systemic effects AND C) One of the following: Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated OR systemic treatment (for example, immunosuppressants) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Duragesic Patch

**Products Affected**

- DURAGESIC-100
- DURAGESIC-12
- DURAGESIC-25
- DURAGESIC-50
- DURAGESIC-75
- *fentanyl*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is requesting or using as an as-needed analgesic OR Individual has one of the following conditions: (a) Significant respiratory depression OR (b) Acute or severe bronchial asthma or hypercarbia OR (c) Known or suspected paralytic ileus. |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 2 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure) AND Individual is not opioid naïve as noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic OR (c) already receiving at least 60 mg/day of oral morphine, 30 mg/day of oral oxycodone, 8 mg/day of oral hydromorphone, or an equianalgesic dose of another opioid. For continued use, Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline AND prescriber has consulted with individual regarding risks of opioid therapy AND clear treatment goals have been defined and outlined as part of overall pain. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Egrifta

**Products Affected**

- EGRIFTA
- EGRIFTA SV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For initial requests, individual has a body mass index (BMI) is greater than 20 kg/m2 AND waist circumference and a waist-to-hip ratio of one of the following (Falutz 2010): (a) For males, waist circumference greater than or equal to 95cm and waist-to-hip ratio greater than or equal to 0.94 OR (b) For females, waist circumference greater than or equal to 94cm and waist-to-hip ratio greater than or equal to 0.88 AND fasting blood glucose (FBG) is less than 150 mg/dL (8.33 mmol/L) AND no history of type 1 diabetes or insulin-treated type 2 diabetes AND no active malignancy (e.g., a potential cancer which is being evaluated or a diagnosed cancer which is being treated). For continuation, individual must demonstrate there is a clear response in reduction of visceral adipose tissue measured by waist circumference or computed tomography (CT) scan. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 6 months, renewal 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Elaprase

**Products Affected**

- ELAPRASE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Documented deficiency in iduronate 2-sulfatase enzyme activity as measured in fibroblasts or leukocytes combined with normal enzyme activity level of another sulfatase OR Documented pathologic iduronate 2-sulfatase gene mutation. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has symptoms attributable to MPS II such as: (a) Developmental delay or cognitive impairment or (b) Frequent infections or (c) Hearing loss or (d) Hepatosplenomegaly or (e) Hernias or (f) Impaired respiratory function or (g) Joint pain or (h) Skeletal deformities or (i) Sleep apnea or (j) Valvular heart disease. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Elidel

**Products Affected**

- ELIDEL
- *pimecrolimus*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 2 years of age and older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual had a trial of and inadequate response or intolerance to one topical prescription strength corticosteroid. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# ELIGARD_GNRH

**Products Affected**

- ELIGARD SUBCUTANEOUS KIT 22.5 MG, 30 MG, 45 MG, 7.5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Other advanced, recurrent, or metastatic disease. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Elitek

**Products Affected**

- ELITEK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a diagnosis of glucose-6-phosphate dehydrogenase (G6PD) deficiency. |
| **Required Medical Information** | Individual is receiving treatment in a setting appropriate for providing necessary monitoring and supportive care for tumor lysis syndrome AND Individual has not received a course of Elitek therapy in the past. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 30 days |
| **Other Criteria** | Individual has been diagnosed with leukemia, lymphoma or other hematologic malignancy with risk factors for tumor lysis syndrome AND Individual is receiving chemotherapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Elzonris

**Products Affected**

- ELZONRIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has a current Eastern Cooperative Oncology Group (ECOG) status of 0-1. |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Emflaza

**Products Affected**

- EMFLAZA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | One of the following: (1) Documentation has been provided for excessive weight-gain with prednisone (increase of greater than 0.5 Z score from prior growth curve expectations [American Academy of Pediatrics/CDC Weight for Age Growth Chart, Z-score data files, CDC, Weight-for-age charts, 2 to 20 years, selected weight z-scores in kilograms, by sex and age]) AND Weight gain is likely to be a direct result of prednisone use. Or (2) Documentation has been provided regarding the presence of clinically significant neuropsychiatric side effects while on prednisone (such as but not limited to aggression) AND Neuropsychiatric side effects are likely to be the direct result of prednisone use. |
| **Age Restrictions** | Individual is 5 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial treatment of Duchenne Muscular Dystrophy (DMD) AND Individual has had a 6 month trial of oral prednisone (AAN 2016, DrugPoints B, IIa). Request for continuation of therapy when one of the following: (1) when approved due to excess weight gain with prednisone, individual has experienced a return to baseline growth curve expectations or remained on the same growth curve that was in effect when Emflaza was initiated (American Academy of Pediatrics/CDC Weight for Age Growth Chart, Z-score data files, CDC, Weight-for-age charts, 2 to 20 years, selected weight z-scores in kilograms, by sex and age) Or (2) When approved due to neuropsychiatric side effects while on prednisone, individual has shown improvement in neuropsychiatric symptoms. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Empliciti

**Products Affected**

- EMPLICITI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Emsam

**Products Affected**

- EMSAM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individuals with pheochromocytoma OR Individual is currently taking one of the following: (1) Selective serotonin reuptake inhibitors (SSRIs) (for example, fluoxetine) OR (2) Serotonin and norepinephrine reuptake inhibitors (SNRIs) (for example, venlafaxine) OR (3) Tricyclic antidepressants (clomipramine or imipramine) OR (4) Opiate analgesics (meperidine, tramadol, methadone, pentazocine) OR (5) Dextromethorphan OR (6) Carbamazepine. |
| **Required Medical Information** | Individual has no known contraindications to the use of a monoamine oxidase inhibitor (MAOI). |
| **Age Restrictions** | Individual is 18 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Enbrel

**Products Affected**

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 25 MG/0.5ML, 50 MG/ML
- ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED
- ENBREL SURECLICK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Entanercept used in combination with other TNF antagonist JAK inhibitors, other biologic drugs (such as, abatacept, anakinra, vedolizumab), or cyclophosphamides. Tuberculosis, other active serious infections or history of recurrent infections. Individual who have not had a tuberculin skin test or a CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating etanercept. |
| **Required Medical Information** | For chronic moderate to severe plaque psoriasis with either of the following: Individual has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). |
| **Age Restrictions** | Individual is 18 years of age or older, except for the diagnosis of JIA and plaque psoriasis. For JIA individual is 2 years of age or older. For plaque psoriasis, 4 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year except for Initial high dose tx chronic plaque psoriasis 12 wk |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For moderate to severe Ankylosing Spondylitis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapies: (such as NSAIDs or nonbiologic DMARDs) (ACR 2015). For Moderate to severe Chronic Plaque Psoriasis, individual has had inadequate response to, is intolerant of, or has a medical contraindication to phototherapy OR ONE other systemic therapies (such as, methotrexate, acitretin, or cyclosporine). For moderate to severe Rheumatoid Arthritis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, leflunomide or hydroxychloroquine)] (ACR 2015). For moderate to severe Polyarticular JIA, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDs such as methotrexate] (ACR 2011). For moderate to severe Psoriatic Arthritis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine or leflunomide)] (AAD 2011). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Enhertu

**Products Affected**

- ENHERTU

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has unresectable or metastatic HER2-positive (HER2+) breast cancer confirmed (written or verbal) by either Immunohistochemistry (IHC) is 3+ OR In situ hybridization (ISH) positive |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual is using Enhertu as monotherapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Entresto

**Products Affected**

- ENTRESTO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is pregnant/ wishing to become pregnant OR breastfeeding OR has a history of angioedema related to previous ACE inhibitor or ARB therapy OR has severe hepatic impairment (Child-Pugh C). OR Individual will be utilizing an angiotensin-converting enzyme (ACE) inhibitor OR angiotensin receptor blocker (ARB) in combination with Entresto (sacubitril/valsartan). Individual will be utilizing Entresto (sacubitril/valsartan) in combination with Tekturna (aliskiren)/Tekturna HCT (aliskiren/hydrochlorothiazide) and has a diagnosis of diabetes or renal impairment (eGFR less than 60 mL/min/1.73 m2). |
| **Required Medical Information** | Individual has a left ventricular ejection fraction less than or equal to 40%. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Entyvio

**Products Affected**

- ENTYVIO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Entyvio used in combination with other biologic drugs (such as TNF antagonists or natalizumab or non-TNF antagonists immunomodulatory drugs, such as or Tysabri (natalizumab)). Active, severe infections, or a history of recurrent infections. |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 6 years or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For UC or CD, individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-aminosalicylic acid products, systemic corticosteroids or immunosuppressants) or a tumor necrosis factor (TNF) antagonists AND Individual has had a trial and an inadequate response or is intolerant to Humira (adalimumab) OR the TNF agent (Humira (adalimumab)) tried and failed is not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Entyvio or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, (c) Malignancy [such as, but not limited to, solid or hematologic cancers excluding superficial skin cancers (such as basal and squamous cell], or (d) tuberculosis infection. Entyvio may be allowed without trial of preferred TNF agents (Humira). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Epclusa

**Products Affected**

- EPCLUSA
- *sofosbuvir-velpatasvir*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Epidiolex

**Products Affected**

- EPIDIOLEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Epogen and Procrit

**Products Affected**

- EPOGEN
- PROCRIT
- RETACRIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Anemia in patients due to other factors such as iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic diseases (such as sickle cell anemia, thalassemia, and porphyria). Sudden loss of response with severe anemia and low reticulocyte count. Treatment of anemia in patients with cancer not treated by chemotherapy known to produce anemia. Treatment of in any indication not listed in criteria including anemia of prematurity. Anemia in cancer patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure. Anemia in cancer patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy. Anemia in cancer patients receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. Continued use when the hemoglobin level exceeds 11.0 g/dL unless otherwise specified in the criteria. Use beyond 12 weeks in the absence of response in individuals with chronic renal failure. Use beyond 8 weeks in the absence of response in individuals with myelodysplastic syndrome (MDS). Use beyond 8-9 weeks in the absence of response or if transfusions are still required in individuals with metastatic, non-myeloid cancer being treated with myelosuppressive chemotherapy agents known to produce anemia. Continued use beyond 6 weeks after therapy with myelosuppressive chemotherapy known to produce anemia is completed. Pre-operative use for patients who are willing to donate autologous blood. |

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | Hemoglobin (Hgb) levels are less than 10.0 g/dL, prior to initiation of therapy (unless otherwise specified) AND prior to initiation of therapy, (baseline) evaluation of the individual iron status reveals, transferrin saturation at least 20% or ferritin at least 80 ng/mL or bone marrow demonstrates adequate iron stores AND For individuals with uncontrolled hypertension, blood pressure is adequately controlled before initiation of therapy and closely monitored and controlled during therapy. For MDS, endogenous erythropoietin level is less than 500 mU/ml. For anemia related to zidovudine in HIV-infected patients when the dose of zidovudine is less than or equal to 4200 mg per week, endogenous erythropoietin level is less than or equal 500 mU/ml. Reduction of Allogeneic Blood Transfusion in Pre-Operative Surgery Patients: Patient's hgb is greater than 10.0 and less than or equal to 13.0 g/dL, individual is scheduled to undergo elective, noncardiac, nonvascular surgery, individual is at high risk for perioperative transfusions with significant, anticipated blood loss, individual is unable or unwilling to donate autologous blood, Antithrombotic prophylaxis has been considered. For tx of anemia due to myelosuppressive chemotherapy known to produce anemia when the following are met: chemo is planned for a minimum of 2 months and the dx is non-myeloid cancer and the anticipated outcome is not cure. For anemia associated with CKD ON dialysis use is to achieve and maintain hgb levels within the range of 10.0 to 11.0 g/dL. For anemia associated with CKD NOT ON dialysis use is to achieve and maintain hgb levels of 10.0g/dL. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 8wk. |
| **Other Criteria** | For Hepatitis C, patient is concomitantly treated with combination of ribavirin and interferon alfa, or ribavirin and peginterferon alfa. Myelosuppressive drugs known to produce anemia in individuals with a diagnosis of chronic inflammatory disease. Allogeneic bone marrow transplantation. |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Eraxis

**Products Affected**

- ERAXIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Erbitux

**Products Affected**

- ERBITUX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Erbitux is used in combination with other anti-VEGF agents (e.g., bevacizumab). Erbitux is used in more than one line of therapy. |
| **Required Medical Information** | For stage IV, kras wild type colon, rectal, colorectal, small bowel, appendix, or anal adenocarcinoma when used as a single agent or as part of combination therapy. For squamous cell carcinoma of the Head and/or Neck cancer, Erbitux is used in combination with radiation therapy, for the treatment of locally or regionally advanced disease. Or as a single agent for the treatment of patients with recurrent or metastatic disease for whom prior platinum-based therapy has failed. Or in combination with platinum-based therapy with 5-FU (fluorouracil) as first-line treatment for individuals with recurrent locoregional disease or metastatic SCCHN. OR as a single agent or in combination therapy with or without radiation therapy for any of the following indications, unresectable locoregional recurrence or second primary in individuals who have received prior radiation therapy OR resectable locoregional recurrence in individuals who have not received prior radiation therapy OR distant metastases. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Erivedge

**Products Affected**

- ERIVEDGE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Erleada

**Products Affected**

- ERLEADA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Erwinase

**Products Affected**

- ERWINAZE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | History of serious thrombosis with prior L-asparaginase therapy. History of pancreatitis with prior L-asparaginase therapy. History of serious hemorrhagic events with prior L-asparaginase therapy. |
| **Required Medical Information** | Individual is using Erwinase as a component of a multi-agent chemotherapeutic regimen AND is using for Acute lymphoblastic lymphoma or acute lymphocytic leukemia (ALL) or Extranodal natural killer T-cell lymphoma, nasal type (ENKL). Individual has developed a documented systemic allergic reaction or anaphylaxis to prior treatment with Oncaspar (Pegaspargase). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Esbriet

**Products Affected**

- ESBRIET ORAL CAPSULE
- ESBRIET ORAL TABLET 267 MG, 801 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individuals using in combination with Ofev (nintedanib). Individuals with end-stage renal disease (ESRD). Individuals with severe hepatic impairment (child pugh class C) or end-stage liver disease. |
| **Required Medical Information** | Diagnosis of idiopathic pulmonary fibrosis (IPF) is confirmed by: Exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity AND High resolution computed tomography (HRCT) with or without surgical lung biopsy. Individual has documented pulmonary function tests within prior 60 days with a Forced Vital Capacity (% FVC) greater than or equal to 50%. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ethyol

**Products Affected**

- ETHYOL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Evekeo

**Products Affected**

- *amphetamine sulfate oral tablet 10 mg, 5 mg*
- EVEKEO ODT ORAL TABLET DISPERSIBLE 10 MG, 15 MG, 20 MG, 5 MG
- EVEKEO ORAL TABLET 10 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is using for exogenous obesity/weight loss [Exclusion from Part D]. |
| **Required Medical Information** | |
| **Age Restrictions** | 3 years of age or older for attention deficit hyperactivity disorder (ADHD). 6 years of age or older for narcolepsy. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Evenity

**Products Affected**

- EVENITY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is using Evenity (romosozumab-aqqg) in combination with any of the following: Prolia (denosumab), Bisphosphonates, Evista (raloxifene), Miacalcin/Fortical (calcitonin nasal spray), Reclast (zoledronic acid), Forteo (teriparatide), Tymlos (abaloparatide). |
| **Required Medical Information** | Osteoporosis is defined as a BMD T-Score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young adult reference population OR a Clinical diagnosis based on a history of a low trauma fracture (fragility fracture) at high risk for fracture. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Individual meets one of the following: (A) Individual has been refractory to a trial of an oral bisphosphonate therapy OR (B) Intolerance or contraindications to oral bisphosphonate as defined by having at least one of the following: 1. Hypersensitivity to TWO oral bisphosphonates (one of which must be alendronate) 2. Inability to sit or stand upright for at least 30 minutes, 3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.). 4. Uncorrected hypocalcemia. 5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate. Individual has utilized Evenity (romosozumab-aqqg) for a total duration of less than 12 months in their lifetime. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Evrysdi

**Products Affected**

- EVRYSDI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis of spinal muscular atrophy (SMA) by documentation (written or verbal attestation) of either: (A) Spinal Muscular Atrophy (SMA) diagnostic test results confirming 0 copies of SMN1 OR (B) Molecular genetic testing of 5q SMA for any of the following: (1) Homozygous gene deletion OR (2) Homozygous conversion mutation OR (3) Compound heterozygote. |
| **Age Restrictions** | Individual is 2 months of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial and Continuation 6 months. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Initial requests, individual has documentation (written or verbal attestation) of SMA-associated signs and symptoms AND (1) has documentation (written or verbal attestation) of genetic testing confirming 2 copies of SMN2 (NCT02913482) AND has documentation of symptom onset before 3 months of age (NCT02913482). OR (2) Individual is 2 years of age or older AND is non-ambulant as defined by being unable to walk unassisted for greater than or equal to 10m (NCT02908685). AND Individual does not require use of invasive ventilation or tracheostomy as a result of advanced SMA disease. For continuation, when initial therapy was determined to meet the above criteria AND individual has documentation (written or verbal attestation) of clinically significant improvement in spinal muscular atrophy-associated signs and symptoms (i.e., progression, stabilization, or decreased decline in motor function) compared to the predicted natural history trajectory of disease AND does not require use of invasive ventilation or tracheostomy as a result of advanced SMA disease. For INITIAL use following treatment with Zolgensma (onasemnogene abeparvovec-xioi): individual meets initial criteria above AND individual has experienced a decline in clinical status (for example, loss of motor milestone) since receipt of gene therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Exjade

**Products Affected**

- *deferasirox*
- EXJADE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 2 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Exondys 51

**Products Affected**

- EXONDYS 51

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has a confirmed genetic mutation of the DMD gene that is amenable to exon 51 skipping |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For initial use in the treatment of Duchenne muscular dystrophy (DMD), individual is ambulatory (with or without needing an assistive device, such as a cane or walker). For continued therapy following each 12 month period post initiation of therapy, the initial therapy has been met AND the individual remains ambulatory (with or without needing an assistive device, such as a cane or walker). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Eylea

**Products Affected**

- EYLEA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Fabrazyme

**Products Affected**

- FABRAZYME

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis of Fabry disease is confirmed with either of the following: (a) Documentation of complete deficiency or less than 5% of mean normal alpha-galactosidase A enzyme activity in leukocytes, dried blood spots or serum (plasma) analysis or (b) Documented galactosidase alpha gene mutation by gene sequencing. |
| **Age Restrictions** | Individual is 8 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has one or more symptoms or physical findings attributable to Fabry disease (ACMG), such as, but not limited to: (a) Burning pain in the extremities (Acroparesthesias) or (b) Cutaneous vascular lesions (Angiokeratomas) or (c) Corneal verticillata (whorls) or (d) Decreased sweating (anhidrosis or hypohidrosis) or (e) Personal or family history of exercise, heat, or cold intolerance or (f) Personal or family history of kidney failure. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Farydak

**Products Affected**

- FARYDAK ORAL CAPSULE 10 MG, 15 MG, 20 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Fasenra

**Products Affected**

- FASENRA
- FASENRA PEN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Evidence of asthma is demonstrated by the following (NAEPP, 2008): (a) pretreatment forced expiratory volume in 1 second (FEV1) less than 80% predicted AND (b) FEV1 reversibility of at least 12% and 200 milliliters after albuterol administration. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For Initial use, individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting beta2 -agonists, leukotriene modifiers, theophylline or oral corticosteroids) (ERS/ATS, 2013) AND has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in the individual's usual maintenance dosage of oral corticosteroids (ERS/ATS, 2013) AND has a blood eosinophil count (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection) greater than or equal to 300 cells/microliter (300 cells/mm3) at initiation of therapy. For Continuation use, treatment has resulted in clinical improvement as confirmed by one or more of the following: (a) decreased utilization of rescue medications OR (b) decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled corticosteroid dose or treatment with systemic corticosteroids) OR (c) increase in percent predicted FEV1 from pretreatment baseline OR (d) reduction in reported asthma-related symptoms, such as asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Faslodex

**Products Affected**

- FASLODEX
- *fulvestrant*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Fentora

**Products Affected**

- *fentanyl citrate buccal*
- FENTORA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using for treatment of acute or postoperative pain OR migraine headache pain OR non-cancer related pain. |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (provide diagnosis) AND has tried and failed fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking fentanyl citrate for cancer related breakthrough pain. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ferriprox

**Products Affected**

- *deferiprone*
- FERRIPROX
- FERRIPROX TWICE-A-DAY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Fetzima

**Products Affected**

- FETZIMA ORAL CAPSULE EXTENDED RELEASE 24 HOUR 120 MG, 20 MG, 40 MG, 80 MG
- FETZIMA TITRATION

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | May not be approved for treatment of fibromyalgia |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For MDD, individual has had a trial of TWO of the following: Desvenlafaxine ER, desvenlafaxine Fumerate ER, fluoxetine, fluvoxamine, escitalopram, citalopram, paroxetine, sertraline, mirtazapine, immediate-release venlafaxine, extended-release venlafaxine or bupropion. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Fintepla

**Products Affected**

- FINTEPLA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is using for weight loss/reduction OR using within 14 days of taking a monoamine oxidase inhibitor (MAOI). |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has a diagnosis of seizures associated with Dravet Syndrome AND has responded inadequately to two previous antiepileptic drugs (Lagae 2019, Wirrell 2017, Ziobro 2018). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Firazyr

**Products Affected**

- FIRAZYR
- *icatibant acetate*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Prophylaxis for HAE attacks. |
| **Required Medical Information** | HAE to be confirmed by a C4 level below the lower limit of normal (as defined by the laboratory performing the test) and either a C1 inhibitor antigenic level below the lower limit of normal (as defined by the lab performing test) or a C1 inhibitor functional level below the lower limit of normal (as defined by the lab performing the test). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a history of moderate or severe attacks (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion) and using Icatibant for acute HAE attacks. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Firdapse

**Products Affected**

- FIRDAPSE
- RUZURGI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | History of seizures or Using in combination with compounded form of 3,4 diaminopyridine |
| **Required Medical Information** | Diagnosis is confirmed by one of the following: Presence of anti-P/Q type voltage-gated calcium channel (VGCC) antibodies or Characteristic electrodiagnostic findings. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For initial requests, individual has diagnosis of Lambert Eaton myasthenic syndrome. Continued treatment with Firdapse may be approved when there is objective evidence that the individual achieved and sustained meaningful improvement in muscle strength. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Firmagon

**Products Affected**

- FIRMAGON (240 MG DOSE)
- FIRMAGON SUBCUTANEOUS SOLUTION RECONSTITUTED 120 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Used for progressive castration-naïve disease or for castration-recurrent disease OR Other advanced, recurrent, or metastatic disease. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Flector Patch

**Products Affected**

- *diclofenac epolamine*
- FLECTOR
- LICART

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is using for perioperative pain in the setting of coronary artery bypass graft (CABG) surgery. Individual is using on non-intact or damaged skin resulting from any etiology, including exudative dermatitis, eczema, infection lesions, burns or wounds. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 months |
| **Other Criteria** | Individual is using for the treatment of acute pain from one of the following: (a) Minor strain OR (b) Sprain OR (c) Contusion. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Forteo

**Products Affected**

- FORTEO
- *teriparatide (recombinant)*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is using Forteo (teriparatide) in combination with any of the following: Prolia (denosumab), Bisphosphonates, Evista (raloxifene), Miacalcin/Fortical (calcitonin nasal spray), Recalst (zolendronic acid), or Tymlos (abalaoparatide). |
| **Required Medical Information** | Osteoporosis is defined as a BMD T-Score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young adult reference population OR a Clinical diagnosis based on a history of a low trauma fracture (fragility fracture) at high risk for fracture OR associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5mg or greater of prednisone for at least 3 months) at high risk for fracture. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 2 years. Requests to continue therapy beyond 24 months (2 years) should not be approved. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Individual meets one of the following: (A) Individual has been refractory to a trial of an oral bisphosphonate therapy OR (B) Intolerance or contraindications to oral bisphosphonate as defined by having at least one of the following: 1. Hypersensitivity to TWO oral bisphosphonates (one of which must be alendronate) 2. Inability to sit or stand upright for at least 30 minutes, 3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.). 4. Uncorrected hypocalcemia. 5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Galafold

**Products Affected**

- GALAFOLD

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has severe renal impairment or end-stage renal disease. |
| **Required Medical Information** | Individual has a diagnosis of Fabry disease as confirmed with either Documentation (written or verbal attestation is acceptable) of complete deficiency or less than 5% of mean normal alpha-galactosidase A (a-Gal A) enzyme activity in leukocytes, dried blood spots or serum (plasma) analysis OR Documented (written or verbal attestation is acceptable) galactosidase alpha (GLA) gene mutation by gene sequencing. Individual has an amendable GLA gene variant based on the human embryonic kidney-293 assay. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has one or more symptoms or physical findings attributable to Fabry disease (ACMG), such as but not limited to: (a) Burning pain in the extremities (acroparesthesias), or (b) Cutaneous vascular lesions (angiokeratomas), or (c) Corneal verticillata (whorls), or (d) Decreased sweating (anhidrosis or hypohidrosis), or (e) Personal or family history of exercise, heat, or cold intolerance, or (f) Personal or family history of kidney failure. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# GamaSTAN

**Products Affected**

- GAMASTAN
- GAMASTAN S/D

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual with isolated immunoglobulin A (IgA) deficiency. Individual with severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections. Prophylaxis of viral hepatitis type B. Routine post-exposure prophylaxis or treatment of rubella, poliomyelitis, mumps, or varicella. Allergy or asthma in individuals who have normal levels of immunoglobulin. Treatment to prevent recurrent spontaneous abortion in pregnant women with a history of recurrent spontaneous abortion (ASRM 2012). |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Pre-Exposure of HAV, mbr will get IM inj prior to exposure AND mbr has no clinical manifestations of hepatitis A AND is unvaccinated (CDC 2007/2015) along with one of the following: unable to receive HAV vaccine (such as, contraindication to or unavailability of the vaccine) OR mbr is considered high-risk (such as but not limited to, travel to an endemic area, older adults, immunocompromised, or diagnosis of chronic liver disease) and will receive a simultaneous dose of HAV vaccine unless contraindicated. Post-Exposure of HAV, mbr will get IM inj within 2 weeks of exposure AND mbr has no clinical manifestations of hepatitis A AND is unvaccinated (CDC 2007/2015) along with one of the following: unable to receive HAV vaccine (such as, contraindication to or unavailability of the vaccine) OR mbr is considered high-risk (such as but not limited to, immunocompromised, diagnosis of chronic liver disease, or vaccine contraindication). For post exposure prophylaxis of rubeola, must be given within 6 days of exposure and not concomitantly with a vaccine containing the measles virus AND eligible exposed, non-immune individuals will receive a vaccine containing the measles virus greater than or equal to 6 months after receiving intramuscular immune globulin (CDC 2013) AND used in mbr considered at risk for severe disease and complications: infants or previously unvaccinated and ineligible to receive a vaccine containing the measles virus (such as, but not limited to, vaccine contraindication or an initial exposure greater than 72 hours) or no evidence of measles immunity in particular pregnant woman or severely immunocompromised individuals. For post-exposure prophylaxis of varicella infection in susceptible individuals (such as, immunocompromised) AND varicella-zoster immune globulin (human) (VZIG) and immune globulin intravenous (IGIV) are not available. For post-exposure prophylaxis administered within 72 hours of exposue to a confirmed case of rubella to modify to suppress symptoms (label, CDC 2001) AND |
| | mbr is in the early stages (first trimester) of pregnancy, and will not consider terminating the pregnancy under any circumstance. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Gamifant

**Products Affected**

- GAMIFANT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has a diagnosis of active primary active primary hemophagocytic lymphohistiocytosis (HLH) as confirmed (written or verbal attestation is acceptable) by one of the following: 1) A genetic mutation known to cause HLH or 2) A family history consistent with primary HLH or 3) Individual meets five of the following criteria: Fever, Splenomegaly, Cytopenias affecting 2 of 3 lineages in the peripheral blood (HGB less than 9g/dL (or less than 10g/dL in infants), platelets less than 100 x 10 9/L, neutrophils less than 1 x 10 9/L), Hypertriglyceridemia (fasting TG greater than or equal to 265mg/dL) and/or hypofibrinogenemia (fibrinogen less than or equal to 1.5g/L), Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy, Low or absent NK-cell activity, Ferritin greater than or equal to 500 mcg/L, Soluble CD25 greater than or equal to 2400U/mL |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual is using in combination with dexamethasone AND has had an inadequate response to, is intolerant of or has a contraindication to conventional therapy (such as etoposide, dexamethasone or cyclosporine). |
| **Indications** | All Medically-accepted Indications. |

Y0114_20_114079_I_012 December 2020

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# Gattex

**Products Affected**

- GATTEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For diagnosis of Short Bowel Syndrome (SBS) individual has been dependent on parenteral nutrition/intravenous (PN/IV) support, For at least 12 months AND requires PN at least 3 times per week. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Gauchers

**Products Affected**

- CEREZYME
- ELELYSO
- VPRIV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use of enzyme replacement therapy (ERT) agents in conjunction with one another or in conjunction with a substrate reduction therapy (SRT) agent. Use of ERT agents for the treatment of type 2 gaucher disease. |
| **Required Medical Information** | Type 1 Gaucher is confirmed by either (Weinreb 2004, Wang 2011): Deficiency in Glucocerebrosidase activity as measured in white blood cells or skin fibroblasts OR genotype tests indicating mutation of two alleles of the glucocerebrosidase genome. And indiv has clinically significant manifestations of gauchers (Andersson 2005, Weinreb 2004) including for type 1,3: [Adults] skeletal disease (such as but not limited to avascular necrosis, Erlenmeyer flask deformity, osteopenia or pathological fracture) OR presents with 2 or more of the following: clinically significant hepatomegaly/splenomegaly, hgb at least 1 gm/dl below lower limit for normal for age and sex, platelet counts less than or equal to 120,000 mm3. [Children] clinical manifestations such as but not limited to hepatomegaly, splenomegaly, anemia, thrombocytopenia, skeletal disease or growth failure (Andersson 2005) OR Type 3 gauchers is confirmed by genotype testing indicating mutation of 2 alleles of the glucocerebrosidase genome (Kaplan 2013, Wang 2011) And has clinically significant manifestations of gauchers listed above in type 1 AND Neurological findings are consistent with type 3 gaucher disease based on neurological evaluation including brain imaging[MRI or CT and EEG]. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Gavreto

**Products Affected**

- GAVRETO

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

# Gazyva

**Products Affected**

- GAZYVA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 Year |
| **Other Criteria** | Gazyva may be approved for treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma for any of the following: a) first-line in individuals without del (17p) mutation when used in combination with chlorambucil or bendamustine OR as first-line single agent in individuals who are frail or with del (17p) mutation OR as a single agent for the treatment of relapsed/refractory disease without del (17p) mutation. Approved for the treatment of follicular lymphoma when used as a component of ONE of the following combination therapies regimens and as monotherapy for up to 24 months or until disease progression, following the listed combination therapy regimens: cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP regimen) or cyclophosphamide, vincristine, and prednisone (CVP regimen) or bendamustine. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Gilenya

**Products Affected**

- GILENYA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other MS disease modifying agents (such as, Aubagio, Tecfidera, Tysabri, Ocrevus, Copaxone/Glotopa, Extavia, Rebif, Avonex, Plegridy, Betaseron). Individual has history or presence of Mobitz Type II second- or third-degree atrioventricular (AV) block or sick sinus syndrome, unless individual has a functioning pacemaker. Individual has a baseline QTc interval greater than or equal to 500 ms. Individual is being treated with Class Ia (such as quinidine, procainamide, or disopyramide) or Class III [such as amiodarone, Multaq (dronedarone), Tikosyn (dofetilide), or sotalol] anti-arrhythmic drugs. Individual has had a recent (within the past 6 months) occurrence of one of the following: Myocardial infarction, Unstable angina, Stroke, Transient ischemic attack (TIA), Decompensated heart failure requiring hospitalization, Class III/IV heart failure or individual has an active acute or chronic infection at the initiation of therapy. |
| **Required Medical Information** | I. Individual has had a trial and inadequate response or intolerance to one of the following: Avonex (interferon beta-1a), Plegridy (interferon beta-1-a), Betaseron (interferon beta-1b), Tecfidera (dimethyl fumarate), Copaxone/Glatopa (glatiramer) OR II. Individual has high disease activity despite treatment with a disease modifying drug (Aubagio, Avonex, Plegridy, Rebif, Betaseron, Extavia, Copaxone/Glatopa, Tecfidera) defined as the following: At least 1 relapse in the previous year while on therapy AND At least 9 T2-hyperintense lesions in cranial MRI OR At least 1 Gadolinium-enhancing lesion. OR III. Individual is treatment naive (no previous history of use of disease modifying drugs such as Aubagio, Avonex, Plegridy, Rebif, Betaseron, Extavia, Copaxone/Glatopa, Tecfidera) AND IV. Individual has rapidly evolving severe relapsing multiple sclerosis defined as the following: Two or more disabling relapses in 1 year AND One or more Gadolinium-enhancing lesions on brain MRI. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Gilotrif

**Products Affected**

- GILOTRIF

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Test results confirmed for individuals with metastatic non-small cell lung cancer (NSCLC) with non-resistant epidermal growth factor receptor (EGFR) mutation. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Givlaari

**Products Affected**

- GIVLAARI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has acute hepatic porphyria and confirmation (written or verbal) of one of the following subtypes (APF 2010-2019): Acute intermittent porphyria (AIP) OR Hereditary coproporphyria (HCP) OR Variegate porphyria (VP) OR ALA dehydratase-deficiency porphyria (ADP) AND documentation (written or verbal) of elevated urinary or plasma porphobiligen or delta-aminolevulinic acid within the past year (NCT03338816) AND individual has active symptomatic disease with at least 2 documented (written or verbal) porphyria attacks within the last 6 months (NCT03338816). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial: 6 months and continuance: 1 year |
| **Other Criteria** | For Continuation Therapy: Individual has experienced a clinical response to therapy (for example, a reduction in the number of porphyria attacks) AND does not have severe or clinically significant transaminase elevations defined as alanine aminotransferase (ALT) greater than 5 times the upper limit of normal (Balwani 2019). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Gleevec

**Products Affected**

- GLEEVEC ORAL TABLET 100 MG, 400 MG
- *imatinib mesylate oral tablet 100 mg, 400 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Gleostine

**Products Affected**

- GLEOSTINE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Granix

**Products Affected**

- GRANIX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use as prophylaxis for FN during concomitant chemotherapy and radiation therapy. Continued use if no response is seen within 28-42 days (individuals who have failed to respond within this time frame are considered non-responders). |
| **Required Medical Information** | Primary prophylaxis of FN in Individual that has a risk of developing FN is greater than or equal to 10% and less than of 20% based on chemotherapy regimens and individuals have any of the following risk factors for FN: Individual age greater than 65 years, Poor performance status, Bone marrow involvement by tumor producing cytopenias, persistent neutropenia (ANC less than 1500mm3), poor renal function (GFR less than 60mL/min), liver dysfunction, recent surgery and/or presence of open wounds. Individual has not received prophylactic therapy with granulocyte colongy stimulating factor AND has a high-risk for infection associated complications as demonstrated by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10to the power of 9/L) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infections, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, prior episode of febrile neutropenia or Hospitalized at the time of the development of fever. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Individual has trial and inadequate response to Zarxio (filgrastim-sndz). Individual is using to mobilize progenitor cells into peripheral blood for collection by leukapheresis as adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Grastek

**Products Affected**

- GRASTEK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Severe, unstable or uncontrolled asthma. History of any severe systemic allergic reaction. History of eosinophilic esophagitis. Or, individual is receiving concomitant therapy with other allergen immunotherapy products. |
| **Required Medical Information** | For grass pollen induced allergic rhinitis, individual has a confirmed (verbal or written attestation) positive skin test OR positive in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. Individual has had a trial of, and inadequate symptom control or intolerance to (1) nasal steroid and (1) non-sedating antihistamine AND individual has a confirmed (verbal or written attestation) prescription for an auto-injectable epinephrine product. |
| **Age Restrictions** | Individual is between the ages of 5 years and 65 years old. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Treatment is initiated at least 12 weeks before the expected onset of grass pollen season and is continued throughout the season. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Haegarda

**Products Affected**

- HAEGARDA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Hereditary angioedema (HAE) is confirmed by a C4 level below the lower limit of normal as defined by the laboratory performing the test AND ANY of the following (a, b, or c): (a) C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test or (b) C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test or (c) Presence of a known HAE-causing C1-INH mutation. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a history of moderate or severe attacks and is using Haegarda as prophylaxis for short-term use prior to surgery, dental procedures or intubation OR for long-term prophylaxis and individual has failed, or is intolerant to, or has contraindication to 17-alpha-alkylated androgens or antifibrinolytic agents. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Halaven

**Products Affected**

- HALAVEN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Halven is used as a single agent and in a single line of therapy for recurrent or metastatic breast cancer. Member has previously received at least two chemotherapeutic regimens for locally recurrent or metastatic disease. Individual is using in combination with trastuzumab (Herceptin) in the treatment of locally recurrent or metastatic HER2+ breast cancer with: (a) Symptomatic visceral disease OR (b) Either hormone receptor-negative disease or hormone receptor-positive and endocrine refractory disease. For soft tissue sarcoma, agent is used as a single agent in a single line of therapy and has previously received at least 2 chemotherapeutic regimens for locally recurrent or metastatic disease. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Harvoni

**Products Affected**

- HARVONI
- *ledipasvir-sofosbuvir*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Documentation is provided for a diagnosis of chronic Hepatitis C virus (CHC) infection, which includes Genotype and a positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Hepsera

**Products Affected**

- *adefovir dipivoxil*
- HEPSERA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 12 years of age and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had a previous trial and inadequate response or intolerance to or has a contraindication to an alternative antiviral agent with a higher genetic barrier to resistance for Hepatitis B [such as entecavir or tenofovir] (AASLD 2016). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Hetlioz

**Products Affected**

- HETLIOZ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Horizant

**Products Affected**

- HORIZANT ORAL TABLET EXTENDED RELEASE 300 MG, 600 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For diagnosis post herpetic neuralgia (PHN), individual has had a trial of immediate release gabapentin. For diagnosis restless leg syndrome (RLS) individual has has had a trial of or contraindication/intolerance to either pramipexole OR Ropinirole. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# HP Acthar

**Products Affected**

- ACTHAR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | All other uses except those listed under Other Criteria section. |
| **Required Medical Information** | |
| **Age Restrictions** | For West Syndrome, infant or child less than 2 years of age. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 month |
| **Other Criteria** | Individual is using for infantile spasm (West Syndrome). |
| **Indications** | Some FDA-approved Indications Only. |
| **Off Label Uses** | |

# HRM Age

**Products Affected**

- *amitriptyline hcl*
- *amoxapine*
- ANAFRANIL
- *chlordiazepoxide-amitriptyline*
- *clomipramine hcl*
- *desipramine hcl*
- *doxepin hcl oral capsule*
- *doxepin hcl oral concentrate*
- *imipramine hcl*
- *imipramine pamoate*
- NEMBUTAL
- NORPRAMIN
- *nortriptyline hcl*
- PAMELOR
- *pentobarbital sodium*
- *perphenazine-amitriptyline*
- *phenobarbital oral elixir*
- *phenobarbital oral solution*
- *phenobarbital oral tablet 100 mg, 15 mg, 16.2 mg, 30 mg, 32.4 mg, 60 mg, 64.8 mg, 97.2 mg*
- *phenobarbital sodium*
- *protriptyline hcl*
- TOFRANIL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Prescriber must acknowledge this is a high risk medication (HRM) (as identified by American Geriatric Society) for individuals greater than 65 and medication benefits outweigh potential risk for this individual. |
| **Age Restrictions** | Individuals that are 64 years of age or younger are NOT subject to the prior authorization requirements. Prior Authorization applies to individuals that are 65 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# HRM Age AU

**Products Affected**

- ACTIVELLA
- ALLZITAL
- ALORA
- *amabelz*
- AMBIEN
- AMBIEN CR
- AMRIX
- AMYTAL SODIUM
- ANGELIQ
- ARMOUR THYROID
- ASCOMP-CODEINE
- *benztropine mesylate oral*
- BIJUVA
- BONJESTA
- BUPAP
- *butalbital-acetaminophen*
- *butalbital-apap-caff-cod*
- *butalbital-apap-caffeine*
- *butalbital-asa-caff-codeine*
- *butalbital-asa-caffeine*
- *butalbital-aspirin-caffeine*
- BUTISOL SODIUM
- *carbinoxamine maleate*
- *carisoprodol*
- *carisoprodol-aspirin*
- *carisoprodol-aspirin-codeine*
- *chlordiazepoxide-clidinium*
- *chlorzoxazone oral tablet 250 mg, 500 mg*
- CHLORZOXAZONE ORAL TABLET 375 MG, 750 MG
- *clemastine fumarate*
- CLIMARA
- CLIMARA PRO
- COMBIPATCH
- *cyclobenzaprine hcl*
- *cyclobenzaprine hcl er*
- *cyproheptadine hcl*
- DEMEROL
- *dexchlorpheniramine maleate*
- DICLEGIS
- *digitek oral tablet 250 mcg*
- *digox oral tablet 250 mcg*
- *digoxin injection*
- *digoxin oral tablet 250 mcg*
- *diphenhydramine hcl oral*
- *dipyridamole oral*
- *disopyramide phosphate*
- DIVIGEL
- DOTTI
- *doxepin hcl oral tablet*
- *doxylamine-pyridoxine*
- EDLUAR
- ELESTRIN
- *ergoloid mesylates*
- ESGIC
- ESTRACE ORAL
- *estradiol oral*
- *estradiol transdermal patch twice weekly*
- *estradiol transdermal patch weekly*
- *estradiol-norethindrone acet*
- ESTROGEL
- EVAMIST
- FEMHRT LOW DOSE
- FEXMID
- FIORICET
- FIORICET/CODEINE
- FIORINAL
- FIORINAL/CODEINE #3
- *fyavolv*
- *glyburide micronized oral tablet 1.5 mg, 3 mg, 6 mg*
- *glyburide oral tablet 1.25 mg, 2.5 mg, 5 mg*
- *glyburide-metformin oral tablet 1.25-250 mg, 2.5-500 mg, 5-500 mg*
- GLYNASE ORAL TABLET 1.5 MG, 3 MG, 6 MG
- *guanfacine hcl*
- *hydroxyzine hcl*

- *hydroxyzine pamoate*
- INDOCIN ORAL
- *indomethacin*
- *indomethacin er*
- INTERMEZZO
- *jinteli*
- KARBINAL ER
- *ketorolac tromethamine injection*
- *ketorolac tromethamine intramuscular*
- *ketorolac tromethamine oral*
- LANOXIN INJECTION
- LANOXIN ORAL TABLET 187.5 MCG, 250 MCG
- *levothyroxine-liothyronine*
- LIBRAX
- *lopreeza*
- LORZONE
- MEGACE ES
- *megestrol acetate oral suspension 625 mg/5ml*
- MENEST
- MENOSTAR
- *meperidine hcl injection*
- *meperidine hcl oral solution*
- *meperidine hcl oral tablet*
- *meprobamate*
- METAXALL
- *metaxalone*
- *methocarbamol*
- *methyldopa*
- *methyldopa-hydrochlorothiazide*
- *mimvey*
- *mimvey lo*
- MINIVELLE
- MOTOFEN
- *nifedipine*
- *norethindrone-eth estradiol*
- *norgesic forte*
- NORPACE
- NORPACE CR
- *np thyroid*
- *orphenadrine citrate*
- *orphenadrine citrate er*
- *orphenadrine-asa-caffeine*
- *orphenadrine-aspirin-caffeine*
- ORPHENGESIC FORTE
- *pentazocine-naloxone hcl*
- PHENADOZ
- PHENERGAN
- PHRENILIN FORTE
- PREFEST
- PREMARIN ORAL
- PREMPHASE
- PREMPRO
- PROCARDIA
- *promethazine hcl*
- *promethazine vc plain*
- *promethazine-phenylephrine*
- PROMETHEGAN
- *propantheline bromide*
- ROBAXIN
- ROBAXIN-750
- RYCLORA
- RYVENT
- SECONAL
- SILENOR
- SKELAXIN
- SOMA
- TENCON
- *thyroid oral tablet 120 mg, 15 mg, 30 mg, 60 mg, 90 mg*
- THYROID ORAL TABLET 65 MG
- *trihexyphenidyl hcl*
- VANADOM
- VANATOL LQ
- VANATOL S
- VISTARIL
- VIVELLE-DOT
- VTOL LQ
- ZEBUTAL
- *zolpidem tartrate*
- *zolpidem tartrate er*
- ZOLPIMIST

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Prescriber must acknowledge this is a high risk medication (HRM) (as identified by American Geriatric Society) for individuals greater than 65 and medication benefits outweigh potential risk for this individual. |
| **Age Restrictions** | Individuals that are 64 years of age or younger are NOT subject to the prior authorization requirements. Prior Authorization applies to individuals that are 65 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Human Growth Hormone

**Products Affected**

- NORDITROPIN FLEXPRO
- OMNITROPE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use of GH tx when applicable criteria have not been met may not be approved for, but not limited to, the following: Renal transplant, Anabolic tx, except for AIDS, provided to counteract acute or chronic catabolic illness (e.g. surgery, trauma, cancer,chronic hemodialysis) producing catabolic (protein wasting) changes in both adult and ped. Anabolic tx to enhance body mass or strength for professional, recreational or social reasons, Constitutional delay of growth and development. Cystic fibrosis, GH Tx in combo with GnRH agonist (Lupron-leuprolide) as a Tx of precocious puberty. Hypophosphatemic rickets, osteogenesis imperfecta, osteoporosis, Short Stature associated with GH insensitivity (Laron Syndrome). Therapy in older adults with normally occurring decrease in GH, who are not congenitally GH deficient and who have no evidence of organic pituitary dz (this is referred to as age-related GH deficiency). Tx of CHF, burn patients, fibromyalgia, glucocorticoid-induced growth failure. Tx of HIV lipodystrophy (fat redistribution syndrome), also referred to as altered body habitus (e.g. buffalo hump), associated with antiviral therapy in HIV-infected patients. Tx of intrauterine growth restriction (IUGR)or Russell-Silver Syndrome that does not result in SGA. Tx of obesity. Other etiologies of SS where GH has not been shown to be associated with an increase in final height, including but not limited to achondrodoplasia and other skeletal dysplasias. GH tx used for reconstruction should not continue when BA =16 yr (M), or = 14 yr (F) is reached OR Epiphyseal fusion has occurred OR Mid-parenteral height is achieved. Child over 12: an X-ray report with evidence that epiphyses have closed or SMR of 3 or more. |

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | Initial Requests, For idiopathic GHD, has signs/sym of GHD, GV 2 SD below age-appropriate mean or ht 2.25 SD below age-appropriate mean and A subnormal (SubNL) response (less than10ng/ml)to 2GH stim tests OR Neonates with hypoglycemia and clinical/hormone evidence of hypopit and low GH (less than 10ng/ml)OR 2other pit hormone deficiencies and low IGF-1 OR mbr has cranial irradiation with low IGF1 and normal thyroid tests.Child born SGA(birth wt or length 2 or more SD below the mean for gest age),Child fails to manifest catch up growth by age 2 yr(ht 2 or more SD below the mean for age,gender)AND Other causes for SS have been ruled out.Transitioning adolescent: completed linear growth(growth rate of less than 2cm/yr) AND either of the following: A)GH tx has been stopped at least a month and GHD reconfirmed by: 1)idiopathic isolated GHD(SubNL response to 2 GH stim tests OR SubNL response (GH conc of less than10 ng/mL)to 1 provocative test and low IGF-I/IGFBP-3) OR 2)multiple pit hormone deficiency,(SubNL response to 1 provocative GH test and/or low IGF-I/IGFBP-3)or 3) with cranial irradiation, low IGF with normal thyroid OR B) any of the following:known genetic mutation assoc with def GH production/secretion or Hypothalamic-pit tumor/structural defect or 3 other pit hormone deficiencies.Adult GHD confirmed/reconfirmed:SubNL response in adults to 2 GH stim tests (GH conc of less than or equal to 5ng/ml when using insulin induced hypoglycemia OR GH conc of less than or equal to 4.1ng/ml when using arginine)OR SubNL response to 1 stim test for adults with hypothalamic or pit dz and 1 pit hormone deficits OR 3 other pit hormone deficiencies.Initial requests for therapy in child: Reconstructive GH tx may be approved if either mean ht is at least 2.25 but less than 2.5SD below the mean for age, gender and GV is less than the 10th percentile over 1yr OR mean ht is at least 2.5SD below the mean for age, gender for conditions known responsive to GH. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Continuation therapy in child (including reconstructive tx) when following are met: individ evaluated AND growth rate remains above 2.5cm/year (does not apply to children with prior documented hypopituitarism)(Grimberg2016). GH may be approved for Adolescents with childhood onset GHD who have completed linear growth. Treatment with GH in other populations approved when: Individual has AIDS wasting syndrome, defined as greater than 10% of baseline wt loss that cannot be explained by a concurrent illness other than HIV infection AND is being tx with antiviral therapy AND continues tx until above definition is no longer met OR individual dx with short bowel syndrome AND is receiving specialized nutritional support. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Humira

**Products Affected**

- HUMIRA PEDIATRIC CROHNS START SUBCUTANEOUS PREFILLED SYRINGE KIT 40 MG/0.8ML, 40 MG/0.8ML (6 PACK), 80 MG/0.8ML, 80 MG/0.8ML & 40MG/0.4ML
- HUMIRA PEN
- HUMIRA PEN-CD/UC/HS STARTER SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.8ML, 80 MG/0.8ML
- HUMIRA PEN-PS/UV/ADOL HS START SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.8ML, 80 MG/0.8ML & 40MG/0.4ML
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 10 MG/0.2ML, 20 MG/0.2ML, 20 MG/0.4ML, 40 MG/0.4ML, 40 MG/0.8ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using adalimumab in combination with other TNF agents, JAK inhiitors, or other biologic drugs (such as, Abatacept, anakinra or vedolizumab). Tuberculosis or other active serious infections or a history of recurrent infections. Individuals who have not had a tuberculin skin test or CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating adalimumab. |
| **Required Medical Information** | For Chronic moderate to severe plaque psoriasis with either of the following: Patient has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia) AND agent is used to reduce signs/symptoms OR to induce/maintain clinical response. |
| **Age Restrictions** | Patient is 18 years of age or older for all indications except JIA, non-infectious Uveitis, Hidradenitis Suppurativa (HS) and Crohns disease. Patient must be at least 2 years old for JIA and non-infectious uveitis. Patient must be at least 6 years of age for Crohns disease. Patient must be at least 12 years old for HS. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For moderate to severe RA, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy [nonbologic DMARDs (such as methotrexate, sulfasalazine, leflunomide, or hydroxylchloroquine)] (ACR 2015). For moderate to severe Psoriatic Arthritis, individual has had an inadequate response to, is intolerant of, has medical contraindication to ONE conventional therapy [non-biologic DMARDs (such as methotrexate, sulfasalazine or leflunomide)]. For moderate to severe Ankylosing Spondylitis (AS), individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine). For moderate to severe Crohn's disease, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (e.g. 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressants). For chronic moderate to severe plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to phototherapy or ONE other systemic therapy (e.g. methotrexate, acitretin, or cyclosporine). For moderate to severe Polyarticular Juvenile Idiopathic Arthritis (PJIA), individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy [nonbologic DMARDs (such as methotrexate)] (ACR 2011). For moderate to severe Ulcerative Colitis (UC), individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as 5-ASA products, Sulfasalazine, systemic corticosteroids, or immunosuppressive drugs). For uveitis, individual has chronic, recurrent, treatment-refractory or vision-threatening disease and has had an inadequate response to, is intolerant of, or has a medical contraindication to conventional therapy (such as corticosteroids or immunosuppressive drugs [azathioprine, cyclosporine, or methotrexate]). For chronic, |

| PA Criteria | Criteria Details |
|---|---|
| | progressive, treatment-refractory Sarcoidosis (Sweiss 2014), individual has had an inadequate response to, is intolerant of or has a contraindication to systemic corticosteroids AND nonbiologic DMARDs (such as methotrexate or azathioprine). For moderate to severe Hidradenitis Suppurativa (Hurley stage II or Hurley stage III disease) AND has had an inadequate response to, is intolerant of, or has a medical contraindication to conventional therapy (such as oral antibiotics). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Humulin U500

**Products Affected**

- HUMULIN R U-500 (CONCENTRATED)
- HUMULIN R U-500 KWIKPEN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | For use as a continuous subcutaneous infusion. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has a diagnosis of diabetes mellitus AND requires more than 200 units of insulin per day. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ibrance

**Products Affected**

- IBRANCE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Iclusig

**Products Affected**

- ICLUSIG ORAL TABLET 15 MG, 45 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Idhifa

**Products Affected**

- IDHIFA ORAL TABLET 100 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has confirmed (written or verbal attestation) isocitratedehydrogenase-2 (IDH2) mutation. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ilaris

**Products Affected**

- ILARIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Tuberculosis, invasive fungal infection, other active serious infection, or a history of recurrent infection. Individual who have not had a tuberculin skin test or a CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating Ilaris (canakinumab). Using Ilaris in combination with other biologic disease-modifying antirheumatic drugs (DMARDs), such as, tumor necrosis factor (TNF) antagonists, IL-1R antagonists, Janus kinase inhibitors (for example, tofacitinib citrate), selective co-stimulation modulators or IL-6 receptor antagonists. |
| **Required Medical Information** | |
| **Age Restrictions** | For cryopyrin-associated periodic syndromes age 4 years and older and for systemic juvenile idiopathic arthritis 2 years of age and older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | FFor SIJA, individual has had an inadequate response to, intolerant of, or has a medical contraindication to ONE corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs) AND may be used alone or in combination with corticosteroids, methotrexate or NSAIDs. For FMF, individual has active type 1 FMF disease with genetic confirmation of the diagnosis (MEFV gene exon 10 mutation) and confirmed recurrent, active disease (that is, at least one flare per month) and has failed to respond to, or is intolerant of colchicine therapy. For HIDS/MKD, individual has HIDS with genetic confirmation of the diagnosis by deoxyribonucleic acid (DNA) analysis or enzymatic studies (that is, mutations in the MVK gene or markedly reduced mevalonate kinase activity) and confirmed prior history of greater than or equal to three febrile acute flares within a 6-month period when not receiving prophylactic treatment. For TRAPS, genetic confirmation of the diagnosis (TNFRSF1A gene mutation) and has chronic or recurrent disease activity defined as six flares in a 12-month period. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ilumya

**Products Affected**

- ILUMYA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using in combination with other biologic drugs or phototherapy. Tuberculosis, other active serious infections, or a history of recurrent infections. Individual has not had a tuberculin skin test or a Centers for Disease Control and Prevention-recommended equivalent test to evaluate for latent tuberculosis prior to initiating Ilumya. |
| **Required Medical Information** | Diagnosis of moderate to severe plaque psoriasis with either of the following: Patient has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For of chronic plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine) AND individual has had a trial of and an inadequate response or is intolerant to Humira (adalimumab) OR Enbrel (etanercept). For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Ilumya or (b) Individuals age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Ilumya may be allowed without trial of preferred TNF agents (Enbrel/Humira). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Imbruvica

**Products Affected**

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG, 560 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Imfinzi

**Products Affected**

- IMFINZI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | History of immunodeficiency or severe autoimmune disease. Requires systemic immunosuppression, active immune-medicated disease, severe or life-threatening infections or untreated central nervous system (CNS) metastases. Has received treatment with another anti-PD-1 or anit-PD-L1 agent. |
| **Required Medical Information** | For locally advanced or metastatic urothelial carcinoma, Inoperable or metastatic transitional-cell urothelial carcinoma histologically or cytologically confirmed. For locally advanced, unresectable non-small cell lung cancer, histologically or cytologically confirmed stage III and current Eastern Cooperative Oncology Group performance status 0-2. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has inoperable or metastatic urothelial carcinoma AND Either the disease has progressed during or following platinum-containing therapy OR disease has progressed within 12 months of neoadjuvant or adjuvant treatment with platinum-containing therapy. For locally advanced, unresectable non-small cell lung cancer (NSCLC), disease has not progressed after definitive chemoradioation and disease has progressed or individual has reached a maximum of 12 months of treatment. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

Y0114_20_114079_I_012 December 2020

# Imlygic

**Products Affected**

- IMLYGIC

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is immunocompromised. Individual is pregnant. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has diagnosis of unresectable melanoma AND is using as intralesional treatment for one of the following: a) Stage III disease with clinical or satellite/in-transit metastases b) Local satellite recurrence of disease c) in-transit recurrence of disease. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Increlex

**Products Affected**

- INCRELEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has suspected or known malignancy. Individual has closed. Individual has of secondary IGF-1 deficiency (for example, due to GH deficiency, untreated malnutrition, untreated hypothyroidism). |
| **Required Medical Information** | For initial treatment of growth failure associated with severe primary IGF-1 deficiency as defined by: Height standard deviation score of less than or equal to -3.0 AND Basal IGF-1 standard deviation score of less than or equal to -3.0 AND normal or elevated growth hormone levels (greater than 10ng/mL on standard GH stimulation tests) are present OR GH gene deletion who have development of neutralizing antibodies to GH. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For Continuation of treatment with Increlex (mecasermin), Growth velocity is greater than or equal to 2cm (greater than equal to 2.0 cm) total growth in 1 year AND Final adult height has not been reached. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ingrezza

**Products Affected**

- INGREZZA ORAL CAPSULE 40 MG, 80 MG
- INGREZZA ORAL CAPSULE THERAPY PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Has congenital long QT-syndrome or arrhythmia associated with a prolonged QT interval. Individual is currently using a strong CYP 3A4 inducer (examples, rifampin, carbamazepine, phenytoin, St. John's wort). Individual is currently using a monoamine oxidase inhibitor (MAOI) (examples, isocarboxazid, phenelzine, selegiline) |
| **Required Medical Information** | Tardive dyskinesia confirmed by the following (DSM-5): A) At least 60 days of stable (drug, dose) medication exposure (either typical or first generation antipsychotic agents [such as, chlorpromazine, haloperidol, fluphenazine], atypical or second-generation antipsychotic agents [such as, clozapine, risperidone, olanzapine, quetiapine, aripiprazole], or certain dopamine receptor-blocking used in treatment of nausea and gastroparesis [such as prochlorperazine, promethazine, metoclopramide] AND B) Presence of involuntary athetoid or choreiform movements lasting at least 30 days. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Requests for continuation of therapy may be approved for individuals who meet the following criteria: Individual has experienced an improvement in symptoms deemed to be clinically significant by the provider. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Inlyta

**Products Affected**

- INLYTA ORAL TABLET 1 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Inqovi

**Products Affected**

- INQOVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Inrebic

**Products Affected**

- INREBIC

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Interferons for MS

**Products Affected**

- AVONEX
- AVONEX PEN
- AVONEX PREFILLED
- BETASERON
- PLEGRIDY
- PLEGRIDY STARTER PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individuals with primary progressive MS. Individuals with secondary progressive MS without relapsing disease. Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, tecfidera, tysabri, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavoa. Rebif, Avonex, Plegridy or Betaseron). |
| **Required Medical Information** | Individual has experienced a first clinical episode and has MRI features consistent with multiple sclerosis OR Individual has a diagnosis of relapsing multiple sclerosis (RMS) OR Individual has secondary progressive MS (SPMS) with a history of superimposed relapses (AHFS). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Intuniv

**Products Affected**

- *guanfacine hcl er*
- INTUNIV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual is using for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD). |
| **Age Restrictions** | Individual is 6 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Istodax

**Products Affected**

- ISTODAX (OVERFILL)
- *romidepsin*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Isturisa

**Products Affected**

- ISTURISA ORAL TABLET 1 MG, 10 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# ITRACONAZOLE

**Products Affected**

- *itraconazole oral capsule*
- SPORANOX ORAL CAPSULE
- SPORANOX PULSEPAK
- *tolsura*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | For fingernail/toenail onychomycosis 12 weeks. For all other indications 1 year. |
| **Other Criteria** | For second-line non-onychomycosis indications include tinea infections (including, but limited to tinea versicolor, tinea cruris, tinea corporis, tinea pedis, tinea manuum, and tinea capitis) where the individual has received at least one prior topical therapy: clotrimazole, ketoconazole, econazole, or nystatin. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# IVIG

**Products Affected**

- GAMUNEX-C
- OCTAGAM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Hyperimmunoglobulinemia E synd when dx is evidenced by high level of serum IgE. Autoimmune mucocutaneous blistering dx when mbr had inadeq response/intolerance/contraindication to other tx such as corticosteroids,immunosuppressants. For autoimmune neutropenia, active INFECT is excluded as cause. For tx of 1 neurologic DZ: A) Lambert-Eaton myasthenic syndrome when having muscle weakness AND dx confirmed w/characteristic electrodiagnostic (ED) finding using nerve conduction tests, repetitive nerve stimulation (RNS), exercise testing or single fiber electromyography (SFE) or presence of antibodies (AB) directed against voltage-gated Ca channels B) Myasthenia Gravis (MG) and dx confirmed by presence of AB against the acetylcholine receptor or muscle specific tyrosine kinase or characteristic ED findings using RNS or SFE AND using for worsening sx or exacerbation or short-term therapy as immunosuppressive tx is taking effect or MAINT therapy of MG when mbr had inadeq response/intolerance/contraindication to other tx such as steroids, immunosuppressants C) Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), as INIT trial up to 12wks when muscle weakness or sensory dysfx is caused by neuropathy in more than 1 limb and nerve conduction studies or diagnostic criteria confirm evidence of demyelinating neuropathy and other polyneuropathies. For cont use of CIDP, clinically sig improvement in neurological sx on exam and cont need is shown by attempts on annual basis to titrate dose or interval of therapy result in sx worsening. As INIT exam(up to 12wks), clinical presentation w/electrodiagnostic test confirm MMN. For MMN cont use, mbr had improvement in strength and fx and need shown by attempts annually to titrate dose or interval therapy results in worse sx. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Tx of primary humoral immunprimaryodeficiency (PI) when hx of recurrent sinopulmonary infection (SI) req ABX tx AND lack of/inadeq response to immunization AND no evidence of renal (nephrotic synd) and GI as causes of hypogammaglobulinemia (HGG) AND INIT pre-tx total serum IgG below the lower limit of age adj lab ref range or more than 2SD below adj mean. hyperimmunoadj mean AND hx of recurrent SI requiring ABX therapy AND lack of/inadeq response to immunization OR Use for ONE: A) B-cell CLL w/ hx of recurrent bacterial or active INFECT not responding to antimicrobial therapy and HGG w/ total IgG less than 500mg/dL B)Multiple myeloma with hx of recurrent bacterial or clinically severe INFECT and HGG with total IgG less than 500mg/dL C) HIV infected children to prevent opportunistic bacterial infection w/HGG (IgG less than 400mg/dL) or recurrent INFECT D) PARVO B19 chronic INFECT and severe anemia assoc w/bone marrow suppression OR using in context of transplant for ONE: 1) hematopoietic stem cell transplant 2) Solid organ transplantation including prior desensitization for transplantation for suppression of panel reactive anti-HLA antibody (AB) in ppl with high panel reactive AB (PRA) levels to human leukocyte antigens OR Transplant recipients at risk of CMV 3) Transplant recipients experiencing AB-mediated rejection w/ donor-specific AB OR for tx of ONE autoimmune DZ: A) ITP w/either active bleed or platelet count less than 30,000 mcL B) Fetal alloimmune TCP w/AB to paternal platelet antigen in maternal serum and ONE: Previously affected PREG, family hx of maternofetal alloimmune TCP or fetal blood sample shows TCP C) Isoimmune hemolytic dx of newborn, tx of severe hyperbilirubinemia D) Dermatomyositis (DMM) or polymyositis when mbr had inadeq response/intolerance/contraindication to other tx,e.g., corticosteroids, immunosuppressive agents AND Dx confirmed having at least 4 sx: weak trunk/proximal extremities, high serum CK or aldolase levels, unexplainable muscle pain, electromyography |

| PA Criteria | Criteria Details |
|---|---|
| | findings, anti-Jo-1 AB, arthralgia/arthritis w/out joint destruction, sign of systemic inflamm, e.g.,fever/elevated C-reactive protein/high SED rate or inflamm myositis seen on muscle biopsy AND using for DMM and skin lesions present. For 1 MISC DX: post-exposure prophylaxis to stop measles, give in 6dys of exposure (not w/VACC having measles virus), eligible/exposed/non-immune mbr will get a VACC w/measles virus greater than/equal to 8 mth after Ig admin and used in mbrs at risk of severe dx/complications and no evidence of measles immunity in PREG or severely immunocompromised ppl OR for Kawasaki Dz tx initiated w/in 10dys of onset and tx for more than 5dys. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ixempra

**Products Affected**

- IXEMPRA KIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Jadenu

**Products Affected**

- *deferasirox*
- *deferasirox granules*
- JADENU
- JADENU SPRINKLE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | For dx non-transfusion-dependent thalassemia (NTDT) syndrome, 10 years of age or older. For dx of chronic iron overload, 2 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Jakafi

**Products Affected**

- JAKAFI ORAL TABLET 10 MG, 15 MG, 20 MG, 25 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Jetrea

**Products Affected**

- JETREA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | "Individual has any of the following: Proliferative diabetic retinopathy, Neovascular age-related macular degeneration, Retinal vascular occlusion, Aphakia, High myopia (more than ?8 diopters), Uncontrolled glaucoma, Macular hole greater than 400 ?m in diameter, Vitreous opacification, Lenticular or zonular instability, History of retinal detachment in either eye, Prior vitrectomy in the affected eye, Prior laser photocoagulation of the macula in the affected eye, Prior treatment with ocular surgery, intravitreal injection or retinal laser photocoagulation in the previous 3 months." |
| **Required Medical Information** | Posterior segment optical coherence tomography (OCT) demonstrates all of the following: there is vitreous adhesion within 6-mm of the fovea (center of macula) AND elevation of the posterior vitreous cortex (outer layer of the vitreous). Individual has best-corrected visual acuity of 20/25 or worse in the eye to be treated with ocriplasmin. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Jevtana

**Products Affected**

- JEVTANA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For hormone-refractory metastatic prostate cancer, individual has a Eastern Cooperative Oncology Group (ECOG) performance status is 0-2. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Juxtapid

**Products Affected**

- JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 40 MG, 5 MG, 60 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has a clinical diagnosis of homozygous familial hypercholesterolemia (HoFH), based on the presence of the following (Cuchel 2014, Singh 2015): (A) Genetic confirmation of two (2) mutant alleles at the LDL receptor, apoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene locus OR (B) One of the following: 1. an untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) OR 2. Treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) AND one of the following: (i) cutaneous or tendonous xanthoma before age of 10 years OR (ii) untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than 190 mg/dL). |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had an adequate trial and titration of Repatha and achieved suboptimal lipid lowering response. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Jynarque

**Products Affected**

- JYNARQUE ORAL TABLET
- JYNARQUE ORAL TABLET THERAPY PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has an uncorrected abnormal blood sodium level or urinary outflow obstruction OR unable to sense or appropriately respond to thirst OR has dx of hypovolemia OR is anuric OR has underlying significant liver disease (not including uncomplicated polycystic liver disease) OR will be concurrently utilizing a strong CYP3A inhibitor (such as clarithromycin, ketoconazole, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir or nefazodone) |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Kadcyla

**Products Affected**

- KADCYLA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Tumor(s) have been evaluated with an assay validated to predict HER2 positive (HER2+) protein overexpression. Individuals are considered HER2 positive (HER2+) as documented by one of the following, immunohistochemistry (IHC) 3+ or In Situ hybridization (ISH) positive by any of the following: Single probe average HER2 copy number greater than or equal to 6.0 signals/cell OR Dual-probe HER2/CEP 17 ratio greater than or equal to 2.0 OR Dual-probe HER2/CEP 17 ratio less than 2.0 with an average HER2 copy number greater than or equal to 6.0 signals/cell. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For metastatic breast cancer, individual has previously received trastuzumab and a taxane, separately or in combination. AND has either received prior therapy for metastatic disease OR developed disease recurrence during or within six (6) months of completing adjuvant therapy. Kadcyla is only used in a single line of therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Kalbitor

**Products Affected**

- KALBITOR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Prophylaxis for HAE attacks. |
| **Required Medical Information** | HAE to be confirmed by a C4 level below the lower limit of normal (as defined by the laboratory performing the test) and either a C1 inhibitor antigenic level below the lower limit of normal (as defined by the lab performing test) or a C1 inhibitor functional level below the lower limit of normal (as defined by the lab performing the test). |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a history of moderate or severe attacks (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion) and using Kalbitor for acute HAE attacks. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Kalydeco

**Products Affected**

- KALYDECO ORAL PACKET
- KALYDECO ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using Kalydeco (ivacaftor) monotherapy, without concurrent use of lumacaftor or tezacaftor, for the F508del mutation in the CFTR gene. |
| **Required Medical Information** | Individual has a diagnosis of cystic fibrosis (CF). Individual has confirmed (verbal or written attestation) mutation positive result in the cystic fibrosis membrane conductance regulator (CFTR) gene. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Kanuma

**Products Affected**

- KANUMA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis has been confirmed by one of the following: (1) A dried blood spot (DBS) test demonstrating deficient lysosomal acid lipase (LAL) activity or (2) Documented molecular genetic test revealing mutations in the lipase A, lysosomal acid type (LIPA) gene. |
| **Age Restrictions** | For diagnosis of lysosomal acid lipase deficiency (LAL-D) disorder [also known as Wolman disease (WD)], individual is equal to or less than 4 year of age. For diagnosis of LAL-D disorder [also known as cholesteryl ester storage disease (CESD)], individual is greater than 4 years of age. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial request: 6 months, Maintenance: 1 year |
| **Other Criteria** | FFor diagnosis of LAL-D disorder [also known as cholesteryl ester storage disease (CESD)], Individual has a baseline alanine aminotransferase (ALT) level greater than or equal to 1.5 times the upper limit of normal (ULN). Maintenance therapy requests for Kanuma (sebelipase alfa) may be approved if the following criteria are met: Individual has had clinical improvement in symptoms and/or lab values. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Keveyis

**Products Affected**

- KEVEYIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a diagnosis of hepatic insufficiency OR severe pulmonary obstruction OR a known hypersensitivity to sulfonamides OR individual is concurrently using high-dose aspirin. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 3 months, renewal 1 year |
| **Other Criteria** | For initial therapy, individual experiences greater than or equal to one episode of muscle weakness per week. For continuation therapy individual has provided written or verbal attestation that the individual has achieved and sustained clinically significant improvement in the number of episodes of muscle weakness experienced per week. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Kevzara

**Products Affected**

- KEVZARA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using in combination with other biologic disease modifying anti-rheumatic drugs such as anti-CD20 monoclonal antibodies, IL-1R antagonists, selective co-stimulation modulators, or tumor necrosis factor antagonists. At initiation of therapy, absolute neutrophil count less than 2000/mm3 , platelet count less than 150,000/mm3 , alanine aminotransferase or aspartate aminotransferase greater than 1.5 times the upper limits of normal. Tuberculosis, invasive fungal infection, or other active serious infections or a history of recurrent infections. Individual has not had a tuberculin skin test or Centers for Disease Control and Prevention-recommended equivalent to evaluate for latent tuberculosis prior to initiating sarilumab. |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For Rheumatoid Arthritis, individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate)] AND individual has had an inadequate response or is intolerant to Humira OR Enbrel. For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Kevzara or (b) Individuals age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Kevzara may be allowed without trial of preferred TNF agents (Enbrel/Humira). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Keytruda

**Products Affected**

- KEYTRUDA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Previous treatment with another programmed death receptor-1 (PD-1) blocking antibody agent. OR Presence of human immunodeficiency virus (HIV) infection, hepatitis B virus infection, or hepatitis C virus infection. Receiving therapy for an autoimmune disease or chronic condition requiring treatment with an immunosuppressant. |
| **Required Medical Information** | Current ECOG (Eastern Cooperative Oncology Group) performance status of 0-2. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For melanoma, used as single agent and tx is 1st line in untreated dz or 2nd line in dz progression while receiving or since completing most recent therapy. For adv melanoma w/lymph node, resected high risk stage III. For colorectal cancer, used as single agent, primary tx as single agent for unresectable metachronous metastases (defective mismatch repair/high microsatellite instability [dMMR/MSIH] only) and previous adjuvant FOLFOX or Cape OX w/in past 12mon or subsequent therapy as single agent if nivolumab or pembrolizumab not previously given following oxaliplatin-irinotecan and fluropyrimidine based therapy or oxaliplatin-irinotecan. For adv/metastatic NSCLC, used as 1st line, single agent, cytologically confirmed stage III or IV, tumor expresses PD_L1 gene on at least 1% or grtr of tumor cells, no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) translocations. For 1st line adv/metastatic nonsquamous NSCLC, used in combo w/pemetrexed and carboplatin, cytologically confirmed stage IIIb or IV, no sensitizing EFGR mutation or ALK translocations. For 1st line metastatic squamous NSCLC, used in combo with carboplatin and paclitaxel or nab-paclitaxel and cytologically confirmed stage IV and has not undergone prev systemic tx for dz. For CONT/MAINT of recurrent/metastatic nonsquamous NSCLC, used in combo w/pemetrexed if part of 1st line pembrolizumab/pemetrexed and platinum based regimen and achieved tumor response or stable dz after initial cytotoxic therapy. For CONT/MAINT therapy of recurrent/metastatic squamous NSCLC, used as single agent, given 1st line as part of pembrolizumab/carboplatin/paclitaxel regimen, achieved tumor response or stable dz after initial cytotoxic therapy. For metastatic NSCLC, Used 2nd line, single agent, tumors w/ PD-L1 gene expression level greater than/equal to 1% w/demonstrated dz progression or after platinum-containing chemo, ALK or EGFR genomic tumor aberrations present and dz progression on FDA approved therapy for aberrations prior to |

| PA Criteria | Criteria Details |
|---|---|
| | receiving pembrolizumab. For small cell lung cancer, used as single agent and demonstrated dz relapse w/in 6mon after complete or partial response or stable dz with initial tx or primary progressive dz and not received another PD-1 agent. For cHL, except for those with lymphocyte-predominant HL, or who have relapsed after 3 or more prior lines of therapy. For Merkel-cell carcinoma (MCC), used as single agent, Presence of metastatic or recurrent locoregional MCC determined to be not amendable to definitive surgery or radiation therapy. For unresectable or metastatic solid tumors (dMMR/MSIH only), used as single agent. For hepatocellular carcinoma, used as single agent, demonstrated dz progression or intolerance on or after tx w/an approved 1st line agent. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Kineret

**Products Affected**

- KINERET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is using Kineret in combination with other tumor necrosis factor (TNF) antagonists. Tuberculosis or other active serious infections or a history of recurrent infections. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC) Prevention-recommended equivalent to evaluate for latent tuberculosis prior to initiating Kineret. In combination with Xeljanz (tofacitinib) or with NONTNF immunomodulatory drugs [such as but not limited to Actemra (tocilizumab) or Orencia (abacept)]. |
| **Required Medical Information** | |
| **Age Restrictions** | For RA, individual is 18 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For RA, Individual has had an inadequate response to is intolerant of or has a contraindication to at least ONE conventional therapy [disease modifying anti-rheumatic agent (DMARD)] AND Individual has had a trial and an inadequate response to or intolerance to Humira (adalimumab) OR Enbrel (etanercept) or the TNF agent (Humira(adalimumab)/Enbrel(etanercept)) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with kineret or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR the individual has either concomitant clinical condition: 1) Demyelinating disease or 2) Heart failure with documented left ventricular dysfunction. Kineret may be allowed without trial of preferred TNF agents (Enbrel/Humira). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Kisqali

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Korlym

**Products Affected**

- KORLYM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | History of unexplained vaginal bleeding. Current endometrial hyperplasia with atypia or endometrial carcinoma. Diagnosis of severe hepatic impairment (Child Pugh Class C). Concomitant use with any of the following: (1) Long term systemic corticosteroids for serious medical conditions or illnesses OR (2) Simvastatin or lovastatin OR (3) CYP3A substrates with narrow therapeutic ranges (such as but not limited to cyclosporine, fentanyl, sirolimus, tacrolimus) OR (4) Agents or co-morbid conditions which prolong the QT interval |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Initial therapy: Individual is not a candidate for surgery that is expected to correct the cause of endogenous Cushing's Syndrome OR disease persists or recurs following surgery intended to correct the cause of endogenous Cushing's Syndrome. For continuation of therapy: Individual continues to meet the initial request approval criteria AND has experienced an improvement in or stabilization of glucose control as assessed by fasting serum glucose test, oral glucose tolerance test or hemoglobin A1c test. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# Koselugo

**Products Affected**

- KOSELUGO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 2 years old or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Krystexxa

**Products Affected**

- KRYSTEXXA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has asymptomatic hyperuricemia. Individual has a known glucose-6-phosphate dehydrogenase (G6PD) deficiency. |
| **Required Medical Information** | Individual has 1 or more of the following: 3 or more gout flares in the previous 18 months OR 1 or more tophus OR History of chronic gouty arthropathy, defined clinically or radiographically as joint damage due to gout. Individual has a baseline serum uric acid of 6 mg/dL or greater prior to initiating pegloticase. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has chronic, treatment-refractory and has failed to respond to, is intolerant of, or has a medical contraindication to ONE of the following conventional therapies: A xanthine oxidase inhibitor (allopurinol or febuxostat) or combination therapy of 1 xanthine oxidase inhibitor given with a uricosuric agent (for example, probenecid). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Kuvan

**Products Affected**

- KUVAN
- *sapropterin dihydrochloride*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | If blood phenylalanine levels do not decrease from baseline at a dose of 10mg/kg/day administered for up to one month. The dose may be increased up to 20mg/kg/day. Individuals are non-responders if phenylalanine levels do not decrease after 1 month and tx should be discontinued |
| **Required Medical Information** | For initial requests, Individual has Dx of Hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4) responsive PKU. For continued use, individual is showing signs of continuing improvement as evidenced by blood phenylalanine levels. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 8 weeks, 1 year for continuation |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# KYNAMRO

**Products Affected**

- KYNAMRO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has a diagnosis of homozygous familial hypercholesterolemia (HoFH), based on the presence of the following (Cuchel 2014, Singh 2015): (A) Genetic confirmation of two (2) mutant alleles at the LDL receptor, apoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene locus OR (B) One of the following: 1. an untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) OR 2. Treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) AND one of the following: (i) cutaneous or tendonous xanthoma before age of 10 years OR (ii) untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than 190 mg/dL). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had an adequate trial and titration of Repatha and achieved suboptimal lipid lowering response. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Kyprolis

**Products Affected**

- KYPROLIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 Year |
| **Other Criteria** | For multiple myeloma (for primary treatment) and being used in combination with lenalidomide plus dexamethasone. For the treatment of Waldenstrom's macroglbulinemia when the following criteria are met: (a) Used as a primary agent, in combination with rituximab and dexamethasone OR (b) Used for relapsed disease when the primary therapy of carfilzomib, rituximab and dexamethasone was given and relapse is greater than 12 months after therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lartruvo

**Products Affected**

- LARTRUVO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a histologically confirmed diagnosis of late stage soft tissue sarcoma (locally advanced or metastatic) not previously treated with an anthracycline and Olaratumab is used in combination with doxorubicin and Radiotherapy or surgery is not a curative treatment option and Individual's current Eastern Cooperative Oncology Group (ECOG) performance status is 0-2. Individual has a histologically confirmed diagnosis of late stage soft tissue sarcoma (locally advanced or metastatic) not previously treated with an anthracycline and Olaratumab is used in combination with doxorubicin and after at least 8 cycles with doxorubicin or earlier discontinuation of doxorubicin due to toxicity, and then if so chosen, continuing olaratumab as monotherapy in the absence of unacceptable toxicities until disease progression and Radiotherapy or surgery is not a treatment option and Individual's current Eastern Cooperative Oncology Group (ECOG) performance status is 0-2. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# Lazanda

**Products Affected**

- LAZANDA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Treatment of acute or postoperative pain, migraine headache pain OR non-cancer related breakthrough pain |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (provide diagnosis) AND has tried and failed fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking Lazanda (fentanyl) for cancer related breakthrough pain. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lemtrada

**Products Affected**

- LEMTRADA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual with primary progressive MS. Individual with secondary progressive MS. Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Tecfidera, Tysabri, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy, Betaseron). |
| **Required Medical Information** | Individual is Human immunodeficiency virus (HIV) negative. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has received prior treatment with at least two alternative drug therapies indicated for the treatment of MS (for example, interferons, glatiramer) and failed to achieve an adequate response. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lenvima

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Letairis

**Products Affected**

- *ambrisentan*
- LETAIRIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has idiopathic pulmonary fibrosis (IPF). Individual has a diagnosis of moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment. Individual is initiating therapy and has a diagnosis of clinically significant anemia/severe anemia. Using in combination with other endothelin receptor antagonist (ERA) agents, such as but not limited to Opsumit (macitentan) or Tracleer (bosentan). |
| **Required Medical Information** | Individual has catheterization-proven diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) AND individual has WHO Functional Class II-IV symptoms. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Leukine

**Products Affected**

- LEUKINE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individuals who are at high risk for infection-associated complications demonstrated by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10to the power of 9/L) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infection, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Prior episode of febrile neutropenia, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have other patient specific risk factors for FN including any of the following: Individual age greater than 65 years, Poor performance status (ECOG status 3-4), Bone marrow involvement by tumor producing cytopenias, Persistent neutropenia (ANC less than 1500mm3), poor renal function (GFR less than 60mL/min) , liver dysfunction, Recent surgery and/or presence of open wounds. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Adjunctive tx and individual as a high risk for infection-associated complications. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For acute myeloid leukemia and using shortly after completion of induction or repeat induction chemo of AML. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500mm3 or experiencing recurrent/resistant infection. For mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation. For acceleration of myeloid reconstitution after autologous or allogenic bone marrow transplantation or peripheral blood progenitor cell transplantation. For delayed neutrophil recovery/graft failure after autologous or allogenic bone marrow transplantation. Used to increase survival in individual exposed to myelosuppressive doses of radiation such as Hematopoietic Syndrome of Acute Radiation Syndrome. For malignant melanoma. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Levoleucovorin

**Products Affected**

- FUSILEV
- KHAPZORY
- *levoleucovorin calcium*
- *levoleucovorin calcium pf*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Libtayo

**Products Affected**

- LIBTAYO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lidocaine Topical

**Products Affected**

- *lidocaine external ointment*
- *lidocaine hcl external cream*
- *lidocaine hcl external solution*
- *lidocaine hcl mouth/throat*
- *lidocaine pak*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual is using for local analgesia OR Individual is using for relief of pain and itching due to minor cuts, minor scrapes, minor skin irritations, minor burns, and insect bites. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lidoderm Patch

**Products Affected**

- *lidocaine external patch*
- LIDODERM
- ZTLIDO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lonsurf

**Products Affected**

- LONSURF

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lorbrena

**Products Affected**

- LORBRENA ORAL TABLET 100 MG, 25 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lotronex

**Products Affected**

- *alosetron hcl*
- LOTRONEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual is a Female with Severe diarrhea-predominant Irritable Bowel Syndrome (IBS) defined as including diarrhea and 1or more of the following: Frequent and severe abdominal pain/discomfort, Frequent bowel urgency or fecal incontinence, Disability or restriction of daily activities due to IBS. Member is female AND Member has chronic symptoms of IBS that have persisted for 6 months or longer AND does not have an anatomic or biochemical abnormality of the gastrointestinal tract. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a documented trial of, an inadequate response or intolerance TWO (2) of the following medications: (a) Loperimide (b) antispasmodics (for example, dicyclomine), or (c) tricyclic antidepressants (AGA 2014). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lucentis

**Products Affected**

- LUCENTIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lumizyme

**Products Affected**

- LUMIZYME

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For infantile-onset Pompe disease, dx is confirmed with acid alpha-glucosidase deficiency (GAA) activity in skin fibroblasts of less than 1% of the normal mean or by GAA gene sequencing AND presence of symptoms (for example respiratory and/or skeletal muscle weakness) of infantile-onset Pompe disease AND evidence of hypertrophic cardiomyopathy. For non-infantile onset (late-onset) Pompe disease, dx is confirmed by GAA enzyme assay which shows reduced enzyme activity less than 40% of the lab specific normal mean value AND confirmed by a second GAA enzyme activity assay in a separate sample (from purified lymphocytes, fibroblasts or muscle) or by GAA gene sequencing AND forced vital capacity (FVC) 30 -79% of predicted value while in the sitting position AND ability to walk 40 meters on a 6-minute walk test (assistive devices permitted) AND muscle weakness in the lower extremities. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lumoxiti

**Products Affected**

- LUMOXITI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individuals with severe renal impairment (CrCl less than 29 mL/min). |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lupaneta

**Products Affected**

- LUPANETA PACK COMBINATION KIT
  11.25 & 5 MG, 3.75 & 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | For initial or retreatment of endometriosis. Individual has utilized Lupaneta for a combined total duration of less than 12 months (initial and retreatment). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lupron Depot

**Products Affected**

- FENSOLVI (6 MONTH)
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)
- LUPRON DEPOT-PED (1-MONTH)
- LUPRON DEPOT-PED (3-MONTH)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For Prostate cancer: Clinically localized dz with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) or higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Other advanced, recurrent, or metastatic disease. For Gynecology Uses: Initial treatment/retreatment of endometriosis (not to continue beyond 6 months) OR Dysfunctional uterine bleeding OR Preoperative tx as adjunct to surgical tx of uterine fibroids (leiomyoma uteri). May be used to reduce size of fibroids to allow for a vaginal procedure, prior to surgical tx (myomectomy or hysterectomy) in patients with documented anemia (Letheby et al. 2001). To induce amenorrhea in women (such as but not limited to menstruating women diagnosed with severe thrombocytopenia or aplastic anemia). For Endocrine Uses: Precocious puberty, defined as beginning of secondary sexual characteristics before age 8 in girls and before age 9 in boys. Ovarian Cancer (including fallopian tube cancer and primary peritoneal cancer): Hormonal therapy for clinical relapse in individuals with stage II-IV granulosa cell tumors or Hormonal therapy for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer as a single agent for persistent dz or recurrence. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 1 year, except for Endometriosis:6months, Uterine Fibroids:3months |
| **Other Criteria** | For Gender Dysphoria in Adolescents (Hembree 2009)m 2017): Fulfills the DSM V criteria for gender dysphoria (American Psychiatric Assoc 2013) AND has experienced puberty to at least Tanner stage 2 (Hembree 2009, 2017) AND has (early) pubertal changes that have resulted in an increase of their gender dysphoria (Hembree 2009, 2017) AND does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment (Hembree 2009, 2017) AND has psychological and social support during treatment (Hembree 2009, 2017) AND demonstrates knowledge and understanding of the expected outcomes of GnRH analog treatment(Hembree 2009, 2017). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lupron Kit IR

**Products Affected**

- *leuprolide acetate*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) or higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Other advanced, recurrent, or metastatic disease. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lynparza

**Products Affected**

- LYNPARZA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Test results from an FDA-approved test confirms (written or verbal) the BRCA mutation for individuals with ovarian cancer or individuals with metastatic human epidermal growth factor receptor 2 (HER2) negative breast cancer. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Lyrica CR

**Products Affected**

- LYRICA CR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had a prior trial of immediate-release form of Lyrica (pregabalin) AND Documentation (verbal or written) has been provided which defines the following: (a.) The inadequate response to Lyrica (pregablin) AND (b.) The medical reason extended release Lyrica CR is clinically necessary, and the same medical reason and clinical reason benefits are not expected with Lyrica. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Makena

**Products Affected**

- *hydroxyprogesterone caproate*
- MAKENA INTRAMUSCULAR
- MAKENA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Women with multiple gestations. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Therapy initiated between 16 weeks, 0 days and 20 weeks, 6 days of gestation and Singleton pregnancy and absence of preterm labor within the current pregnancy and individual is between 16 and 36 weeks of gestation with a singleton pregnancy. Prior history of a preterm singleton delivery before 37 weeks gestation due to either spontaneous preterm labor or premature rupture of membranes. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Mavenclad

**Products Affected**

- MAVENCLAD (10 TABS)
- MAVENCLAD (4 TABS)
- MAVENCLAD (5 TABS)
- MAVENCLAD (6 TABS)
- MAVENCLAD (7 TABS)
- MAVENCLAD (8 TABS)
- MAVENCLAD (9 TABS)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Mayzent, Tecfidera, Tysabri, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy, or Betaseron). Individual with clinically isolated syndrome (CIS) OR human immunodeficiency virus (HIV) infection. Individual with an active acute or chronic infection at the initiation of therapy OR moderate to severe renal impairment (creatinine clearance less than 60 mL/min) OR moderate to severe hepatic impairment (Child-Pugh class B or C) OR has completed two treatment courses (two years) of Mavenclad therapy. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has a diagnosis of relapsing multiple sclerosis (RMS), including relapsing-remitting disease and active secondary progressive disease AND has had a trial and inadequate response or intolerance to at least one alternative drug indicated for the treatment of multiple sclerosis. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Mavyret

**Products Affected**

- MAVYRET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a genotype and a positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2017). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Mayzent

**Products Affected**

- MAYZENT ORAL TABLET 0.25 MG, 2 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Mavenclad, Tecfidera, Tysabri, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy, or Betaseron). Individual who has been tested for CYP2C9 genotype and is homozygous for CYP2C9*3 (ie, CYP2C9*3/*3 genotype). Individual has had a recent (within the past 6 months) occurrence of one of the following: Myocardial infarction or Unstable angina or Stroke or Transient ischemic attack (TIA) or Decompensated heart failure requiring hospitalization or Class III/IV heart failure.Individual has history or presence of Mobitz Type II second- or third-degree atrioventricular (AV) block or sick sinus syndrome, unless individual has a functioning pacemaker. Individual has an active acute or chronic infection at the initiation of therapy. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Megace Suspension HRM

**Products Affected**

- *megestrol acetate oral suspension 40 mg/ml, 400 mg/10ml*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual is using for the treatment of anorexia, cachexia, or unexplained weight loss in individuals with HIV/AIDS. Prescriber must acknowledge this is a high risk medication (HRM) [as identified by American Geriatric Society] for individuals greater than 65 and medication benefits outweigh potential risk for this individual |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Megace Tabs HRM

**Products Affected**

- *megestrol acetate oral tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Prescriber must acknowledge this is a high risk medication (HRM) [as identified by American Geriatric Society] for individuals greater than 65 and medication benefits outweigh potential risk for this individual. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has advanced, inoperable, recurrent breast cancer and using for palliative management. Individual has endometrial/uterine cancer and is suing for palliative management. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Mekinist

**Products Affected**

- MEKINIST ORAL TABLET 0.5 MG, 2 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | BRAF V600E or V600K mutation results must be confirmed (written or verbal attestation). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 Year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Mektovi

**Products Affected**

- MEKTOVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | BRAF V600E or V600K mutation results must be confirmed (written or verbal attestation is acceptable). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Mepron

**Products Affected**

- *atovaquone*
- MEPRON

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Intolerance to trimethoprim-sulfamethoxazole (TMP-SMX) |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Mepsevii

**Products Affected**

- MEPSEVII

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 6 months. Continuation 6 months. |
| **Other Criteria** | For initial use in individuals with a diagnosis of Mucopolysaccharidosis type VII (Sly syndrome) and confirmed (written or verbal) diagnosis of leukocyte or fibroblast glucuronidase enzyme assay or genetic testing and individual has elevated urine glycosaminoglycans excretion at a minimum of 3-fold over the mean normal for age at screening. For continued use, there is confirmation (written or verbal attestation) of clinically significant improvement or stabilization in clinical signs and symptoms of disease compared to the predicted natural history trajectory of disease. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Methylphenidate

**Products Affected**

- ADHANSIA XR
- APTENSIO XR
- CONCERTA ORAL TABLET EXTENDED RELEASE 18 MG, 27 MG, 36 MG, 54 MG
- COTEMPLA XR-ODT
- JORNAY PM
- *metadate er*
- METHYLIN ORAL SOLUTION 10 MG/5ML, 5 MG/5ML
- *methylphenidate hcl er (cd)*
- *methylphenidate hcl er (la) oral capsule extended release 24 hour 10 mg, 20 mg, 30 mg, 40 mg, 60 mg*
- *methylphenidate hcl er (xr)*
- *methylphenidate hcl er oral tablet extended release 10 mg, 18 mg, 20 mg, 27 mg, 36 mg, 54 mg, 72 mg*
- *methylphenidate hcl er oral tablet extended release 24 hour 18 mg, 27 mg, 36 mg, 54 mg*
- *methylphenidate hcl oral solution 10 mg/5ml, 5 mg/5ml*
- *methylphenidate hcl oral tablet*
- *methylphenidate hcl oral tablet chewable 10 mg, 2.5 mg, 5 mg*
- QUILLICHEW ER ORAL TABLET CHEWABLE EXTENDED RELEASE 20 MG, 30 MG, 40 MG
- QUILLIVANT XR
- RELEXXII
- RITALIN
- RITALIN LA ORAL CAPSULE EXTENDED RELEASE 24 HOUR 10 MG, 20 MG, 30 MG, 40 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual is using for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) or Narcolepsy. |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |

# Mircera

**Products Affected**

- MIRCERA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Continued use when the hemoglobin level exceeds 11.0 g/dL (except when the dose of methoxy polyethylene glycol-epoetin beta is adjusted to achieve and maintain target hemoglobin not to exceed 11.0 g/dL). Uncontrolled hypertension. Use beyond 12 weeks in the absence of response in individuals with chronic kidney disease. As treatment in the presence of a sudden loss of response with severe anemia and a low reticulocyte count. |
| **Required Medical Information** | Hemoglobin (Hgb) levels are less than 10 g/dL, prior to initiation of therapy AND (prior to initiation) the individuals iron status, including transferrin saturation or serum ferritin or bone marrow, (baseline) evaluation reveals: transferrin saturation at least 20% or ferritin at least 80 ng/mL or evidence of bone marrow demonstrates adequate iron stores And individual is using for one of the following:  anemia associated with chronic kidney disease (CKD) for Individual on dialysis to achieve and maintain hemoglobin levels within the range of 10.0 to 11.0 g/dL OR anemia associated with CKD for Individual not on dialysis to achieve and maintain hemoglobin levels of 10.0 g/dL. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 weeks. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Modafinil

**Products Affected**

- *modafinil oral tablet 100 mg, 200 mg*
- PROVIGIL ORAL TABLET 100 MG, 200 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For Narcolepsy type 1: confirmed by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following: 1. Clear cataplexy (defined as more than one episode of generally brief) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND 2.Multiple Sleep Latency Test (MSLT) showing one of the following: a. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014)OR b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR 3.Cerebrospinal fluid hypocretin-1 deficiency (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay). For Narcolepsy type 2: confirmed by 1.Multiple sleep latency test (MSLT) with one of the following: a.Mean sleep latency of less than 8 minutes with and evidence of two sleep-onset rapid eye movement periods (SOREMPs) ICSD-3, 2014) OR b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) AND 2.The absence of cataplexy AND 3.Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and Polysomnography. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 1 year |
| **Other Criteria** | For obstructive sleep apnea/hypopnea syndrome objectively confirmed by polysomnography (PSG) or home testing with portable monitor showing one of the following (AASM 2009): (1).Greater than 15 obstructive events (defined as apneas, hypopneas plus respiratory event related arousal) per hour of sleep OR (2)Greater than 5 obstructive events per hour of sleep and individual reports any of the following: a.Unintentional sleep episodes during wakefulness or b. Daytime sleepiness or c. Unrefreshing sleep or d. Fatigue or e. Insomnia or f.Waking up breath holding, gasping or choking or g.Bed partner describing loud snoring, breathing interruptions or both or h. Presence of comorbid conditions including hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation or type 2 diabetes mellitus. And has an Epworth Sleepiness Scale score greater than or equal to 10. For Shift-Work Sleep Disorder (SWSD) confirmed by all of the following: (1)No other medical disorder or mental disorder accounts for the symptoms AND (2)Symptoms do not meet criteria for any other sleep disorder (i.e. jet lag) AND (3)Symptoms have occurred for at least 3 months, AND (4)Individual has one of the following: a.Individual has excessive sleepiness or insomnia associated with a work period that occurs during the usual sleep phase OR b.Polysomnography demonstrates loss of a normal sleep-wake pattern (such as, disturbed chronobiological rhythmicity). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Mozobil

**Products Affected**

- MOZOBIL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using as a mobilizing agent for an allogeneic stem cell donor (NCCN, ASBMT 2014), mobilizer of leukemic cells or as a component of a conditioning regimen prior to an allogeneic hematopoietic stem cell transplant. |
| **Required Medical Information** | Using in combination with granulocyte colony stimulating factor (G-CSF) (such as Neupogen, Nivestym, Zarxio or Granix) and after stem cell mobilization and collection, a subsequent autologous hematopoietic stem cell transplant is anticipated. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 months |
| **Other Criteria** | Individual may use a maximum of up to four consecutive doses of plerixafor (Mozobil) injections per cycle for up to 2 cycles. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Mulpleta

**Products Affected**

- MULPLETA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Used to normalize platelet counts in those with chronic liver disease |
| **Required Medical Information** | Individual has a platelet count of less than 50 X 109/L |
| **Age Restrictions** | 18 years of age |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Myalept

**Products Affected**

- MYALEPT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is using for the treatment of complications of partial lipodystrophy. Individual is using for the treatment of liver disease, including nonalcoholic steatohepatitis (NASH). Individual is using for the treatment of HIV-related lipodystrophy. Individual is using for treatment in patients with general obesity or metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of congenital or acquired generalized lipodystrophy |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Mycapssa

**Products Affected**

- MYCAPSSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For continuation therapy, individual meets initial criteria AND IGF-1 levels remain less than 1.3 X the upper limit of normal (ULN) and a serum growth hormone level less than 2.5ng/mL (Melmed 2015). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a diagnosis of acromegaly AND has responded to and tolerated treatment with octreotide or lanreotide (defined as currently receiving a stable dose of either for at least the previous 3 months (Label, Melmed 2015). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Mylotarg

**Products Affected**

- MYLOTARG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Relapsed or refractory CD33-positive AML: 2 years and older. For newly diagnosed CD33-positive AML: 1 month and older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Naglazyme

**Products Affected**

- NAGLAZYME

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Mucopolysaccharidosis VI is confirmed: (a) with an increase in dermatan sulfate in the urine and (b) Decrease in the activity of N-acetylgalactosamine-4-sulfatase (arylsulfatase B) enzyme as measured in fibroblasts or leukocytes combined with normal enzyme activity level of another sulfatase OR (c) N-acetylgalactosamine-4-sulfatase (arylsulfatase B) gene mutation confirmed (written or verbal attestation). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Namenda Line

**Products Affected**

- *memantine hcl er*
- *memantine hcl oral solution*
- *memantine hcl oral tablet 10 mg, 28 x 5 mg & 21 x 10 mg, 5 mg*
- NAMENDA ORAL TABLET 10 MG, 5 MG
- NAMENDA TITRATION PAK
- NAMENDA XR
- NAMENDA XR TITRATION PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Individuals that are 50 years of age or older are NOT subject to the prior authorization requirements. Prior Authorization applies to individuals that are 49 years of age or younger. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a diagnosis of moderate to severe dementia of the Alzheimer's type. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Natpara

**Products Affected**

- NATPARA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Serum corrected total calcium levels maintained within therapeutic range on calcium supplements and active vitamin D forms alone OR serum corrected total calcium level of less than or equal to 7.5 mg/dL at initiation of therapy. Individual is using to treat hypoparathyroidism caused by a gene mutation in the calcium-sensing receptor OR using to treat acute (duration of less than 6 months, Bilezikian et al. 2011) postoperative hypoparathyroidism OR Individual is at increased risk for osteosarcoma (such as but not limited to, concomitant Paget's disease of bone, open epiphyses, prior history of skeletal external beam or implant radiation therapy). |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Diagnosis of chronic (duration of greater than or equal to 18 months, mannstadt et, al 2013) hypoparathyroidism. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Nerlynx

### Products Affected

- NERLYNX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Nexavar

**Products Affected**

- NEXAVAR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Confirmed (verbal or written attestation) results of FLT3-ITD mutation with acute myeloid leukemia, relapsed/refractory disease. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ninlaro

**Products Affected**

- NINLARO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | For multiple myeloma, individual received at least two prior therapies, including immunomodulatory agent and a proteasome inhibitor AND demonstrated disease progression on or within 60 days of completion therapy AND Ninlaro is given as part of a treatment regimen containing dexamethasone and pomalidomide. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Nityr

**Products Affected**

- NITYR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual's plasma tyrosine level is maintained below 500 micromol/L to reduce risk of ocular symptoms, developmental delay, or hyperkeratotic plaques. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Northera

**Products Affected**

- NORTHERA ORAL CAPSULE 100 MG, 200 MG, 300 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had a trial (resulting in inadequate response, therapeutic failure or intolerance) of at least one prior pharmacologic therapy (which may include midodrine or fludrocortisone) for treatment of symptoms of NOH. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Nourianz

**Products Affected**

- NOURIANZ ORAL TABLET 20 MG, 40 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individuals with severe hepatic impairment (Child Pugh Class C) |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Noxafil

**Products Affected**

- NOXAFIL ORAL
- *posaconazole*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# NP CSF SA Agents

**Products Affected**

- NEUPOGEN
- NIVESTYM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Febrile neutropenic individuals who are at risk for infection-associated complications or have any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10to the power of 9/L) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infection, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, prior episode of FN, or Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have other patient specific risk factors for FN including any of the following: Individual age greater than 65 years, Poor performance status (ECOG status 3-4), prior chemotherapy or radiation therapy, Bone marrow involvement by tumor producing cytopenias, persistent neutropenia (ANC less than 1500mm3), poor renal function (GFR less than 60mL/min) , liver dysfunction (liver function tests at least 2x upper limit of normal) or recent surgery and/or presence of open wounds. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Individual has had a trial and inadequate response to intolerance to Zarxio (Filgrastim-sndz). Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Using for adjunctive tx for FN and has been prophylactic therapy with GCSF agent or has not received prophylactic therapy with a GCSF and who are at high risk for infection-associated complications. Use in acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy. Use in individuals with acute myeloid leukemia (AML) shortly after the completion of induction or repeat induction chemotherapy, or after the completion of consolidation chemotherapy for AML. For tx of moderate to severe aplastic anemia. Tx of severe neutropenia in individuals with hairy cell leukemia. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm3 or experiencing recurrent infection. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. For tx of (non-chemotherapy) drug-induced neutropenia. For tx of low neutrophil counts in individuals with glycogen storage disease type 1b. For tx of neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected. After accidental or intentional total body radiation of myleosuppressive doses (greater than 2 Grays [Gy] (such as Hematopoietic |

| PA Criteria | Criteria Details |
|---|---|
| | Syndrome of Acute Radiation Syndrome). After hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT). Use as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# NP Human Growth Hormone

**Products Affected**

- GENOTROPIN
- GENOTROPIN MINIQUICK
- HUMATROPE
- NUTROPIN AQ NUSPIN 10
- NUTROPIN AQ NUSPIN 20
- NUTROPIN AQ NUSPIN 5
- SAIZEN
- SAIZENPREP
- SEROSTIM
- ZOMACTON
- ZORBTIVE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use of GH tx when applicable criteria have not been met may not be approved for, but not limited to, the following: Renal transplant, Anabolic tx, except for AIDS, provided to counteract acute or chronic catabolic illness (e.g. surgery, trauma, cancer,chronic hemodialysis) producing catabolic (protein wasting) changes in both adult and ped. Anabolic tx to enhance body mass or strength for professional, recreational or social reasons, Constitutional delay of growth and development. Cystic fibrosis, GH Tx in combo with GnRH agonist (Lupron-leuprolide) as a Tx of precocious puberty. Hypophosphatemic rickets, osteogenesis imperfecta, osteoporosis, Short Stature associated with GH insensitivity (Laron Syndrome). Therapy in older adults with normally occurring decrease in GH, who are not congenitally GH deficient and who have no evidence of organic pituitary dz (this is referred to as age-related GH deficiency). Tx of CHF, burn patients, fibromyalgia, glucocorticoid-induced growth failure. Tx of HIV lipodystrophy (fat redistribution syndrome), also referred to as altered body habitus (e.g. buffalo hump), associated with antiviral therapy in HIV-infected patients. Tx of intrauterine growth restriction (IUGR)or Russell-Silver Syndrome that does not result in SGA. Tx of obesity. Other etiologies of SS where GH has not been shown to be associated with an increase in final height, including but not limited to achondrodoplasia and other skeletal dysplasias. CONT therapy: evaluated annually AND growth rate above 2.5cm/yr (not for child w/prior documented hypopituitarism)(Grimberg 2016) AND Child over 12: an X-ray report with evidence that epiphyses have closed or SMR of 3 or more. GH tx for reconstruction is terminated when BA =16 yr (M), or = 14 yr (F) is reached OR Epiphyseal fusion has occurred OR Mid-parenteral height is achieved. |

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | For initial idiopathic GHD requests, has signs/sym sx of GHD, GV 2 SD below age-appropriate mean or ht 2.25 SD below age-appropriate mean and A subnormal (SubNL) response (less than10ng/ml)to 2GH stim tests OR Neonates with hypoglycemia and clinical/hormone evidence of hypopit and low GH (less than 10ng/ml)OR 2other pit hormone deficiencies and low IGF-1 OR mbr has cranial irradiation with low IGF1 and normal thyroid tests.Child born SGA(birth wt or length 2 or more SD below the mean for gest age),Child fails to manifest catch up growth by age 2yr(ht 2 or more SD below the mean for age,gender)AND Other causes for SS have been ruled out.Transitioning adolescent: individual completed linear growth (less than 2cm/yr) AND either GH tx has been stopped for at least a month, and GHD has been reconfirmed:idiopathic isolated GHD(SubNL response to 2 GH stim tests, OR SubNL response (GH conc of less than10 ng/mL)to 1 provocative test and low IGF-I/IGFBP-3)OR multiple pit hormone deficiency,(SubNL response to 1 provocative GH test and/or low IGF-I/IGFBP-3)or for mbr with cranial irradiation, low IGF with normal thyroid or any of the following, known genetic mutation associated with def GH production or secretion or Hypothalamic-pit tumor or structural defect or 3 other pit hormone deficiencies.Adult GHD must be confirmed/reconfirmed:SubNL response in adults to 2 GH stim tests (GH conc of less than or equal to 5ng/ml when using insulin induced hypoglycemia OR GH conc of less than or equal to 4.1ng/ml when using arginine)OR SubNL response to 1 stim test for adults with hypothalamic or pit dz and 1 pit hormone deficits OR 3 other pit hormone deficiencies.Initial request for Reconstructive GH tx in child w/ mean ht is at least 2.25 but less than 2.5SD below the mean for age, gender and GV is less than 10th percentile over 1yr or mean ht at least 2.5SD below the mean for age, gender for conditions known responsive to GH. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For Non Preferred Growth hormone agents, individual has had trial of TWO preferred GH agents (Norditropin AND Omnitrope) or preferred GH agent is not FDA-approved and does not have an accepted off-label use per CMS recognized compendia for the prescribed indication and the requested non-preferred agent is. GH may be approved for Adolescents with childhood onset GHD who have completed linear growth. GH tx in other populations approved when: individual has AIDS wasting (defined as greater than 10% of baseline wt loss that is not explained by concurrent illness other than HIV) AND is being treated with antiviral therapy AND will continue tx until definition not met OR individual dx with short bowel syndrome AND is receiving specialized nutritional support. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# NP Interferon for MS

**Products Affected**

- EXTAVIA
- REBIF
- REBIF REBIDOSE
- REBIF REBIDOSE TITRATION PACK
- REBIF TITRATION PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individuals with primary progressive MS. Individuals with secondary progressive MS without relapsing disease. Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Tecfideria, Tysabri, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy or Betaseron). |
| **Required Medical Information** | Individual has experienced first clinical episode and has MRI features consistent with multiple sclerosis OR individual has MS with relapsing disease (RMS) OR individual with secondary progressive MS (SPMS) with a history of superimposed relapses. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has been on Extavia or Rebif in the past 180 days OR member has tried therapy with ONE of the following agents: Avonex (interferon beta-1a) OR Plegridy (interferon beta-1a) OR Betaseron (interferon beta-1b) OR Tecfidera (dimethyl fumarate) OR Copaxone/Glatopa (glatiramer). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# NP IVIG

**Products Affected**

- ASCENIV
- BIVIGAM
- CARIMUNE NF
- CUTAQUIG
- CUVITRU
- FLEBOGAMMA DIF
- GAMMAGARD
- GAMMAGARD S/D LESS IGA
- GAMMAKED
- GAMMAPLEX
- HIZENTRA
- HYQVIA
- PANZYGA
- PRIVIGEN
- XEMBIFY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | For initial CIDP trial (up to 12wks): has muscle weakness/sensory dysfx caused by neuropathy in more than 1 limb, nerve conduction studies or diagnostic criteria confirm demyelinating neuropathy and other polyneuropathies was ruled out. For CIDP continued use, there is improvement in neurological sx on exam AND continued need shown by attempts annually to titrate dose or interval of therapy result is worsening of sx. For initial trial (up to 12wks) to tx Multifocal Motor Neuropathy (MMN) when clinical presentation combined w/ electrodiagnositic test, labs or diagnostics confirm/suggest MMN. CONT MMN use: mbr had strength improvement and fx after initial tx and CONT need is shown by attempts on yearly basis to titrate dose or interval of therapy result in worsening of sx. Desensitization prior to Solid Organ transplantation for suppression on panel reactive anti-HLA AB in mbr w/PRA level to HLA (AAAAI 2016). Transplant recipient having AB-mediated rejection w/donor specific AB (KDIGO 2009). Tx of ITP with either active bleeding or platelet count less than 30,000mcL (ASH 2011). Tx of fetal alloimmune TCP with AB to paternal platelet antigen found in maternal serum AND one of the following: a previously affected pregnancy or family hx of maternofetal alloimmune TCP or Fetal blood samples shows TCP. For isoimmune hemolytic dz of newborn, tx of severe hyperbilirubinemia. Tx of Lambert-Eaton myasthenic (AAAAI 2016) syndrome: has muscle weakness and dx confirmed by either eletrodiagnostic findings using nerve conduction tests, RNS, exercise testing or SFEMG OR presence of AB directed against VGCC. Stiff person syndrome when mbr had inadeq response/intolerance/contraind to other tx such as benzo or baclofen (AAAAI 2016). Kawasaki Syndrome tx no more than 5dys (AHA 2004). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | NP IG may be approved if trial/inadeq response/intol to 1 PF IG (Gammunex, Gammunex-C, Octagam) OR PF Ig is not FDA/Off-label approved or due to concomitant clinical condition(s) such as but not limited to: Renal insuff/impairmt, Non-O blood type, Severe IgA def, DM/pre-DM, CVD, Hyper-prolinemia, Hypernatremia, hi-risk of thrombosis (such as but not limited to hyperviscosity syn OR hypercoagulable cond), documented hypersensitivity manifested by severe systemic/allergic or anaphylactic rxn to any ingred not also present in requested NP agent OR if SCIG-only dose forms are designated as NP, may be approved for difficult vein access that precludes use of any IVIG or hx of serious systemic rxn to IVIG expected to be avoided by using SCIG or hx of inconsistent serum levels of IgG with IVIG. Tx of PI when hx of recurrent sinopulmonary infection req abx tx AND lack of/inadeq response to immunization AND no evidence of renal and GI as causes of HGG AND initial pre-tx total serum IgG is BLL of age adj lab ref range or more than 2SD below adj mean. Tx of other PI when no evidence of renal/GI causes of HGG AND initial pre-tx total serum IgG is below lower limit of age adj lab ref range or more than 2SD below adj mean. Tx of IgG sub-class deficiency (IgG1-4) when 1 or more serum IgG subclasses are BLL of age adj lab ref range or more than 2 SD below age adj mean AND hx of recurrent sinopulmonary infect requiring abx therapy AND lack of/inadeq response to immunization. For autoimmune neutropenia, active infect is excluded as the cause. For ELS: has muscle weakness, characteristic electromyography and presence of AB directed against voltage-gated Ca-channels. Autoimmune mucocutaneous blistering dz or dermatomyosistiis(DM)/polymyositis when mbr had inadeq response/intolerance/contraind to other tx such as corticosteroids or immunosuppressive agents (AAAAI 2016). Myasthenia Gravis (AAAAI 2016): clinical presentation is characteristic AND dx confirmed by AB against the acetylcholine receptor or muscle specific tyrosine kinase OR electrodiagnostic |
| | finding RNS or SFEMG AND using for worsening sx or short term therapy as immunosuppressive tx or MAINT therapy when mbr had inadeq response/intolerance/contraind to other tx such as steroids or immunosuppressants. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# NP LA Opioid

**Products Affected**

- CONZIP
- DOLOPHINE
- *hydromorphone hcl er*
- KADIAN
- *methadone hcl oral tablet*
- *morphine sulfate er beads*
- *morphine sulfate er oral capsule extended release 24 hour*
- *morphine sulfate er oral tablet extended release 100 mg, 15 mg, 200 mg, 30 mg, 60 mg*
- MS CONTIN ORAL TABLET EXTENDED RELEASE 100 MG, 15 MG, 200 MG, 30 MG, 60 MG
- NUCYNTA ER
- *oxymorphone hcl er*
- *tramadol hcl er*
- *tramadol hcl er (biphasic)*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is requesting or using as an as-needed analgesic OR Individual has one of the following conditions: (a) Significant respiratory depression OR (b) Acute or severe bronchial asthma or hypercarbia OR (c) Known or suspected paralytic ileus. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure) AND for initial therapy, individual is not opioid naïve as noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic. For continued use, Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline AND Prescriber has consulted individual regarding risks of opioid therapy AND clear treatment goals have been defined and outline as part of overall plan AND has one of the following: Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# NP LA Opioid Abuse Deterrent

**Products Affected**

- ARYMO ER
- BELBUCA
- *buprenorphine transdermal patch weekly 10 mcg/hr, 15 mcg/hr, 20 mcg/hr, 5 mcg/hr, 7.5 mcg/hr*
- BUTRANS TRANSDERMAL PATCH WEEKLY 10 MCG/HR, 15 MCG/HR, 20 MCG/HR, 5 MCG/HR, 7.5 MCG/HR
- EMBEDA
- *hydrocodone bitartrate er*
- HYSINGLA ER
- MORPHABOND ER
- XTAMPZA ER
- ZOHYDRO ER

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is requesting or using as an as-needed analgesic OR Individual has one of the following conditions: (a) Significant respiratory depression OR (b) Acute or severe bronchial asthma or hypercarbia OR (c) Known or suspected paralytic ileus. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure) AND for initial therapy, individual is not opioid naïve as noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic. AND If an abuse deterrent formulation is needed [such as but not limited to Embeda ER, Hysingla ER, Targiniq ER, Troxyca ER, Xtampza ER and Zohydro ER], and individual has a history of substance abuse disorder OR individual's family member or household resident has active substance abuse disorder or a history of substance abuse disorder OR If is there is concern for abuse or dependence with pure opioid agents. For continued use, Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline AND Prescriber has consulted individual regarding risks of opioid therapy AND clear treatment goals have been defined and outline as part of overall plan AND has one of the following: Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR diagnosis of terminal illness and is receiving palliative/end-of-life care |
| | (provide terminal diagnosis) OR has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# NP SGLT2

**Products Affected**

- INVOKAMET
- INVOKAMET XR
- INVOKANA ORAL TABLET 100 MG, 300 MG
- SEGLUROMET
- STEGLATRO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has had a trial and inadequate response or intolerance to metformin OR has a contraindication to metformin therapy [such as but not limited to, renal insufficiency (eGFR is less than 45 mL/minute/1.73m2)]. AND has had a trial and inadequate response or intolerance to Jardiance (empagliflozin), Synjardy (empagliflozin/metformin), or Synjardy XR (empagliflozin/metformin extended-release). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# NP SGLT2 DPP4 Combo

**Products Affected**

- GLYXAMBI
- QTERN
- STEGLUJAN
- TRIJARDY XR ORAL TABLET EXTENDED

RELEASE 24 HOUR 10-5-1000 MG, 12.5-2.5-1000 MG, 25-5-1000 MG, 5-2.5-1000 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has had a trial and inadequate response or intolerance to ONE preferred DPP4 AND ONE preferred SGLT2 AND Individual has had an adequate response (achieved glucose control) with trial of the DPP-4 inhibitor and SGLT2 inhibitor at the same time AND Documentation (Verbal or Written) has been provided for why the combination agent is clinically necessary and not for convenience. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# NP Statin

**Products Affected**

- ALTOPREV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has had a trial of generic statin at any dose and provider attests the member has experienced failure, contraindication, or intolerance to a generic statin. Or Individual is currently on a product that interacts with generic statin. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# NP Topical Androgens

**Products Affected**

- ANDRODERM
- ANDROGEL TRANSDERMAL GEL 25 MG/2.5GM (1%), 50 MG/5GM (1%)
- FORTESTA
- TESTIM
- *testosterone transdermal gel 10 mg/act (2%), 12.5 mg/act (1%), 25 mg/2.5gm (1%), 50 mg/5gm (1%)*
- *testosterone transdermal solution*
- VOGELXO
- VOGELXO PUMP

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older. For transgender use, individual is 16 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had a trial of androgel 1.62% AND Individual has a dx of one: (1) primary hypogonadism (congenital or acquired) (for example, bilateral torsion, cryptorchidism, chemotherapy, Klinefleter Syndrome, orchitis, orchiectomy, toxic damage from alcohol or heavy metals, vanishing testis syndrome, idiopathic primary hypogonadism, age-related hypogonadism [also referred to as late-onset hypogonadism]) OR (2) Hypogonadotropic hypogonadism (also called secondary hypogonadism) (congenital or acquired) [for example, idiopathic gonadotropin or luteinizing hormone-relapsing hormone (LHRH) deficiency, pituitary-hypothalamic injury] OR (3) Individual is transgender AND is using for a diagnosis of gender Dysphoria or gender Identity Disorder AND Goal of treatment is female-to-male gender reassignment. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# NP TZD

**Products Affected**

- AVANDIA ORAL TABLET 2 MG, 4 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had a trial and inadequate response or intolerance to metformin OR Individual has a contraindication to metformin therapy [such as but not limited to, renal insufficiency (eGFR is less than 45mL/minute/1.73m2)] AND Individual has had a trial with ONE of the following: dipeptidyl peptidase-4 (DPP-4), glucagon-like peptide-1 (GLP-1), or a sodium-glucose co-transporter-2 (SGLT2) inhibitor. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Nplate

**Products Affected**

- NPLATE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using Nplate to normalize platelet counts. Using for low platelet count caused by any condition other than chronic ITP. |
| **Required Medical Information** | For initial therapy, individual's degree of thrombocytopenia (platelet count less than 30,000/mm3) and clinical condition increase the risk for bleeding AND individual demonstrated an insufficient response to corticosteroids, immunoglobulins (for example, IVIg or anti-D), or splenectomy. For maintenance therapy, individual demonstrated response to therapy as evidenced by increased platelet counts, and the goal of ongoing treatment is to maintain an adequate platelet count (50,000-100,000/mm3) to decrease the risk of bleeding. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | For ITP: Initial 6 months, renewal 1 year. For all other diagnoses: 1 year |
| **Other Criteria** | For treatment of myelodysplastic syndrome (MDS) in individual with severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents or immunosuppressive therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Nubeqa

**Products Affected**

- NUBEQA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Nucala

**Products Affected**

- NUCALA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For severe eosinophilic asthma: In the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease and known or suspected parasitic infections, the individual has a blood eosinophil count that is either greater than or equal to 150 cells/microliter at ignition of therapy OR greater than or equal 300 cells/microliter in the prior 12 months. Evidence of asthma is demonstrated by the following (NAEPP 2008): The individual has a pretreatment forced expiratory volume in one second (FEV1) less than 80% predicted AND FEV1 reversibility of at least 12% and 200mL after albuterol (salbutamol) administration. |
| **Age Restrictions** | For eosinophilic asthma: 6 years old or older. For eosinophilic granulomatosis with polyangitis (EGPA): 18 years old or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For severe eosinophilic asthma, individual has had a 3 month trial/inadequate response to combination controller therapy (high dose inhaled corticosteroids plus LA beta2-agonist, leukotriene modifiers, theophylline or oral corticosteroids) (ERS/ATS 2013) AND has experienced 2 or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in the individual's usual maintenance of oral corticosteroids (ERS/ATS 2013). For Continuation Therapy after 12 months in individuals with severe eosinophilic asthma: Treatment has resulted in clinical improvement as confirmed by either i) Decreased utilization of rescue medications OR ii) A decreased frequency of exacerbation (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroid) OR iii) An increase in percent predicted FEV1 from pretreatment baseline OR iv) A reduction in reported asthma-related symptoms, such as, to wheezing, shortness of breath, coughing, fatigue, sleep disturbance or asthmatic symptoms upon awakening. For individuals with relapsing or refractory eosinophilic granulomatosis with polyangiitis for 6 months or greater and 1) a history or presence of asthma and 2) blood eosinophil level of greater than or equal to 10% of leucocytes or an absolute eosinophil count of greater than 1000 cells per cubic millimeter (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease and known or suspected parasitic infection) and 2) the presence of 2 or more features of eosinophilic granulomatosis with polyangiitis (such as, biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil-rich granulomatosis inflammation, neuropathy, mono or poly(motor deficit or nerve conduction abnormality), pulmonary infiltrates, non-fixed sino-nasal abnormality, cardiomyopathy, glomerulonephritis, alveolar hemorrhage, palpable purpura or antineutrophil cytoplasmic antibody positive status. For |

| PA Criteria | Criteria Details |
|---|---|
| | Continuation Therapy after 12 months in individuals with eosinophilic granulomatosis with polyangiitis when treatment has resulted in clinical improvement as confirmed by the achievement of remission at some point during tx, defines as the following: Birmingham Vasculitis Activity Score, version 3, of zero on scale from 0 to 63 and receipt of prednisolone or prednisone at dose of 4mg or less per day. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Nuedexta

**Products Affected**

- NUEDEXTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with any of the following: (i.) Agents containing quinidine, quinine, or mefloquine OR (ii.) Agents that both prolong the QT interval and are metabolized by CYP2D6 (for example, thioridazine, pimozide) OR Concomitant monoamine oxidase inhibitor (MAOI) use or use in the preceding 14 days OR Individual has any of the following cardiovascular conditions: (i.)Prolonged QT interval, congenital long QT syndrome, or history suggestive of torsades de pointes OR (ii.) Heart failure OR (iii.) Complete atrioventricular (AV) block without an implanted pacemaker or at high-risk of a complete AV block. |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has a diagnosis of pseudobulbar affect (PBA) AND has a concomitant diagnosis with an unrelated neurologic disease or injury [amyotrophic lateral sclerosis (AAN 2014, Pioro et al. 2010), multiple sclerosis (AAN 2016, Pioro et al, 2010), stroke (2016 AHA/ASA)]. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Nulojix

**Products Affected**

- NULOJIX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Nuplazid

**Products Affected**

- NUPLAZID

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial:3 months, Maintenance: 1 Year |
| **Other Criteria** | Initial therapy: Individual has a diagnosis of Parkinson's disease AND Symptoms of psychosis developed after the PD diagnosis AND Symptoms of psychosis include at least one of the following: (1) Visual hallucinations, (2) Auditory hallucination OR (3) Delusions AND Symptoms have been present for at least one month AND Individual has experienced symptoms at least once weekly. Psychiatric symptoms cannot be attributed to disorders such as schizophrenia, schizoaffective disorder, delusional disorder, or mood disorder with psychotic features, or a general medical condition including delirium. For continued therapy, the individual has had a reduction in symptoms of psychosis compared to baseline. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Nurtec

**Products Affected**

- NURTEC

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has had a trial of and inadequate response or intolerance to two oral triptans (AHS 2019) OR has one of the following cardiovascular or non-coronary vascular contraindications to use of triptans: (a) Ischemic coronary artery disease (CAD) including angina pectoris, history of myocardial infarction, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina) or (b) History of stroke or transient ischemic attack (TIA) or (c) Peripheral vascular disease or (d) Ischemic bowel disease or (e) Uncontrolled hypertension. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Nuvigil

**Products Affected**

- *armodafinil oral tablet 150 mg, 200 mg, 250 mg, 50 mg*
- NUVIGIL ORAL TABLET 150 MG, 200 MG, 250 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For Narcolepsy type 1: confirmed by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following: 1. Clear cataplexy (defined as more than one episode of generally brief) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND 2.Multiple Sleep Latency Test (MSLT) showing one of the following: a. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014)OR b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR 3.Cerebrospinal fluid hypocretin-1 deficiency (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay). For Narcolepsy type 2: confirmed by 1.Multiple sleep latency test (MSLT) with one of the following: a.Mean sleep latency of less than 8 minutes with and evidence of two sleep-onset rapid eye movement periods (SOREMPs) ICSD-3, 2014) OR b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) AND 2.The absence of cataplexy AND 3.Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and Polysomnography. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 1 year |
| **Other Criteria** | For obstructive sleep apnea/hypopnea syndrome objectively confirmed by polysomnography (PSG) or home testing with portable monitor showing one of the following (AASM 2009): (1).Greater than 15 obstructive events (defined as apneas, hypopneas plus respiratory event related arousal) per hour of sleep OR (2)Greater than 5 obstructive events per hour of sleep and individual reports any of the following: a.Unintentional sleep episodes during wakefulness or b. Daytime sleepiness or c. Unrefreshing sleep or d. Fatigue or e. Insomnia or f.Waking up breath holding, gasping or choking or g.Bed partner describing loud snoring, breathing interruptions or both or h. Presence of comorbid conditions including hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation or type 2 diabetes mellitus. And has an Epworth Sleepiness Scale score greater than or equal to 10. For Shift-Work Sleep Disorder (SWSD) confirmed by all of the following: (1) No other medical disorder or mental disorder accounts for the symptoms AND (2)Symptoms do not meet criteria for any other sleep disorder (i.e. jet lag) AND (3) Symptoms have occurred for at least 3 months, AND (4) Individual has one of the following: a.Individual has excessive sleepiness or insomnia associated with a work period that occurs during the usual sleep phase OR b.Polysomnography demonstrates loss of a normal sleep-wake pattern (such as, disturbed chronobiological rhythmicity). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ocaliva

**Products Affected**

- OCALIVA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a diagnosis of nonalcoholic steatohepatitis (NASH), nonalcoholic fatty liver disease (NAFLD), primary sclerosing cholangitis (PSC), or biliary atresia. Individual has complete biliary obstruction. |
| **Required Medical Information** | Individual has a diagnosis of primary biliary cholangitis (PBC) as confirmed by TWO of the following (Lindor, 2009): (a) Elevated alkaline phosphatase. (b) Positive antimitochondrial antibodies (AMA) titer. (c) Liver biopsy with findings consistent with PBC. |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For Initial request, Individual has had a one year trial of ursodiol (Urso 250, Urso Forte) with an inadequate response as demonstrated by one of the following (FDA Ad Com, Lindor, 2009): (a) Alkaline phosphatase greater than or equal to 1.67 times the upper limit of normal OR (b) Total bilirubin greater than the upper limit of normal but less than two times the upper limit of normal) AND Individual will be utilizing Ocaliva (obeticholic acid) in combination with ursodiol (Urso 250, Urso Forte) OR has an intolerance to ursodiol (Urso 250, Urso Forte). For continuing treatment with Ocaliva (obeticholic acid), individual has previously met the initiation criteria above and: (a) Individual has achieved an adequate response of alkaline phosphatase or total bilirubin AND (b) Documentation has been provided. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# Ocrevus

**Products Affected**

- OCREVUS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Diagnosis of hepatitis B virus infection or hepatitis C virus infection or another active infection at initiation of therapy OR History of life-threatening infusion reaction of ocrelizumab OR treating secondary progressive multiple sclerosis (MS), systemic lupus erythematosus or rheumatoid arthritis OR concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Tecifdera, Tysabri, Lemtrada, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy or Betaseron). |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For diagnosis of primary progressive multiple sclerosis (PPMS) and individual able to ambulate more than 5 meters (not considered wheelchair bound). For diagnosis of relapsing multiple sclerosis (RMS) and individual able to ambulate without aid or rest for at least 1000 meters AND individual has not experienced a least 2 relapses within the previous 2 years or one relapse within the previous year. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Octreotide Line

**Products Affected**

- BYNFEZIA PEN
- *octreotide acetate*
- SANDOSTATIN
- SANDOSTATIN LAR DEPOT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Individual has (A) diagnosis of carcinoid tumors for any of the following: Metastatic carcinoid tumors OR Carcinoid syndrome to suppress or inhibit severe diarrhea and flushing episodes associated with the disease OR Prophylactic administration prior to biopsy in an individual with a suspected functioning carcinoid tumor OR Prophylactic administration prior to induction of anesthesia in an individual with a functional carcinoid tumor OR Prophylactic administration to a surgical procedure in an individual with a functional carcinoid tumor. OR (B) Diagnosis of Bleeding gastroesophageal varices when GE varices are associated with liver disease AND octreotide acetate is used in combination with endoscopic therapy or alone if endoscopic therapy is not available. OR (C) Chemotherapy or radiation-induced diarrhea that is unresponsive to conventional antidiarrheal medications (for example, diphenoxylate and atropine or loperamide) OR (D) Malignant bowel obstruction to manage GI symptoms (such as nausea, vomiting or pain). OR (E) central nervous system meningiomas that are surgically inaccessible, recurrent, or progressive and is not a candidate for further radiation therapy OR (F) thymic carcinoma or thymoma with or without prednisone OR (G) Using for rapid relief of symptoms or for breakthrough symptoms in individuals taking long-acting octreotide acetate when any of the criteria are met for the above uses OR (H) Neuroendocrine Tumors: (i) Management of unresectable locoregional disease or distant metastasis or (ii) As treatment of the profuse watery diarrhea associated with VIPomas or (iii) Treatment of underlying hypergastrinemic Zollinger-Ellison syndrome or (iv) Prophylactic treatment prior to surgery for gastrinoma. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Odactra

**Products Affected**

- ODACTRA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Severe, unstable or uncontrolled asthma. History of any severe systemic allergic reaction. History of eosinophilic esophagitis. Or, individual is receiving concomitant therapy with other allergen immunotherapy product. |
| **Required Medical Information** | For house dust mite-induced allergic rhinitis, individual has a documented positive skin test OR positive in vitro testing for pollen-specific IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites. Individual has had a trial of, and inadequate symptom control or intolerance to (1) nasal steroid and (1) non-sedating antihistamine AND individual has a confirmed (verbal or written attestation) prescription for an auto-injectable epinephrine product. |
| **Age Restrictions** | Individual is between the ages of 18 years and 65 years old. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Odomzo

**Products Affected**

- ODOMZO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 Year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ofev

**Products Affected**

- OFEV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using in combination with Esbriet (pirfenidone). Individuals with severe hepatic impairment (child pugh class C) or end-stage liver disease. |
| **Required Medical Information** | Diagnosis of idiopathic pulmonary fibrosis (IPF) is confirmed by: Exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity AND High resolution computed tomography (HRCT) with or without surgical lung biopsy. Individual has documented pulmonary function tests within prior 60 days with a Forced Vital Capacity (% FVC) greater than or equal to 50%. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Olumiant

**Products Affected**

- OLUMIANT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using in combination with other JAK inhibitors (such as Xeljanz), biologic drugs (such as but not limited to, TNF agents, anti-CD20 monoclonal antibodies, IL-1R antagonists, selective co-stimulation modulators) or potent immunosuppressants (such as azathioprine and cyclosporine). At initiation of therapy, absolute neutrophil count (ANC) less than 1000 cells/mm3, lymphocyte count less than 500 cells/mm3, or hemoglobin less than 8 g/dL. Tuberculosis or other active serious infections or a history of recurrent infection. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis prior to initiating Olumiant. Individual has severe hepatic impairment (Child Pugh class C) OR has a diagnosis of moderate [30-59 mL/min/1.73 m2 (KDIGO 2012)] or severe [less than 30 mL/min/1.73 m2 (KDIGO 2012)] renal impairment. |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For moderate to severe RA, individual has had an inadequate reponse to/intolerant of/contraindication to conventional therapy [nonbiologics DMARDS 9such as methotrexate, sulfasalazine, leflunomide or hydroxychloroquine)] AND a trial and inadequate response/intolerance to Enbrel(etanercept) OR Humira(adalimumab) OR agents tried and failed (Humira(adalimumab) and /Enbrel(etanercept)) are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Olumiant (baricitinib) or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Oncaspar

**Products Affected**

- ONCASPAR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | History of serious thrombosis with prior L-asparaginase therapy. History of pancreatitis with prior L-asparaginase therapy. History of serious hemorrhagic events with prior L-asparaginase therapy. |
| **Required Medical Information** | Individual is using Oncaspar as a component of a multi-agent chemotherapeutic regimen AND is using for Acute lymphoblastic lymphoma or acute lymphocytic leukemia (ALL) or Extranodal natural killer T-cell lymphoma, nasal type (ENKL). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Onfi

**Products Affected**

- *clobazam oral suspension*
- *clobazam oral tablet 10 mg, 20 mg*
- ONFI ORAL SUSPENSION
- ONFI ORAL TABLET 10 MG, 20 MG
- SYMPAZAN ORAL FILM 10 MG, 20 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis (all ages) and if over 65 years of age or older, Prescriber must acknowledge this is a high risk medication (HRM) [as identified by American Geriatric Society] and medication benefits outweigh potential risk for this individual. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Onpattro

**Products Affected**

- ONPATTRO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has TTR (transthyretin) mutation confirmed by genotyping |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Opdivo

**Products Affected**

- OPDIVO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Receiving therapy for an autoimmune disease or chronic condition requiring treatment with an immunosuppressant. Previous treatment with another programmed death receptor-1 (PD-1) blocking antibody agent. |
| **Required Medical Information** | Current ECOG performance status 0-2. For renal cell carcinoma, histologic confirmation with clear-cell component. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For unresectable or metastatic melanoma: used as a single agent or in combination with Yervoy, as first-line therapy for untreated melanoma OR used as a single agent or in combination with Yervoy, as second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy if PD-1 (programed death receptor -1) agent not previously used. For resected advanced melanoma for up to 12 months of adjuvant therapy when individual has resected state IIIB, IIIC or stage IV disease AND nivolumab is used as a single agent. For malignant pleural mesothelioma, used as subsequent therapy OR individual is ineligible for platinum-based therapy, defined as having one or more of the following risk factors for platinum-based chemotherapy toxicity: ECOG performance status equal to 2, Glomerular filtration rate less than 60ml/min, hearing loss (measured at audiometry) of 25 dB at two contiguous frequencies, or Grade 2 or greater peripheral neuropathy. For first-line tx of stage IV or recurrent NSCLC when: agent is used in combination with ipilmumab AND cytologically confirmed stage IV or recurrent NSCLC AND high tumor mutation burden (greater than or equal to 10 mutations per megabase) AND no sensitizing epidermal growth factor receptor mutations or anaplastic lymphoma kinase translation in nonsquamous carcinoma AND individual has not received prior systemic therapy as primary therapy for advanced or metastatic NSCLC, prior adjuvant or neoadjuvant chemotherapy is permitted as long as the administration of the prior regimen occurred at least 6 months prior. For renal cell carcinoma, agent used as single agent OR used in combination with ipilmumab if no checkpoint blockade (PD-1, PD-L1 or CTLA-4) antibody treatment has been previously administered. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Opsumit

**Products Affected**

- OPSUMIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is initiating therapy and has a diagnosis of clinically significant/severe anemia or in combination with other endothelin receptor antagonist (ERA) agents, such as but not limited to Letairis (ambrisentan) or Tracleer (bosentan). |
| **Required Medical Information** | Individual has catheterization-proven diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) AND Individual has WHO Functional Class II-IV symptoms. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Oralair

**Products Affected**

- ORALAIR
- ORALAIR CHILDRENS STARTER PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Severe, unstable or uncontrolled asthma. History of any severe systemic allergic reaction. Or, individual is receiving concomitant therapy with other allergen immunotherapy product. History of eosinophillic esophagitis. |
| **Required Medical Information** | For grass pollen induced allergic rhinitis, individual has a confirmed (verbal or written attestation) positive skin test OR positive in vitro testing for pollen-specific IgE antibodies for at least one of the following grass pollens: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass pollen. Individual has had a trial of, and inadequate symptom control or intolerance to one (1) nasal steroid and (1) non-sedating antihistamine AND individual has a confirmed (verbal or written attestation) prescription for an auto-injectable epinephrine product. |
| **Age Restrictions** | Individual is between the ages of 10 years and 65 years old. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Treatment is initiated at least 16 weeks before the expected onset of grass pollen season and is continued throughout the season. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Orencia

**Products Affected**

- ORENCIA CLICKJECT MG/0.4ML, 87.5 MG/0.7ML
- ORENCIA INTRAVENOUS
- ORENCIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 125 MG/ML, 50

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using in combination with TNF antagonists or other biologic RA therapy, such as anakinra. Tuberculosis, other active serious infections or a history of recurrent infections. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis. |
| **Required Medical Information** | |
| **Age Restrictions** | For RA, Patient is 18 years of age or older. For JIA, Patient is 2 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For RA, Individual has had an inadequate response to ONE conventional therapy [non-biologic DMARD (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] or a tumor necrosis factor (TNF) antagonist AND has had a trial and inadequate response or intolerance to Humira (adalimumab) OR Enbrel (etanercept). For PsA, individual has had an inadequate response to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, or leflunomide)] or a tumor necrosis factor antagonist AND has had a trial and inadequate response or intolerance to Humira (adalimumab) OR Enbrel (etanercept). For JIA, Individual has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional Therapy [non-biologic DMARD such as methotrexate)] or a TNF antagonist AND has had a trial and inadequate response or intolerance to Humira (adalimumab) OR Enbrel (etanercept). For any of the above indications, if the TNF agent (Enbrel(etanercept)/Humira(adalimumab)) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Orencia or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Orencia may be allowed without trial of preferred TNF agents (Enbrel(etanercept)/Humira(adalimumab)). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Orenitram

**Products Affected**

- ORENITRAM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Moderate (child-Pugh Class B) or severe hepatic impairment (Child Pugh Class C). Using in combination with other treprostinil dosage forms (SQ, IV, and inhalation) unless transitioning from one dose form to another. Using in combination with other prostacyclin analogs [such as but not limited to epoprostenol (Flolan, Veletri, Ventavis (iloprost)] or prostacyclin receptor agonists [such as but not limited to Uptravi (selexipag)]. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Orfadin

### Products Affected

- *nitisinone*
- ORFADIN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual's plasma tyrosine level is maintained below 500 micromol/L to reduce risk of ocular symptoms, developmental delay, or hyperkeratotic plaques. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Orilissa

**Products Affected**

- ORILISSA ORAL TABLET 150 MG, 200 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has any of the following: (a) osteoporosis (b) Individual has severe hepatic impairment [Child-Pugh class C] (c) Individual is requesting in concurrent therapy with hormonal contraceptives (d) Individual is requesting in concurrent therapy with contraindicated agents, such as but not limited to, cyclosporine or gemfibrozil. |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial approval is 6 months, Renewal is 6 months. Requests to continue therapy beyond 24 months (2 |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial requests, Individual is using for moderate or severe endometriosis-associated pain AND has had a trial and inadequate response or intolerance to two of the following medications or has a contraindication to all of the following medications (ACOG 2010): (a) Nonsteroidal antiinflammatory drugs (NSAIDs) OR (b) Combined oral contraceptives (OCs) OR (c) Oral or depot medroxyprogesterone (Provera, Depo-Provera) OR (d) Oral norethindrone. AND one of the following: (a) is naive to Orilissa (elagolix) OR (b) is using low dose (150 mg once daily), has mild (Child-Pugh class A) or no hepatic impairment, and has utilized Orilissa (elagolix) for a combined total duration of less than 24 months in their lifetime OR (c) is using high dose (200 mg twice daily) or has moderate hepatic impairment (Child-Pugh class B), and has utilized Orilissa (elagolix) for a combined total duration of less than 6 months in their lifetime. For continuation requests, Individual is using low dose (150 mg once daily) and does not have moderate hepatic impairment (Child-Pugh class B) AND has experienced a clinically significant improvement in endometriosis-associated pain. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Orkambi

**Products Affected**

- ORKAMBI ORAL PACKET
- ORKAMBI ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Mutation testing confirms (verbal or written) the individual has two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. |
| **Age Restrictions** | Individual is 2 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Otezla

**Products Affected**

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual is unable to take biologic agent due to product warning or contraindication for any of the following: Serious infection or sepsis, Chronic or recurrent infection, Tuberculosis infection, OR Malignancy. For plaque psoriasis (Ps) involves greater than five percent (5%) body surface area (BSA) or involves less than or equal to five percent (5%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For Psoriatic Arthritis (PsA), Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDS (such as methotrexate, sulfasalazine, leflunomide)] AND individual has had a trial and an inadequate response or is intolerant to: Humira (adalimumab) OR Enbrel (etanercept). For plaque psoriasis (Ps), Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine or methotrexate) AND individual has had a trial and an inadequate response or is intolerant to: Humira (adalimumab) OR Enbrel (etanercept). For any of the above indications, if the TNF agent (Enbrel(etanercept)/Humira(adalimumab)) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Otezla or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Oxandrin

**Products Affected**

- *oxandrolone oral tablet 10 mg, 2.5 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Carcinoma of the prostate or breast in male individuals OR Carcinoma of the breast in females with hypercalcemia. Using to enhance athletic performance or physique. Individual has a diagnosis of nephrosis (nephrotic phase of nephritis). Individual has a diagnosis of hypercalcemia. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# OxyContin

**Products Affected**

- *oxycodone hcl er*
- OXYCONTIN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is requesting or using as an as-needed analgesic OR Individual has one of the following conditions: (a) Significant respiratory depression OR (b) Acute or severe bronchial asthma or hypercarbia OR (c) Known or suspected paralytic ileus. |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 11 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure). Individual is not opioid naïve as noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic OR (c) already receiving and tolerating a minimum daily opioid dose of at least 20mg oxycodone orally or its equivalent. For continued use, Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline AND Prescriber has consulted with individual regarding risks of opioid therapy AND Clear treatment goals have been defined and outlined as part of overall plan. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ozurdex Implant

**Products Affected**

- OZURDEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Padcev

**Products Affected**

- PADCEV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individuals have moderate or severe hepatic impairment (Child-Pugh B or C) OR the criteria not met. |
| **Required Medical Information** | Individual has diagnosis of locally advanced or metastatic urothelial cancer AND using as subsequent therapy after progression with anti-PD-1 and anti-PD-L1 agent AND individual has current ECOG performance status of 0 - 2. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# PAH - B

**Products Affected**

- *epoprostenol sodium*
- FLOLAN
- VELETRI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnostic Criteria for PAH: right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than 25mmhg, a pulmonary capillary wedge pressure (PCWP), left atrial pressure or left ventricular end diastolic pressure (LVEDP) less than or equal to 15mmhg AND a pulmonary vascular resistance (PVR) greater than 3 wood units. Criteria for Vasodilator Response: a favorable response is defined as a fall in mPAP of at least 10mmhg to an absolute mPAP of less than 40mmhg without a decrease in cardiac output, when challenged with inhaled nitric oxide, intravenous epoprostenol or intravenous adenosine. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For continuous intravenous infusion of Epoprostenol, individual must meet all of the following: meets diagnostic criteria for PAH AND demonstrates an unfavorable acute response to vasodilators AND individual has New York Heart Association (NYHA) functional class III, or IV symptoms AND World health Organization (WHO) Group I PAH (idiopathic PAH, PAH associated with connective tissue disorders, PAH associated with congenital heart defects, and all Group 1 subtypes). |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# Palynziq

**Products Affected**

- PALYNZIQ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has a confirmed prescription for an auto-injectable epinephrine agent. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For initial requests, individual has a diagnosis of phenylketonuria (PKU) and has uncontrolled blood phenylalanine (PHE) concentrations (greater than 600 micromol/L) on existing management, including but not limited to the following: (a) Dietary phenylalanine and/or protein restriction (b) Kuvan (sapropterin dihydrochloride) agents. For continued use, Individual is showing signs of continuing improvement, as evidenced by blood PHE levels decrease of at least 20% from pretreatment baseline or a reduction below 600micromol/L after 16 weeks of treatment at a maximum dose of 40mg/day. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Pegfilgrastim Agents

**Products Affected**

- FULPHILA
- NEULASTA
- NEULASTA ONPRO
- UDENYCA
- ZIEXTENZO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individuals who are at high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10 to the power of 9/L) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infections, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Prior episode of febrile neutropenia, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have risk factors for FN including any of the following: Individual age greater than 65 years, Poor performance status (ECOG status 3-4), Prior chemotherapy or radiation therapy, Bone marrow involvement by tumor producing cytopenias, persistent neutropenia (ANC less than 1500mm3), poor renal function (GFR less than 60mL/min) , liver dysfunction, recent surgery and or presence of open wounds. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Individual with nonmyeloid malignancy is using for Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Adjunctive use in neutropenic patients who are at high risk for infection-associated complications. In an individual with acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy. For use after accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome). For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution OR when engraftment is delayed or has failed. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Pemazyre

**Products Affected**

- PEMAZYRE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual is using as monotherapy AND has confirmed disease progression (written or verbal) after one or more prior lines of systemic therapy AND confirmation (written or verbal) of fibroblast growth factor receptor 2 (FGFR2) fusion or non-fusion rearrangement as detected by an FDA-approved test. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Perjeta

**Products Affected**

- PERJETA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | If administered after Herceptin (trastuzumab) is discontinued or as part of a regimen without Herceptin (trastuzumab). Concomitant use with other targeted biologic agents (including but not limited to erlotinib, cetuximab, panitumumab, bevacizumab, ziv-aflibercept and lapatinib). |
| **Required Medical Information** | Tumor(s) have been evaluated with an assay validated to predict HER2 positive (HER2+) protein overexpression. Individuals are considered HER2 positive (HER2+) as documented by one of the following, immunohistochemistry (IHC) 3+ or In Situ hybridization (ISH) positive by any of the following: Single probe average HER2 copy number greater than or equal to 6.0 signals/cell OR Dual-probe HER2/CEP 17 ratio greater than or equal to 2.0 OR Dual-probe HER2/CEP 17 ratio less than 2.0 with an average HER2 copy number greater than or equal to 6.0 signals/cell. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For metastatic breast cancer use Perjeta will be used in combination with trastuzumab AND either docetaxel or paclitaxel. (Note If docetaxel or paclitaxel treatment is discontinued (for example, related to toxicity), treatment with Perjeta and trastuzumab may continue.) AND combination chemotherapy with Perjeta (pertuzumab) will be used as single line anti-HER2 chemotherapy for metastatic disease until progression OR individual has early stage, locally advanced or inflammatory breast cancer and will undergo neoadjuvant therapy (prior to surgery) or adjuvant systemic therapy AND primary tumor is larger than 2cm or individual is lymph node positive (for neoadjuvant therapy: clinically evident by palpation or imaging) AND used in combination with trastuzumab and with one of the following: docetaxel with or without carboplatin or paclitaxel AND pertuzumab is used for a maximum of 18 cycles (12 month course). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Phesgo

**Products Affected**

- PHESGO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has HER2-positive breast cancer confirmed (verbal or written) by EITHER immunohistochemistry (IHC) of 3+ OR positive In situ hybridization (ISH). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Piqray

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has confirmed (written or verbal attestation is acceptable) PIK3CA mutation using an FDA-approved test (such as the therascreen PIK3CA RGQ PCR Kit). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Pomalyst

**Products Affected**

- POMALYST ORAL CAPSULE 1 MG, 2 MG, 3 MG, 4 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Praluent

**Products Affected**

- PRALUENT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with Juxtapid or Kynamro. |
| **Required Medical Information** | For (A) Heterozygous Familial Hypercholesterolemia (HeFH) confirmed by: 1.Presence of a mutation in LDLR, apolipoprotein B (ApoB), PCSK9 or ARH adaptor protein gene (LDLRAP1) gene OR 2. World Health Organization (WHO)/Dutch Lipid Network Criteria with score of gtr than 8 points OR (B) History of Clinical Atherosclerotic Cardiovascular Disease (ASCVD), including one of the following: 1.Acute coronary syndromes 2.Coronary Artery Disease (CAD) 3. History of myocardial infarction (MI) 3.Stable or unstable angina 4.Coronary or other arterial revascularization 5.Stroke 6.Transient ischemic attack (TIA) 7.Peripheral arterial disease (PAD). OR (C) Primary hyperlipidemia alone or in combination with other lipid lowering agents. OR (D) using prophylactically for Established CVD. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 3 month. Continuation 1 yr. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial request, individual meets one of the following: (A) Individual is a on high intensity statin therapy, or statin therapy at the maximum tolerated dose, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher OR (B) Individual is statin intolerant OR (C) Individual has a condition that is a contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum hepatic, or pregnancy. Individual also has had an adequate trial and titration of a Repatha (evolocumab) and has achieved suboptimal lipid lowering response despite at least 90 days of Repatha (evolocumab) therapy. For continuation, Individual continues to receive concomitant maximally tolerated statin (unless contraindication or individual is statin intolerant) AND there is confirmation (verbal or written attestation) of LDL reduction. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Probuphine Implant

**Products Affected**

- PROBUPHINE IMPLANT KIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | New entrants to treatment. Treatment for longer than 12 months with Probuphine. Retreatment with Probuphine after a prior 12-month treatment period. For individuals who have not achieved and sustained prolonged clinical stability while being maintained on buprenorphine 8 mg per day or less of a sublingual tablet or its transmucosal buprenorphine product equivalent. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Individual has been diagnosed with opioid dependence (opioid use disorder) and individual has been treated with a stable transmucosal buprenorphine dose (of 8 mg per day or less of a sublingual tablet or its transmucosal buprenorphine product equivalent) for 3 months or longer without any need for supplemental dosing or adjustments and individual is currently on a maintenance dose of 8 mg per day or less of a sublingual tablet or its transmucosal buprenorphine product equivalent to achieve sustained prolonged clinical stability on transmucosal buprenorphine and Probuphine is used as part of a substance use disorder treatment program to include counseling and psychosocial support. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |

# Prolia

**Products Affected**

- PROLIA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Osteoporosis is defined as a BMD T-Score of less than or equal to -2.5 OR a clinical diagnosis based on a history of a low trauma fracture (fragility fracture) at high risk for fracture. Risk factors for osteoporotic fracture is defined as: Hypogonadism or premature ovarian failure, Low body mass, Smoking, Rheumatoid arthritis, Alcohol intake of 3 or more drinks/day, Vitamin D deficiency, Low calcium intake, Hyperkyphosis, Parental hip fracture, Multiple falls, Medication: Anticoagulants, anticonvulsants, aromatase inhibitors, cancer chemotherapeutic drugs, gonadotropin-releasing hormone agonists, (glucocorticoid daily dosage equivalent to 5 mg or greater of prednisone for at least 3 months). Glucocorticoid-induced osteoporosis defined as a T score -2.5 or less and is initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5mg or greater of prednisone and expected or remain on glucocorticoids for a least 6 months. |
| **Age Restrictions** | For Osteoporosis 18 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For osteoporosis/ glucocorticoid-induced osteoporosis treatment, individual has had at least ONE osteoporotic (minimal trauma) fracture OR has two or more risk factors for osteoporotic fracture OR Individual has failed or is intolerant to or has a medical contraindication to other available osteoporosis therapies (such as, bisphosphonates). For male receiving androgen deprivation therapy for non- metastatic prostate cancer, individual has had at least ONE osteoporotic (minimal trauma) fracture OR has one or more risk factors for osteoporotic fracture. Individual is a postmenopausal (natural or induced) female receiving adjuvant aromatase inhibitor therapy for the treatment of breast cancer. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Promacta

**Products Affected**

- PROMACTA ORAL PACKET 12.5 MG, 25 MG
- PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using Promacta to normalize platelet counts. Use in individuals with ITP whose degree of thrombocytopenia and clinical condition (for example, platelet count greater than 30 x 109/L or active bleeding) do not increase the risk of bleeding. Use in individuals with chronic hepatitis C whose degree of thrombocytopenia does not prevent the initiation of peginterferon therapy or limits the ability to maintain an optimal peginterferon-based therapy. Used in individuals with chronic hepatitis C who are no longer on a peginterferon and ribavirin based regimen. Used concomitantly with other thrombopoietin receptor agonists such as romiplostim (Nplate). Used in individuals taking in combination with direct-acting antiviral agents used without concomitant use of a peginterferon agent for treatment of thrombocytopenia associated with chronic hepatitis C infection. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial therapy: 1) Diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP) AND individual has platelet count of less than 30 x 109/L or active bleeding (ASH, 2011. Hicks et al., 2014) AND has had a prior trial and insufficient response to one of the following: a) corticosteroids or b) immunoglobulins [for example, intravenous, anti-D] or c) splenectomy. OR, 2) Diagnosis of severe aplastic anemia AND individual has a platelet count of less than or equal to 30 x 109/L (Olnes et al., 2012.Desmond et al., 2014) AND individual has had a prior trial and insufficient response to an immunosuppressive therapy [such as, anti-thymocte globulin (ATG)]. OR 3) dx of severe aplastic anemia AND is being used in combination with standard immunosuppressive therapy for first-line treatment. For maintenance therapy, individual has demonstrated a response to therapy as evidenced by increased platelet counts AND to maintain an adequate platelet count (50 - 200 x 109/L) to decrease the risk of bleeding. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Protopic

**Products Affected**

- PROTOPIC
- *tacrolimus external*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual had a trial of and inadequate response or intolerance to one topical prescription strength corticosteroid. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Purixan

**Products Affected**

- PURIXAN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Qinlock

**Products Affected**

- QINLOCK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# quinine

**Products Affected**

- QUALAQUIN
- *quinine sulfate*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Treatment or prevention for nocturnal recumbancy leg muscle cramps or related conditions such as but not limited to: Leg cramps, muscle cramps, myoclonus, Periodic Movements of Sleep, Periodic Limb Movements of Sleep (PLMS), Restless Leg Syndrome (RLS), severe hepatic impairment (Child-Pugh C), known prolongation of the QT interval, initial treatment of severe or complicated P. falciparum malaria, prevention of malaria, individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency, individuals with myasthenia gravis, or individuals with optic neuritis . |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has been diagnosed with uncomplicated malaria caused by one of the following: Plasmodium falciparum known or suspected to be resistant to chloroquine (CDC 2013) OR chloroquine-resistant Plasmodium vivax (CDC 2013) OR an unidentified plasmodial species known or suspected to be resistant to chloroquine (CDC 2013). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ragwitek

**Products Affected**

- RAGWITEK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Severe, unstable or uncontrolled asthma. History of any severe systemic allergic reaction. History of eosinophilic esophagitis. Or, individual is receiving concomitant therapy with other allergen immunotherapy product. |
| **Required Medical Information** | For short ragweed pollen induced allergic rhinitis, individual has a documented positive skin test OR positive in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. Individual has had a trial of, and inadequate symptom control or intolerance to (1) nasal steroid and (1) non-sedating antihistamine AND individual has a confirmed (verbal or written attestation) prescription for an auto-injectable epinephrine product. |
| **Age Restrictions** | Individual is between the ages of 18 years and 65 years old. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Treatment is initiated at least 12 weeks before the expected onset of ragweed pollen season and is continued throughout the season. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ravicti

**Products Affected**

- RAVICTI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using for the management of acute hyperammonemia. Using to treat N-acetylglutamate synthase deficiency (NAGS). |
| **Required Medical Information** | |
| **Age Restrictions** | 2 months of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had a trial and inadequate response or intolerance to sodium phenylbutyrate (Buphenyl) OR Individual has any of the following: (a) Congestive heart failure or (b) Severe renal insufficiency or (c) A clinical state where there is sodium retention with edema. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Rayos

**Products Affected**

- RAYOS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Confirmation (Verbal or written) has been provided for why the delayed-release agent is clinically necessary and not for convenience. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has had a prior trial and inadequate response or intolerance to one generic immediate-release oral prednisone agent AND has had a prior consecutive trial and inadequate response to an additional generic oral corticosteroid agents (such as but not limited to, prednisolone, methylprednisolone, hydrocortisone). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Reblozyl

**Products Affected**

- REBLOZYL

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

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For dx beta thalassemia/hg E beta thalassemia, Individual required regular red blood cell transfusions at initiation, defined as both of the following: individual received six to twenty RBC units in the last 24 weeks and had no transfusion-free period greater than 35 days in the last 24 weeks AND individual has a baseline hemoglobin level less than or equal to 11 g/dL. For MDS or MDS/MPN RS T, Individual has required regular red blood cell transfusions of two (2) or more RBC units over eight (8) weeks in the last 16 weeks AND has a baseline hemoglobin (Hgb) level less than or equal to 11 g/dL. AND has one of the following (A or B) (A) has a diagnosis very low to intermediate risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) greater than or equal to 15% (or ring sideroblasts 5% to 14% with an SF3B1 mutation) AND meets one of the following criteria: (1) Serum erythropoietin (EPO) level of greater than 500 mU/mL OR (2) Serum EPO level of less than or equal to 500 mU/mL following no response to combination treatment with erythropoiesis-stimulating agent (ESA) and granulocyte-colony stimulating factor (G-CSF). OR (B) Individual has a diagnosis of myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with all of the following: (1) Ring sideroblasts greater than or equal to 15% (WHO 2017) AND (2) Thrombocytosis (defined as platelets greater than or equal to 450 x109/L) (WHO 2017) AND (3) Insufficient response to ESAs. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Reclast

**Products Affected**

- RECLAST
- *zoledronic acid intravenous solution 5 mg/100ml*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Regranex

**Products Affected**

- REGRANEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 months |
| **Other Criteria** | Individual is using as adjunctive therapy with good ulcer care practices including, but not limited to sharp debridement of the ulcer |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# RELISTOR

**Products Affected**

- RELISTOR ORAL
- RELISTOR SUBCUTANEOUS SOLUTION
  12 MG/0.6ML, 8 MG/0.4ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a known or suspected mechanical gastrointestinal obstruction. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual must have a previous trial of or insufficient response to polyethylene glycol (generic MiraLax) (AGA 2013) AND a trial and inadequate response or intolerance to a preferred agent (Movantik/Amitiza) OR the preferred agent (Movantik/Amitiza) is not acceptable due to concomitant clinical situations, warnings or contraindications, such as but not limited to the following: (1) individual is taking a diphenylheptane opioid (e.g., methadone), where effectiveness has not been established in the treatment of OIC (Amitiza) OR (2) individual has disruption to the blood-brain barrier and may be at increased risk for opioid withdrawal and/or reduced analgesia (Movantik) OR (3) individual is taking strong CYP3A4 inhibitors and may be at increased risk for opioid withdrawal and/or reduced analgesia (Movantik). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Remicade

**Products Affected**

- AVSOLA
- INFLECTRA
- REMICADE
- RENFLEXIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Tuberculosis, other active serious infections or a history of recurrent infection. Individuals who have not had a tuberculin skin test or CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating infliximab. Using in combination with other TNF antagonists, JAK inhibitors, or other biologic drugs (such as, abatacept, anakinra, tocilizumab, or vedolizumab). |
| **Required Medical Information** | For chronic moderate to severe plaque psoriasis: Greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). |
| **Age Restrictions** | For Crohn's Disease or Ulcerative colitis, 6 yr of age or older. For JIA, 2 yr of age or older. For all other indications 18 yr of age. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For RA, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE Conventional Therapy [nonbiological DMARDs (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] (ACR 2015). For Crohn's Disease, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressive drugs). For moderately to severely active Ulcerative Colitis, individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressive drugs). For Ankylosing Spondylitis individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy [such as NSAIDs, or nonbiologic DMARDs(such as sulfasalazine)] (ACR 2015)]. For Psoriatic Arthritis, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy [nonbiological DMARDs (such as methotrexate, sulfasalazine, or leflunomide)]. For chronic plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to phototherapy or ONE other systemic therapy (such as methotrexate, acetretin, or cyclosporine). For Refractory Wegener's Granulomatosis, individual is using in combination with ONE corticosteroid. For PJIA, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE Conventional Therapy [nonbiologic DMARD (such as methotrexate)]. For chronic, recurrent, treatment-refractory or vision-threatening, non-infectious uveitis, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as corticosteroids or immunosuppressive drugs [for example, azathioprine, cyclosporine, or methotrexate]). For Sarcoidosis (Baughman 2006), mbr has had an inadequate response to, is |
| | intolerant of, or has a contraindication to systemic corticosteroids AND has had an inadequate response to, is intolerant of, or has a contraindication to nonbiologic DMARDs (such as methotrexate or azathioprine). |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |

# Remodulin

**Products Affected**

- REMODULIN
- *treprostinil*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnostic Criteria for PAH: right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than or equal to 25mmhg, a pulmonary capillary wedge pressure (PCWP), left atrial pressure or left ventricular end diastolic pressure (LVEDP) less than or equal to 15mmhg AND a pulmonary vascular resistance (PVR) greater than 3 wood units. Criteria for Vasodilator Response: a favorable response is defined as a fall in mPAP of at least 10mmhg to an absolute mPAP of less than 40mmhg without a decrease in cardiac output, when challenged with inhaled nitric oxide, intravenous epoprostenol or intravenous adenosine. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For Remodulin patient must meet all of the following: meets diagnostic criteria for PAH AND demonstrates an unfavorable acute response to one vasodilator AND Individual has New York Heart Association (NYHA) functional class II, III, or IV symptoms: AND World health Organization (WHO) Group I PAH (idiopathic PAH, PAH associated with connective tissue disorders, PAH associated with congenital heart defects, and all Group 1 subtypes). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Repatha

**Products Affected**

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with Juxtapid or Kynamro. |
| **Required Medical Information** | For (A). Homozygous Familial Hypercholesterolemia (HoFH) confirmed by: 1.Presence of two (2) mutant alleles at the LDLR, apoB, PCSK9 or ARH adaptor gene locus OR 2.untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) AND one of the following: i.Cutaneous or tendonous xanthoma before age of 10 years OR ii.Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than190 mg/dL) OR (B). Heterozygous Familial Hypercholesterolemia (HeFH) with diagnosis confirmed by: 1.Presence of a mutation in LDLR, apolipoprotein B (ApoB), PCSK9 or ARH adaptor protein gene (LDLRAP1) gene OR 2. World Health Organization (WHO)/Dutch Lipid Network Criteria with score of gtr than 8 points OR (C). History of Clinical Atherosclerotic Cardiovascular Disease (ASCVD), including one of the following: 1.Acute coronary syndromes 2.Coronary Artery Disease (CAD) 3. History of myocardial infarction (MI) 3.Stable or unstable angina 4.Coronary or other arterial revascularization 5.Stroke 6.Transient ischemic attack (TIA) 7.Peripheral arterial disease (PAD). OR (D) Primary hyperlipidemia alone or in combination with other lipid lowering agents. OR (E) using prophylactically for Established CVD. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 3 month. Continuation 1 yr. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial HoFH request, individual meets the following: (A) Individual is a on high intensity statin therapy, or statin therapy at the maximum tolerated dose, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher OR (B) Individual is statin intolerant OR (C) Statin associated rhabdomyolysis after a trial of a statin OR (D) Individual has a contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum hepatic transaminases, or pregnancy AND Individual is on ezetimibe (applies to individuals on statin therapy only). For initial HeFH or ASCVD requests, individual meets the following: (A) Individual is a on high intensity statin therapy, or statin therapy at the maximum tolerated dose, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher OR (B) Individual is statin intolerant OR (C) Statin associated rhabdomyolysis after a trial of a statin OR (D) Individual has a contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum hepatic transaminases, or pregnancy. For continuation (HeFH, HoFH, ASCVD), mbr continues to receive concomitant maximally tolerated statin (unless contraindication or individual is statin intolerant) AND there is confirmation (verbal or written attestation) of LDL reduction. For continuation (established CVD or Primary Hyperlipidemia), confirmation (verbal or written attestation) of LDL reduction. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Retevmo

**Products Affected**

- RETEVMO ORAL CAPSULE 40 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Retisert Implant

**Products Affected**

- RETISERT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Revatio

**Products Affected**

- REVATIO ORAL SUSPENSION RECONSTITUTED
- REVATIO ORAL TABLET
- *sildenafil citrate oral suspension reconstituted*
- *sildenafil citrate oral tablet 20 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use in combination with phosphodiesterase-5 (PDE5) inhibitors [such as but not limited to, Viagra (sildenafil)]. Use in combination with organic nitrates, such as but not limited to, isosoribide mono/dinitrate or nitroglycerin. Use in combination with guanylate cyclase stimulators [such as but not limited to, Adempas (riociguat)]. Use in individuals requesting for the treatment of erectile dysfunction. Use in individuals with severe hepatic impairment (Child-Pugh Class C). Use in individual has a diagnosis of pulmonary veno-occlusive disease (PVOD). Use in individual has a known hereditary degenerative retinal disorder (such as but not limited to, retinitis pigmentosa). |
| **Required Medical Information** | Catheterization-proven diagnosis of Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO Group I) and WHO Functional Class II-IV symptoms. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Revatio IV

**Products Affected**

- REVATIO INTRAVENOUS
- *sildenafil citrate intravenous*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use in combination with phosphodiesterase-5 (PDE5) inhibitors [such as but not limited to, Viagra (sildenafil)]. Use in combination with organic nitrates, such as but not limited to, isosoribide mono/dinitrate or nitroglycerin. Use in combination with guanylate cyclase stimulators [such as but not limited to, Adempas (riociguat)]. Use in individuals requesting for the treatment of erectile dysfunction. Use in individuals with severe hepatic impairment (Child-Pugh Class C). Use in individual has a diagnosis of pulmonary veno-occlusive disease (PVOD). Use in individual has a known hereditary degenerative retinal disorder (such as but not limited to, retinitis pigmentosa). |
| **Required Medical Information** | Catheterization-proven diagnosis of Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO Group I) and WHO Functional Class II-IV symptoms. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For sildenafil INJ, individual is temporarily unable to take oral dose forms and requires continued therapy. For Individual with a diagnosis of persistent pulmonary hypertension of the newborn (AHA/ATS 2015) AND Individual was started and stabilized on Revatio (sildenafil) in the hospital and requires continued outpatient therapy. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# Revlimid

**Products Affected**

- REVLIMID ORAL CAPSULE 10 MG, 15 MG, 2.5 MG, 20 MG, 25 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Reyvow

**Products Affected**

- REYVOW ORAL TABLET 100 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had a trial/inadequate response or intolerance to 2 oral triptans (AHS 2019) OR Individual has one of the following CV or non-coronary vascular contraindications to use of triptans: Ischemic coronary artery disease (CAD) including angina pectoris, history of MI, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina), history of stroke or TIA, PVD, ischemic bowel disease, or uncontrolled hypertension. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Rinvoq

**Products Affected**

- RINVOQ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using in combination with other JAK inhibitors (such as Xeljanz), biologic drugs (such as but not limited to, TNF antagonists, anti-CD20 monoclonal antibodies, IL-1R antagonists, selective co-stimulation modulators) or potent immunosuppressants (such as azathioprine and cyclosporine). At initiation of therapy, absolute neutrophil count (ANC) less than 1000 cells/mm3, lymphocyte count less than 500 cells/mm3, or hemoglobin less than 8 g/dL. Tuberculosis or other active serious infections or a history of recurrent infection. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention - recommended equivalent to evaluate for latent tuberculosis prior to initiating upadacitinib. Individual has severe hepatic impairment (Child Pugh class C). Individual has end stage renal disease [less than 15 mL/min/1.73 m2 (KDIGO 2012)]. |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | of, or has a contraindication to conventional therapy [nonbiologic DMARDS (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] AND has had an inadequate response to Enbrel (etanercept) OR Humira (adalimumab) OR agents tried and failed (Humira (adalimumab)/Enbrel (etanercept)) are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with upadacitinib or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Rozlytrek

**Products Affected**

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | For metastatic non-small cell lung cancer (NSCLC), 18 years of age or older. For a diagnosis of a solid tumor, 12 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For solid tumors, the individual has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation with confirmed genetic test results. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Rubraca

**Products Affected**

- RUBRACA ORAL TABLET 200 MG, 250 MG, 300 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ruconest

**Products Affected**

- RUCONEST

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is using for prophylaxis or in individuals with laryngeal attacks. |
| **Required Medical Information** | Hereditary Angioedema (HAE) is confirmed by a C4 level below the lower limit of normal as defined by the laboratory performing the test AND ONE of the following (a or b): a) C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test OR b) C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test AND Individual has a history of moderate or severe attacks (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion). |
| **Age Restrictions** | 13 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Rydapt

**Products Affected**

- RYDAPT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Sabril

**Products Affected**

- SABRIL
- *vigabatrin*
- *vigadrone*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | For infantile spasm 1 month to 2yr old. For seizure 10 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Samsca

**Products Affected**

- SAMSCA ORAL TABLET 15 MG, 30 MG
- *tolvaptan*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has an acute, urgent need to raise serum sodium OR is unable to sense/appropriately respond to thirst OR is anuric. Diagnosis of hypovolemic hyponatremia. Individual has underlying liver disease, including cirrhosis OR using to treat autosomal dominant polycystic kidney disease OR is currently receiving a strong CYP3A inhibitor (such as clarithromycin, ketoconazole, itraconazole, ritonavir. indinavir, nelfinavir, saquinavir, nefazodone and telithromycin). |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 30 Days |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# SANCUSO

**Products Affected**

- SANCUSO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had a trial of and inadequate response or intolerance to EITHER generic ondansetron or oral granisetron OR individual is unable to take oral medications due to the following: (A)The presence of head and neck cancer OR (B)Mucositis due to recent radiation to the head and neck area. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Sarclisa

**Products Affected**

- SARCLISA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a diagnosis of multiple myeloma AND has not received treatment with isatuximab or another anti-CD38 agent such as daratumumab) AND has relapsed or refractory disease following treatment with at least two prior lines of therapy including lenalidomide and a proteasome inhibitor (for example, bortezomib, carfilzomib, or ixazomib). |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Signifor IR

**Products Affected**

- SIGNIFOR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a diagnosis of severe hepatic impairment (Child-Pugh C) |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Signifor LAR

**Products Affected**

- SIGNIFOR LAR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Siklos

**Products Affected**

- SIKLOS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has a diagnosis of sickle cell anemia with recurrent moderate to severe painful crises AND is unable to swallow the oral tablet dose form due to a clinical condition such as but not limited to the following: (a) Dysphagia or (b) Individual's age. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Siliq

**Products Affected**

- SILIQ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use of brodalumab in combination with phototherapy OR Use of brodalumab in combination with IL-17 inhibitors or other biologic drugs OR Tuberculosis, other active serious infections, or a history of recurrent infections OR Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control and Prevention (CDC)-recommended equivalent test to evaluate for latent tuberculosis prior to initiating brodalumab OR Individual has Crohn's disease. |
| **Required Medical Information** | Diagnosis of moderate to severe plaque psoriasis with either of the following: Patient has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For a dx of chronic plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine) AND individual has had a trial of and an inadequate response or is intolerant to: Humira(adalimumab) or Enbrel (etanercept) OR if the TNF agent (Enbrel(etanercept)/Humira(adalimumab)) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Siliq or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Siliq may be allowed without trial of preferred TNF agents (Enbrel(etanercept)/ Humira(adalimumab)). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# SIMPONI

**Products Affected**

- SIMPONI SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML, 50 MG/0.5ML
- SIMPONI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 50 MG/0.5ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using golimumab in combination with other TNF antagonists, JAK inhibitors, or other biologic drugs (such as, abatacept, anakinra, or vedolizumab). Tuberculosis, other active serious infections, or a history of recurrent infections. Individuals who have not had a TST or a CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating Simponi (golimumab). |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For RA, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE Conventional Therapy [non-biologic DMARD (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] (ACR 2015) AND individual has had a trial of and inadequate response or intolerance to: Humira (adalimumab) OR Enbrel (etanercept). For Psoriatic Arthritis, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, or leflunomide)] AND individual has had a trial of and an inadequate response or intolerance to Humira(adalimumab) OR Enbrel(etanercept). For Ankylosing Spondylitis, had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (e.g. NSAIDs or nonbiologic DMARDs) AND individual has had a trial of and an inadequate response or intolerance to: Humira(adalimumab) OR Enbrel(etanercept). For UC, individual has had an inadequate response, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as 6-mercaptopurine, azathioprine, oral aminosalicylates, or oral corticosteroids) AND individual has had a trial of and an inadequate response or is intolerant to Humira(adalimumab). For any of the above indications, if the TNF agent (Enbrel(etanercept)/Humira(adalimumab)) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Simponi or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis. Simponi may be allowed without trial of preferred TNF agents (Enbrel(etanercept)/Humira(adalimumab)). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Simponi ARIA

**Products Affected**

- SIMPONI ARIA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use in combination with other TNF antagonists, JAK inhibitors, or other biologic drugs (such as, abatacept, anakinra, or vedolizumab). Tuberculosis, other active serious infections, or a history of recurrent infections. Individuals who have not had a TST or a CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating Simponi (golimumab). |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For RA, individual had an inadequate response to, is intolerant of, or has a medical contraindication to ONE Conventional Therapy [non-biologic DMARD (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] (ACR 2015) AND individual has had a trial of and an inadequate response or intolerance to: Humira (adalimumab) OR Enbrel(etanercept) OR the TNF agent (Enbrel(etanercept)/Humira(adalimumab)) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Simponi Aria or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis, Simponi Aria may be allowed without trial of preferred TNF agents (Enbrel(etanercept)/Humira(adalimumab)). For PsA, individual has had an inadequate response to, is intolerant of or has a medical contraindication to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, or leflunomide)] AND has had a trial of and an inadequate response or intolerance to: Humira (adalimumab) OR Enbrel(etanercept) OR the TNF agent (Enbrel(etanercept)/Humira(adalimumab)) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Simponi Aria or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis. For Ankylosing Spondylitis, individual has had an inadequate response to, is intolerant of or has a medical contraindication to conventional therapy [NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] AND individual has had a trial of and an inadequate response or intolerance to Humira (adalimumab) OR Enbrel(etanercept) OR the TNF agent (Enbrel(etanercept)/Humira(adalimumab)) tried and failed are not acceptable due to concomitant clinical conditions, such as but not |
| | limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Simponi Aria or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |

# Sirturo

**Products Affected**

- SIRTURO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Latent infection due to Mycobacterium tuberculosis OR Drug-sensitive tuberculosis OR Extra-pulmonary tuberculosis OR Infections caused by non-tuberculosis mycobacteria. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a diagnosis of pulmonary multi-drug resistant tuberculosis AND is unable to use an effective regimen for treatment AND the individual is using Sirturo (bedaquiline) with at least 3 drugs to which the multi-drug resistant tuberculosis isolate is susceptible in vitro OR with at least 4 drugs to which the multi-drug resistant tuberculosis isolate is likely to be susceptible if in vitro testing results are unavailable. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Sivextro

**Products Affected**

- SIVEXTRO INTRAVENOUS
- SIVEXTRO ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Treatment of gram-negative infections. |
| **Required Medical Information** | Individual has been diagnosed with acute bacterial skin and skin structure infection (ABSSSI) defined as one of the following (FDA, 2013): Cellulitis/erysipelas OR Wound infection OR Major cutaneous abscess. AND Individual has at least 1 regional or 1 systemic sign of infection as defined by: Lymphadenopathy OR temperature greater than or equal to 38 degrees Celsius OR White blood cell count greater than or equal to 10,000 per microliter OR White blood cell count less than 4000 per microliter OR Greater than 10% of immature neutrophils. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 30 days |
| **Other Criteria** | Individual has had a trial and inadequate response or intolerance to of or has contraindications to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: TMP/SMX, doxycycline, vancomycin, daptomycin, televancin, clindamycin) (IDSA 2014) OR Individual started treatment with intravenous antibiotic(s) in the hospital and requires continued outpatient therapy for an organism susceptible to Sivextro (tedizolid). |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Skyrizi

**Products Affected**

- SKYRIZI (150 MG DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use in combination with other biologic drugs or phototherapy OR Tuberculosis, other active serious infections, or a history of recurrent infections OR Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention - recommended equivalent to evaluate for latent tuberculosis prior to initiating risankizumab-rzaa. |
| **Required Medical Information** | Dx of chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2011): 1. Plaque Ps involving greater than five percent (5%) body surface area (BSA) OR 2. Plaque Ps involving less than or equal to five percent (5%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For dx of chronic moderate to severe plaque Ps, individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate) AND Individual has had a trial and inadequate response or intolerance to Enbrel (etanercept) OR Humira (adalimumab) OR if the agents tried and failed (Humira (adalimumab)/Enbrel (etanercept)) are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Skyrizi (risankizumab-rzaa) or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Solaraze

**Products Affected**

- *diclofenac sodium transdermal gel 3 %*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Dx of Actinic Keratosis |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Soliris

### Products Affected

- SOLIRIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | For initial tx of Paroxysmal nocturnal hemoglobinuria (PNH) as documented by flow cytometry, including the presence: (1.) Paroxysmal nocturnal hemoglobinuria type III red cell clone or a measurable granulocyte or monocyte clone OR (2.) Glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells (PMNs) AND Individual has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of Soliris (eculizumab) (unless the clinical record documents that the risks of delaying Soliris (eculizumab) outweigh the risk of meningococcal infection) AND There is NO evidence of an active meningococcal infection AND Individual has (a)Hemoglobin that is less than or equal to 7 g/dl, or the individual has symptoms of anemia and the hemoglobin is less than or equal to 9 g/dl or (b)Lactate dehydrogenase is greater than 1.5 times the upper limit of normal. OR (c) Documented history of a major adverse vascular event from thromboembolism. For the initial tx of atypical hemolytic uremic syndrome (aHUS) when the following criteria are met: (A) dx of aHUS is supported by the absence of Shiga toxin-producing E. coli infection AND (B) Thrombotic thrombocytopenic purpura has been ruled out (for example, normal ADAMTS 13 activity and no evidence of an ADAMTS 13 inhibitor), or if thrombotic thrombocytopenic purpura cannot be ruled out by laboratory and clinical evaluation, a trial of plasma exchange did not result in clinical improvement AND (C) Individual has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of Soliris (eculizumab) (unless the clinical record documents that the risks of delaying Soliris (eculizumab) outweigh the risk of meningococcal infection) AND (D.) There is NO evidence of an active meningococcal infection. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | For PNH 1yr. For aHUS Initial 3 mon. For MG Initial 7 mon. Continuation is 1 year for all dx. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial tx of generalized myasthenia gravis (MG) when the following criteria are met: (A) Individual has Myasthenia Gravis Foundation of America Clinical Classification Class II to IV disease AND (B) has a documented positive serologic test for binding anti-acetylcholine receptor antibodies (AChR-ab) AND (C) has had an inadequate response to, is intolerant of, or has a medical contraindication to two or more immunosuppressive drug agents (such as, azathioprine, cyclosporine, or methotrexate) as monotherapy or in combination therapy for greater than or equal to 12 months OR (D) has had an inadequate response to, is intolerant of, or has a medical contraindication to one or more immunosuppressive drug agents as monotherapy or in combination therapy and requires chronic plasma exchange or plasmapheresis or intravenous immunoglobulin therapy AND (E)has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of eculizumab (unless the clinical record documents that the risk of delaying eculizumab outweigh the risk of meningococcal infection) AND (F) There is no evidence of an active meningococcal infection. For Continuation following initial tx of aHUS may be approved when the following is met: There is clinical improvement after the initial trial (for example, increased platelet count or laboratory evidence of reduced hemolysis) until an individual becomes a candidate for physician directed cessation as evidenced by the following: (a) Complete clinical remission has been achieved (that is, resolution of thrombocytopenia and mechanical hemolysis, and normalization or new baseline plateau of renal function) and improvement of precipitating illness is clinically apparent AND (b) Duration of clinical remission has been stable for 2 months. Resumption of Soliris (eculizumab) in aHUS may be approved if the following criteria are met (Fakhouri 2017): (A) Individual experienced a relapse after discontinuation of therapy as defined by: (1) Reduction in platelet count to less than 150,000/mm3 or greater |

| PA Criteria | Criteria Details |
|---|---|
| | than 25% from baseline OR (2) Mechanical hemolysis (having 2 or more features of hemoglobin less than 10 g/dL, lactate dehydrogenase greater than 2 times upper limit of normal, undetectable haptoglobin, or presence of schistocytes on smear) OR (3) Acute kidney injury with serum creatinine increase greater than 15% from baseline levels. For Continuation for the tx of gMG may be approved when Individual has experienced a clinical response (that is, a reduction in signs or symptoms that impact daily function). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Somatuline Depot

**Products Affected**

- SOMATULINE DEPOT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Somavert

**Products Affected**

- SOMAVERT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Dx of acromegaly AND member has had an inadequate response to surgery and/or radiation OR Surgery and/or radiation therapy are not an option. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Sovaldi

**Products Affected**

- SOVALDI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has severe renal impairment (CrCl less than 30 mL/min), end stage renal disease, or requires dialysis (AASLD/IDSA 2014). Individual is using in combination with Daklinza (daclatasvir) and a known NS5A polymorphism is present. |
| **Required Medical Information** | Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and a positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD/IDSA guidance. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, Individual has had a prior trial and inadequate response to Harvoni(sofosbuvir/ledipasvir) OR individual is currently on and completing a course of therapy with the requested regimen OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni (ledipasvir/sofosbuvir) which is not also in Sovaldi OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni(sofosbuvir/ledipasvir). For GT 4, individual has had a prior trial and inadequate response to Harvoni(sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir). OR individual is currently on and completing a course of therapy with the requested regimen OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni(sofosbuvir/ledipasvir) or Epclusa (sofosbuvir/velpatasvir) which is not also in Sovaldi OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni (sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Spinraza

**Products Affected**

- SPINRAZA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For initial requests, Individual has documentation (written or verbal attestation is acceptable) of a confirmatory diagnosis by either: (1) Spinal Muscular Atrophy (SMA) diagnostic test results confirming 0 copies of SMN1 OR (2) Molecular genetic testing of 5q SMA for any of the following: (a) homozygous gene deletion or (b) homozygous conversion mutation or (c) compound heterozygote. AND Individual has documentation (written or verbal attestation is acceptable) of either: (1) Genetic testing confirming no more than 2 copies of SMN2 (Finkel 2017) OR (2) Onset of SMA-associated signs and symptoms before 21 months of age (Mercuri 2018). For individuals using Spinraza following treatment with Zolgensma (onasemnogene abeparvovec-xioi), mbr meets the above criteria AND (1) Individual does not require use of invasive ventilatory support (tracheotomy with positive pressure) or use of non-invasive ventilator support (BiPAP) for more than 16 hours per day as a result of advanced SMA disease AND (2) Individual has not achieved the expected benefit from gene therapy, as shown by the following: (a) within 3 months of gene therapy, individual has not achieved and sustained a CHOP INTEND score of more than 40 points. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 Months. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For continuation requests, meets initial criteria AND Individual has documentation (written or verbal) of clinically significant improvement in spinal muscular atrophy-associated signs and symptoms (i.e., progression, stabilization, or decreased decline in motor function) compared to the predicted natural history trajectory of disease. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Spravato

**Products Affected**

- SPRAVATO (56 MG DOSE)
- SPRAVATO (84 MG DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 3 months, continuation 1 year. |
| **Other Criteria** | For initial use, individual has been diagnosed with moderate to severe major depressive disorder AND had an inadequate response to the maximum tolerated dose of two antidepressant therapies during the current major depressive episode (MDE) as defined by less than 50% reduction in symptom severity using a standard rating scale that reliably measures depressive symptoms AND will use Spravato in addition to antidepressant therapy. For continuation, individual has had at least a 50% reduction in symptoms of depression compared to baseline using a standard rating scale that reliably measures depressive symptoms AND will use Spravato in addition to antidepressant therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Spritam

**Products Affected**

- SPRITAM ORAL TABLET DISINTEGRATING SOLUBLE 1000 MG, 250 MG, 500 MG, 750 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has a diagnosis of partial onset seizures OR primary generalized tonic-clonic seizures AND weighs more than 20 kg. |
| **Age Restrictions** | Partial onset seizures: 4 years old. Juvenile myoclonic epilepsy: 12 years old. Primary generalized tonic-clonic seizures: 6 years old. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Sprycel

**Products Affected**

- SPRYCEL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Stelara

**Products Affected**

- STELARA INTRAVENOUS
- STELARA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Known to have reversible posterior leukoencephalopathy syndrome (RPLS) while on tx with Stelara. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC) and Prevention-recommended equivalent test to evaluate for latent tuberculosis prior to initiating Stelara (ustekinumab). Individual has tuberculosis, other active serious infections or a history of recurrent infections. Using ustekinumab in combination with phototherapy. In combination with JAK inhibitors or other biologic drugs (such as TNF antagonists). |
| **Required Medical Information** | Diagnosis of moderate to severe plaque psoriasis with either of the following: Patient has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). |
| **Age Restrictions** | Individual is 18 years of age or older. For Plaque Psoriasis, age 6 and older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For chronic plaque psoriasis, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine) AND individual has had a trial of and an inadequate response or is intolerant to Humira (adalimumab) or Enbrel (etanercept). For psoriatic arthritis, individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy ([nonbiologic DMARDS] such as methotrexate, sulfasalazine, or leflunomide) AND individual has had a trial of and an inadequate response or is intolerant to Humira (adalimumab) or Enbrel (etanercept). For Crohns disease, individual has had an inadequate response to, has lost response to, is intolerant of, or has a medical contraindication to conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants) or a tumor necrosis factor (TNF) antagonist AND individual has had a trial and inadequate response or intolerance to Humira (adalimumab). For any of the above indications, if the TNF agent (Enbrel(etanercept)/Humira(adalimumab)) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Stelara or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Stelara may be allowed without trial of preferred TNF agents (Enbrel(etanercept)/Humira(adalimumab)). For Crohns, if the TNF agent tried and failed are not acceptable due to additional concomitant clinical conditions including: (c) Malignancy [such as but not limited to, solid or hematologic cancers and excluding superficial skin cancers (such as basal and squamous cell)] or (d) Tuberculosis infection. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Stivarga

**Products Affected**

- STIVARGA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Strensiq

**Products Affected**

- STRENSIQ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Total serum alkaline phosphatase is below the lower limit of normal for the individual's age and gender at diagnosis and Plasma pyridoxal 5'-phosphate levels are greater than the upper limit of normal at the time of diagnosis. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 3 mon. Continuation 1 year |
| **Other Criteria** | For initial treatment of perinatal/infantile or juvenile onset hypophosphatasia, individual has onset of symptoms occurred prior to 6 months of age and has one or more of the following: (a) Radiographic evidence of poor bone mineralization such as flared and frayed metaphyses, severe/ generalized osteopenia,or widened growth plates or (b) Genetic test results that confirm infantile HPP or (c) one or more of the following: (1) History or presence of nontraumatic postnatal fracture healing or (2) History of elevated serum calcium or (3) Functional craniosynostosis with decreased head circumference growth or (4) Nephrocalcinosis or (5) Rachitic chest deformity or (6) Respiratory compromise or (7) Vitamin B6-responsive seizures or (8) Failure to thrive. For Continuation of Therapy: The individual has demonstrated clinical improvement in symptoms following asfotase alfa therapy. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |

# Subsys

**Products Affected**

- SUBSYS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using for the treatment of acute or postoperative pain. Using for treatment of migraine headache pain. Using for non-cancer related breakthrough pain. |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (provide diagnosis) AND has tried and failed fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking Subsys (fentanyl) for cancer related breakthrough pain. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Supprelin LA

**Products Affected**

- SUPPRELIN LA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has precocious puberty defined as: Beginning of secondary sexual characteristics before age 8 in girls and age 9 in boys. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Sutent

**Products Affected**

- SUTENT ORAL CAPSULE 12.5 MG, 25 MG, 37.5 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Sylatron

**Products Affected**

- SYLATRON

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Member is being treated for melanoma with microscopic or gross nodal involvement AND Treatment is initiated within 84 days after definitive surgical resection. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Sylvant

**Products Affected**

- SYLVANT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual does not have a concurrent clinically significant infection (for example, Hepatitis B or C) AND No concurrent lymphoma. |
| **Required Medical Information** | Individual is negative for human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Symdeko

**Products Affected**

- SYMDEKO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has a diagnosis of cystic fibrosis (CF) AND has a confirmed mutation-positive result in the cystic fibrosis transmembrane conductance regulator (CFTR) gene and the mutation type is provided and responsive to Symdeko. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Symlin

**Products Affected**

- SYMLINPEN 120
- SYMLINPEN 60

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | May not be approved if individual has any of the following: receiving drugs that stimulate gastric motility (i.e. metoclopramide), diagnosis of severe gastroparesis, hypoglycemia unawareness or recent hypoglycemia requiring assistance within past 6 months |
| **Required Medical Information** | Type 1 or type 2 diabetes AND taking mealtime insulin therapy AND failed to achieve glucose control AND HBA1C is less than or equal to 9. |
| **Age Restrictions** | 18 or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Synagis

**Products Affected**

- SYNAGIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Administration of more than 5 doses of palivizumab in one RSV season. Children who reach 24 months of age prior to the commencement of the RSV season. Treatment in children or infants with known RSV disease. Continued RSV immunoprophylaxis for children who experience breakthrough RSV hospitalization. Primary asthma prevention or to reduce subsequent episodes of wheezing. Children with surgically corrected congenital heart disease or hemodynamically insignificant heart disease (including secundum atrial septal defect, small ventricular septal defect, uncomplicated pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus) who do not otherwise meet approval criteria. Children with Down syndrome who do not otherwise meet approval criteria. |

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | Individual is using when the following are met: A) Maximum of Five (5) doses of palivizumab for infants during the first year of life: Born before 29 weeks 0 days gestation (up to and including 28 weeks, 6 days) and younger than 12 months of age at the start of the RSV season OR Chronic lung disease (CLD) of prematurity (defined as birth at less than 32 weeks, 0 days gestation and a requirement for greater than 21% oxygen for at least 28 days after birth) OR Hemodynamically significant congenital heart disease (CHD) (for example, but not limited to, infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension OR infants with anatomic pulmonary abnormalities (i.e., tracheal ring) or a neuromuscular condition that impairs the ability to clear secretions from the upper airway because of ineffective cough OR Cystic fibrosis with clinical evidence of chronic lung disease or nutritional compromise (weight for length less than tenth percentile). B) Maximum of five (5) doses of palivizumab for children younger than 24 months of age with any of the following: Profoundly immunocompromised, such as severe combined immunodeficiency, advanced acquired immunodeficiency syndrome undergoing organ or hematopoietic stem cell transplant, or an absolute lymphocyte count of less than 100 cell/mm3 OR undergoing cardiac transplantation.of less than 100 cell/mm3 OR undergoing cardiac transplantation. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 5 months |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | C) An additional dose of palivizumab may be allowed for children younger than 24 months of age who have approval for a course of treatment and who undergo cardiopulmonary bypass for surgical procedures. D) A maximum of 5 doses of palivizumab prophylaxis may be approved for children in the second year of life with any of the following: (i) for preterm infants born at less than 32 weeks, 0 days gestation who required at least 28 days of oxygen after birth and who continue to require medical intervention within 6 months of the start of the second RSV season (including, supplemental oxygen, chronic systemic corticosteroid therapy, or diuretics) or (ii) Cystic fibrosis with severe lung disease (history of hospitalization, abnormal chest x-ray or CT scan) or weight for length less than tenth percentile. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Synarel Nasal Solution

**Products Affected**

- SYNAREL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Precocious puberty, defined as the beginning of secondary sexual maturation characteristics before age 8 in girls and before age 9 in boys. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Endometriosis: 6 months, all other indications: 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Synribo

**Products Affected**

- SYNRIBO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tabrecta

**Products Affected**

- TABRECTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has confirmation (written or verbal) of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected by an FDA-approved test AND individual has not received treatment with another MET exon 14 skipping-targeted agent, such as crizotinib. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual is using Tabrecta (capmatinib) as monotherapy |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tafamidis Agents

**Products Affected**

- VYNDAMAX
- VYNDAQEL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a history of liver or heart transplantation. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has a diagnosis of wild type or hereditary transthyretin amyloid cardiomyopathy confirmed by biopsy and DNA mutation analysis (Bozkurt, 2016, Maurer, 2018) AND is using for the treatment of New York Heart Association class I, II or III heart failure symptoms (Maurer, 2018). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tafinlar

**Products Affected**

- TAFINLAR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Tafinlar may not be approved for the treatment of individuals with wild type BRAF melanoma. |
| **Required Medical Information** | BRAF V600E or V600K mutation results must be confirmed (verbal or written). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 Year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tagrisso

**Products Affected**

- TAGRISSO ORAL TABLET 40 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has either: (a) EGFR (epidermal growth factor receptor) T790M mutation is confirmed (verbal or written) OR (b) EGFR exon 19 deletions or exon 21 L858R mutations is confirmed (verbal or written) |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Takhzyro

**Products Affected**

- TAKHZYRO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | 1.Using for prophylaxis against acute attacks of hereditary angioedema (HAE) for either: of the following: a. Short term prophylaxis prior to surgery, dental procedures or intubation OR b. Long term prophylaxis and individual has failed, or is intolerant to, or has contraindication (such as pregnant, or breastfeeding) to 17 alpha-alkylated androgens (e.g., danazol) or antifibrinolytic agents (e.g., aminocaproic acid) AND 2.Diagnosis is confirmed by C4 level below the lower limit of normal as defined by lab test and any of the following: a. C1 inhibitor antigenic level below the lower limit or normal as defined by lab test OR b. C1 inhibitor functional level below the lower limit of normal as defined by lab test OR c. Presence of a known HAE causing C1-INH mutation AND 3. Individual has a history of moderate or severe attacks (such as airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion). |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |

# Taltz

**Products Affected**

- TALTZ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use of Taltz (ixekizumab) in combination with phototherapy. Use of Taltz (ixekizumab) in combination with IL-17 inhibitors or other biologic drugs. Individual with Tuberculosis, other active serious infections, or a history of recurrent infections. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC)-recommended equivalent test to evaluate for latent tuberculosis prior to initiating Taltz (ixekizumab). |
| **Required Medical Information** | Diagnosis of moderate to severe plaque psoriasis with either of the following: Individual has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). |
| **Age Restrictions** | Individual is 6 years of age or older for plaque psoriasis, 18 years of age or older for other indications |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For a dx of moderate to severe psoriatic arthritis, the individual has had an inadequate response to, is intolerant of, or has a medical contraindication to conventional drug therapy [nonbiologic DMARDS (such as methotrexate, sulfasalazine, or leflunomide)] or TNF Antagonists (AAD 2011) AND individual has tried and failed: Humira(adalimumab) OR Enbrel(etanercept). For a dx of moderate to severe plaque psoriasis, had an inadequate response, is intolerant of, or has a medical contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine) AND individual has tried and failed: Humira(adalimumab)OR Enbrel(etanercept). For either of the above indications, if the TNF agent (Humira/Enbrel) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Taltz (ixekizumab) or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR The individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Talzenna

**Products Affected**

- TALZENNA ORAL CAPSULE 0.25 MG, 1 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Written or verbal attestation provided to confirm deleterious or suspected deleterious germline BRCA-mutation (gBRCAm) and human epidermal growth factor receptor 2-negative (HER2) breast cancer. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tarceva

**Products Affected**

- *erlotinib hcl oral tablet 100 mg, 150 mg, 25 mg*
- TARCEVA ORAL TABLET 100 MG, 150 MG, 25 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For NSCLC tumors that have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, a copy of the test results must be provided |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Targretin

**Products Affected**

- *bexarotene*
- TARGRETIN EXTERNAL
- TARGRETIN ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tasigna

**Products Affected**

- TASIGNA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tasmar

### Products Affected

- TASMAR
- *tolcapone*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tavalisse

**Products Affected**

- TAVALISSE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has a platelet count of less than 50 X 109/L |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tazorac

**Products Affected**

- *tazarotene*
- TAZORAC

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | May not be approved for cosmetic purposes such as, but not limited to the following: Photoaging, Wrinkles, Hyperpigmentation, Sun damage, or Melasma. |
| **Required Medical Information** | For psoriasis, individual has up to 20% of body surface area involvement. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For psoriasis, individual has had a prior trial and inadequate response to either of the following (AAD 2009): Any two (2) topical corticosteroids or any one (1) topical corticosteroids plus calcipotriene. For psoriasis use greater than 1 year, efficacy must be documented for continued use. Documentation may include chart notes, consultation notes. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tazverik

**Products Affected**

- TAZVERIK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For Epithelioid Sarcoma, individual has a histologically confirmed (written or verbal) diagnosis and has a current ECOG performance status of 0-2. For follicular lymphoma, tumor is positive for EZH2 mutation as detected by an FDA approved test. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tecentriq

**Products Affected**

- TECENTRIQ INTRAVENOUS SOLUTION
  1200 MG/20ML, 840 MG/14ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has received treatment with another PD-1 agent or PD-L1 (for example, nivolumab or pembrolizumab) and Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant. |
| **Required Medical Information** | Written or verbal attestation is provided for confirmation of mutations where applicable based on use/diagnosis. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For locally advanced or metastatic urothelial carcinoma, has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. For metastatic non-small cell lung cancer (NSCLC), extensive-stage small cell lung cancer has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tecfidera

**Products Affected**

- *dimethyl fumarate*
- *dimethyl fumarate starter pack*
- TECFIDERA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using in combination with other immunomodulatory products (such as Aubagio, Gilenya, Tysabri, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy, Lemtrada, Ocrevus or Betaseron). |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tegsedi

**Products Affected**

- TEGSEDI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a history of acute glomerulonephritis caused by Tegsedi (inotersen) |
| **Required Medical Information** | Individual has a baseline platelet count greater than or equal to 100 x 10 9/L AND urinary protein to creatinine ratio (UPCR) less than 1000 mg/g AND Individual has a TTR mutation confirmed by genotyping. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has diagnosis of hereditary transthyretin (hATTR) amyloidosis or familial amyloid polyneuropathy (FAP) AND associated mild to moderate polyneuropathy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Testosterone Inj

**Products Affected**

- AVEED
- DEPO-TESTOSTERONE
- TESTONE CIK
- *testosterone cypionate*
- *testosterone enanthate*
- *testosterone propionate*
- XYOSTED

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

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial use of replacement therapy, Individual has a dx of (1) primary hypogonadism (congenital or acquired) such as but not limited to: Cryptorchidism OR Bilateral torsion OR Vanishing testis syndrome OR orchitis OR Orchiectomy OR Klinefelter Syndrome OR Chemotherapy OR Toxic damage from alcohol or heavy metals OR idiopathic primary hypogonadism. Or (2) Hypogonadotropic hypogonadism (congenital or acquired), such as but not limited to: Idiopathic luteinizing hormone-releasing hormone (LHRH deficiency) OR Pituitary-hypothalamic injury AND Individual presents with symptoms associated with hypogonadism, such as but not limited to, at least one of the following: (a) Reduced sexual desire (libido) and activity or (b) Decreased spontaneous erections or (c) Breast discomfort/gynecomastia or (d) Loss of body (axillary and pubic) hair, reduced need for shaving or (e) Very small (especially less than 5 mL) or shrinking testes or (f) Inability to father children or low/zero sperm count or (g) Height loss, low trauma fracture, low bone mineral density or (h)Hot flushes, sweats or (i) Other less specific signs and symptoms including decreased energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance. For Continuation of Testosterone Inj agents for replacement therapy, (a) Individual met all diagnostic criteria for initial therapy and (b) Individual has had serum testosterone level measured in the previous 180 days and (c) Individual has obtained clinical benefits as noted by symptom improvement. For treatment of delayed puberty when ALL the criteria below are met: Individual is using to stimulate puberty and individual has few to no signs of puberty. For treatment of breast cancer when the following are met: Female 1-5 years post-menopause and Individual is using secondarily for advanced inoperable metastatic (skeletal) breast cancer OR Premenopausal female who has benefited from oophorectomy and is considered to have a hormone responsive tumor. For treatment of HIV-infected male adults with low |
| | testosterone and HIV-associated weight loss and wasting. For transgender individuals who meet ALL the following criteria: Individual has a diagnosis of gender dysphoria or gender identity disorder and goal of treatment is female-to-male gender reassignment. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# Thalomid

**Products Affected**

- THALOMID ORAL CAPSULE 100 MG, 150 MG, 200 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Thiola

**Products Affected**

- THIOLA
- THIOLA EC

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 9 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a diagnosis of severe homozygous cystinuria AND Individual has urinary cystine greater than 500 mg/day. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tibsovo

**Products Affected**

- TIBSOVO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Documented susceptible isocitrate dehydrogenase-1 (IDH1) (written or verbal attestation is acceptable) |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Topical Acne Antibiotic

**Products Affected**

- *clindamycin-tretinoin*
- VELTIN
- ZIANA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For dx of Acne, Individual has had a prior trial and inadequate response to the following: (1) One preferred generic topical tretinoin agent AND (2) One preferred generic erythromycin/benzoyl peroxide combination agent OR (3) One preferred generic clindamycin/benzoyl peroxide combination agent. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Topical Androgens

**Products Affected**

- ANDROGEL PUMP
- ANDROGEL TRANSDERMAL GEL 20.25 MG/1.25GM (1.62%), 40.5 MG/2.5GM (1.62%)
- *testosterone transdermal gel 1.62 %, 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 40.5 mg/2.5gm (1.62%)*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older. For transgender use, individual is 16 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a dx of (1) primary hypogonadism (congenital or acquired) [for example, Cryptorchidism OR Bilateral torsion OR orchitis OR Vanishing testis syndrome OR Orchiectomy OR Klinefelter Syndrome OR Chemotherapy OR Toxic damage from alcohol or heavy metals OR idiopathic primary hypogonadism]. Or (2) Hypogonadotropic hypogonadism (congenital or acquired) [for example, Idiopathic luteinizing hormone-releasing hormone (LHRH deficiency), OR Pituitary-hypothalamic injury.] Individual is transgender AND is using for a diagnosis of gender Dysphoria or gender Identity Disorder AND Goal of treatment is female-to-male gender reassignment. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Topical Onychomycosis

**Products Affected**

- JUBLIA
- KERYDIN
- *tavaborole*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has a confirmed fungal infection (i.e. physical exam). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had a trial of and inadequate response or intolerance to oral itraconazole and terbinafine. Or has a, contraindication, drug interaction or concomitant clinical condition (such as but not limited history of liver disease or concerns over hepatotoxicity, history of CHF) which make use of oral itraconazole and terbinafine unacceptable OR Individual has used requested medication within the previous 6 months. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Topical Tretinoin Agents

**Products Affected**

- ALTRENO
- ATRALIN
- *avita*
- REFISSA
- RETIN-A
- RETIN-A MICRO
- RETIN-A MICRO PUMP
- *tretinoin (emollient)*
- *tretinoin external*
- *tretinoin microsphere*
- *tretinoin microsphere pump*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Topical tretinoin agents may not be approved for cosmetic purposes such as, but not limited to the following: Photoaging, Wrinkles, Hyperpigmentation, Sun damage, Melasma. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Torisel

**Products Affected**

- *temsirolimus*
- TORISEL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For advanced renal cell carcinoma, individual is using for either of the following (A or B): (A) As first-line therapy as a single agent (monotherapy) for (either i or ii): (i) Relapsed metastatic disease or (ii) Surgically unresectable stage IV renal carcinoma in individuals with a poor prognosis as manifested by having at least 3 of the following (1 through 6): 1. Lactate dehydrogenase greater than 1.5 times the upper limit of normal or 2. Hemoglobin less than the lower limit of normal or 3. Corrected calcium level greater than 10mg/dL (2.5mmol/liter) or 4. Interval of less than a year from original diagnosis to the start of systemic therapy or 5. Karnofsky performance status less than or equal to 70 or ECOG performance score of 2 - 4 or 6. Greater than or equal to 2 sites of metastases. OR (B) For subsequent (second-line) therapy as a single agent (monotherapy) for relapsed metastatic or for surgically unresectable stage IV disease. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |

# Tracleer

**Products Affected**

- *bosentan*
- TRACLEER ORAL TABLET
- TRACLEER ORAL TABLET SOLUBLE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is concomitantly taking cyclosporine A or glyburide. Individual has a diagnosis of moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment or in the treatment of congestive heart failure with left ventricular dysfunction. Or Individual is initiating therapy and has elevated [greater than 3 times the upper limit of normal (ULN)] baseline aminotransferase levels OR In combination with other endothelin receptor antagonist (ERA) agents, such as but not limited to Letairis (ambrisentan) or Opsumit (macitentan). |
| **Required Medical Information** | Catheterization-proven diagnosis of Pulmonary Arterial Hypertension (WHO Group I), and WHO Functional Class II-IV symptoms. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Transmucosal Fentanyl Citrate

**Products Affected**

- *fentanyl citrate buccal*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using for the treatment of acute or postoperative pain. Using for treatment of migraine headache pain  Using for non-cancer related breakthrough pain. |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 16 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has a diagnosis of active cancer with breakthrough cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking transmucosal fentanyl Citrate for cancer related breakthrough pain. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Trelstar Line

**Products Affected**

- TRELSTAR MIXJECT INTRAMUSCULAR SUSPENSION RECONSTITUTED 11.25 MG, 22.5 MG, 3.75 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Following radical prostatectomy as adjuvant therapy when lymph node metastases are present OR Locally advanced disease OR Other advanced, recurrent, or metastatic disease. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tremfya

**Products Affected**

- TREMFYA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using in combination with other biologic drugs or phototherapy. Tuberculosis, other active serious infections, or a history of recurrent infections. Individual has not had a tuberculin skin test or a Centers for Disease Control and Prevention-recommended equivalent test to evaluate for latent tuberculosis prior to initiating Tremfya. |
| **Required Medical Information** | Diagnosis of moderate to severe plaque psoriasis with either of the following: Patient has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For a dx of chronic plaque psoriasis, individual has failed to respond to, is intolerant of, or has a medical contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine) AND individual has had a trial of and had an inadequate response or is intolerant to either: Humira (adalimumab) or Enbrel (etanercept). For any of the above indications, if the TNF agent (Enbrel(etanercept)/Humira(adalimumab)) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Tremfya or (b) Individuals age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Tremfya may be allowed without trial of preferred TNF agents (Enbrel(etanercept)/Humira(adalimumab)). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Trikafta

**Products Affected**

- TRIKAFTA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with Kalydeco (ivacaftor), Orkambi (ivacaftor/lumacaftor) or Symdeko (tezacaftor/ivacaftor) OR Individual with severe hepatic impairment (Child-Pugh Class C). |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 12 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | For dx of CF, mutation testing confirms (verbal or written attestation) the individual has two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene OR testing confirms (verbal or written attestation) the individual has one copy of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene and one other mutation that is unresponsive to Ivacaftor or Tezacaftor/Ivacaftor. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Triptodur

**Products Affected**

- TRIPTODUR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Precocious puberty, defined as beginning of secondary sexual characteristics before age 8 in girls and before age 9 in boys. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For Gender Dysphoria use (Hembree 2009, 2017), individual fulfills the DSM V criteria for gender dysphoria (American Psychiatric Association 2013) AND has experienced puberty to at least Tanner stage 2 (Hembree 2009, 2017) AND has (early) pubertal changes that have resulted in an increase of their gender dysphoria (Hembree 2009, 2017) AND Individual does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment (Hembree 2009, 2017) AND has psychological and social support during treatment (Hembree 2009, 2017) AND demonstrates knowledge and understanding of the expected outcomes of GnRH analog treatment (Hembree 2009, 2017). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Trodelvy

**Products Affected**

- TRODELVY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has recurrent or metastatic, histologically confirmed triple-negative Breast Cancer (lack of estrogen- and progesterone-receptor expression and no overexpression of HER2) AND Individual has confirmation of disease progression (written or verbal) after two prior therapies. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Trogarzo

**Products Affected**

- TROGARZO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual who has received immunomodulating therapy within 12 weeks of initiating treatment with Trogarzo (for example, interferon, systemic steroids or systemic chemotherapy) (NCT00784147) OR Individual is being treated for an acute infection secondary to HIV infection (NCT00784147). |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual is using to treat human immunodeficiency virus (HIV) infection AND has a viral load of greater than 1000 copies/mL AND has a history of at least 6 months of antiretroviral treatment AND is receiving a failing antiretroviral regimen or has failed and is off therapy AND has confirmed resistance to at least one antiretroviral agent from three different classes as measured by resistance testing (FDA Summary, 2018) AND Individual is using in combination with other antiretroviral agents and has confirmed full viral sensitivity/susceptibility to at least one antiretroviral agent (other than Trogarzo) as determined by resistance testing. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tukysa

**Products Affected**

- TUKYSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | HER2-positive breast cancer confirmed (verbal or written) by one of the following:  Immunohistochemistry (IHC) is 3+ or In situ hypridization (ISH) positive. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Turalio

**Products Affected**

- TURALIO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tykerb

**Products Affected**

- *lapatinib ditosylate*
- TYKERB

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Cancer has been confirmed HER2 positive |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tymlos

**Products Affected**

- TYMLOS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has utilized abaloparatide and a parathyroid hormone analog (for example, teriparatide [Forteo]) for a combined total lifetime duration of 2 years or longer. Individual is using Tymlos in combination with any of the following: (1) Prolia (denosumab) OR (2) Bisphosphonate OR (3) Evista (raloxifene) OR (4) Miacalcin/Fortical (calcitonin nasal spray) OR (5) Reclast (zoledronic acid) OR (6) Forteo (teriparatide). |
| **Required Medical Information** | Individual is a postmenopausal female with one of the following: (A) dx of osteoporosis (defined as a bone mineral density [BMD] T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population) OR (B) dx of osteoporosis based on history of an osteoporotic low trauma fracture (fragility fracture) and considered at high risk for additional fracture AND Individual has had one of the following: (a) trial of an oral bisphosphonate OR (b) individual is intolerant to or has a contraindication to oral bisphosphonate therapy as defined by one of the following (1 through 5): (1) Hypersensitivity to TWO oral bisphosphonates (one of which must be generic alendronate) OR (2) Inability to stand or sit upright for at least 30 minutes OR (3) A pre-existing gastrointestinal disorder (for example, Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.) OR (4) Uncorrected hypocalcemia OR (5) Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 2 years. Requests to continue therapy beyond 24 months (2 years) should not be approved. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Tysabri

**Products Affected**

- TYSABRI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using for Types of MS other than relapsing forms. Currently responsive to and tolerating another treatment for MS or CD. Current or prior history of progressive multifocal leukoencephalopathy (PML). Medical condition which significantly compromises the immune system including HIV infection or AIDS, leukemia, lymphoma or organ transplantation. Concurrent use with chronic antineoplastics or immunosuppressants (for example, azathioprine) or TNF inhibitors. Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Tecfidera, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy, or Betaseron). Positive test results for anti- John Cunningham virus (JCV) antibodies. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual is using as monotherapy for relapsing forms of multiple sclerosis (MS) who have had an inadequate response to, or are unable to tolerate, alternative treatments for MS. For diagnosis of Crohns disease, individual is enrolled in and met all conditions of the CD or MS Touch Prescribing Program. |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |

# Tyvaso

**Products Affected**

- TYVASO
- TYVASO REFILL
- TYVASO STARTER

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnostic Criteria for PAH: right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than or equal to 25mmhg, a pulmonary capillary wedge pressure (PCWP), left atrial pressure or left ventricular end diastolic pressure (LVEDP) less than or equal to 15mmhg AND a pulmonary vascular resistance (PVR) greater than 3 wood units. Criteria for Vasodilator Response: a favorable response is defined as a fall in mPAP of at least 10mmhg to an absolute mPAP of less than 40mmhg without a decrease in cardiac output, when challenged with inhaled nitric oxide, intravenous epoprostenol or intravenous adenosine. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For Tyvaso, patient must meet all of the following: meets diagnostic criteria for PAH AND demonstrates an unfavorable acute response to vasodilators AND Individual has New York Heart Association (NYHA) functional class III, or IV symptoms: AND World health Organization (WHO) Group I PAH (idiopathic PAH, PAH associated with connective tissue disorders, PAH associated with congenital heart defects, and all Group 1 subtypes). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

Y0114_20_114079_I_012 December 2020

# Ubrelvy

**Products Affected**

- UBRELVY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using a strong CYP3A4 inhibitor (such as ketoconazole, itraconazole, clarithromycin). |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has had a trial/inadequate response or intolerance to 2 oral triptans (AHS 2019) OR Individual has one of the following CV or non-coronary vascular contraindications to use of triptans: Ischemic coronary artery disease (CAD) including angina pectoris, history of MI, documented silent ischemia, coronary artery vasospasm (including Prinzmetal's angina), history of stroke or TIA, PVD, ischemic bowel disease, or uncontrolled hypertension. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Uceris

**Products Affected**

- *budesonide er*
- UCERIS ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ultomiris

**Products Affected**

- ULTOMIRIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has evidence of active meningococcal infection.<br>Individual has not been immunized with meningococcal vaccine at least 2 weeks prior to administration of the first dose of Ultomiris unless clinical record documents the risks of delaying Ultomiris outweigh the risk of meningococcal infection. |
| **Required Medical Information** | Individual has Paroxysmal Nocturnal hemoglobinuria (PNH) as documented by flow cytometry (Written or Verbal attestation is acceptable)in the presence of 1) PNH type III red cell clone or a measurable granulocyte or monocyte clone OR 2) Glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells(PMNs). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has Lactate dehydrogenase greater than 1.5 times upper limit of normal AND has one or more PNH related symptoms (such as but not limited to anemia or history of major adverse vascular event from thromboembolism) |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Uptravi

**Products Affected**

- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLET THERAPY PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a diagnosis of severe hepatic impairment (Child-Pugh Class C). In combination with prostacyclin analogs [such as but not limited to treprostinil (Orenitram, Remodulin, Tyvaso), Epoprostenol (Flolan, Veletri), Ventavis (iliprost)] |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has catheterization-proven diagnosis of pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group 1) AND individual has WHO functional class II-IV symptoms. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Valchlor

**Products Affected**

- VALCHLOR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vancocin

**Products Affected**

- FIRVANQ
- VANCOCIN
- VANCOCIN HCL ORAL CAPSULE 125 MG, 250 MG
- *vancomycin hcl oral capsule 125 mg, 250 mg*
- *vancomycin hcl oral solution reconstituted*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual is being treated for enterocolitis caused by Staphylococcal aureus including methicillin-resistant strains. Individual is being treated for clostridium difficile. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 14 days |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vectibix

**Products Affected**

- VECTIBIX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has received prior treatment with cetuximab (Erbitux) [Note: a course of cetuximab discontinued because of an adverse reaction is not considered prior treatment] OR Vectibix is used in combination with other anti-VEGF agents (e.g., bevacizumab) OR Vectibix is being used for more than one line (course) of therapy. |
| **Required Medical Information** | Extended RAS gene mutation testing with an FDA approved test and results confirm (written or verbal) the tumor is RAS wild-type. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Used as a single agent or as part of combination therapy for stage IV colon, rectal, colorectal, small bowel or anal adenocarcinoma. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Velcade

**Products Affected**

- *bortezomib*
- VELCADE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vemlidy

**Products Affected**

- VEMLIDY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has end stage renal disease (estimated creatinine clearance below 15 mL/min). Individual has decompensated (Child-Pugh B or C) hepatic impairment |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Venclexta

**Products Affected**

- VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG
- VENCLEXTA STARTING PACK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Ventavis

**Products Affected**

- VENTAVIS

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnostic Criteria for PAH: right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than or equal to 25mmhg, a pulmonary capillary wedge pressure (PCWP), left atrial pressure or left ventricular end diastolic pressure (LVEDP) less than or equal to 15mmhg AND a pulmonary vascular resistance (PVR) greater than 3 wood units. Criteria for Vasodilator Response: a favorable response is defined as a fall in mPAP of at least 10mmhg to an absolute mPAP of less than 40mmhg without a decrease in cardiac output, when challenged with inhaled nitric oxide, intravenous epoprostenol or intravenous adenosine. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For Ventavis, patient must meet all of the following: meets diagnostic criteria for PAH AND demonstrates an unfavorable acute response to vasodilators AND Individual has New York Heart Association (NYHA) functional class III, or IV symptoms: AND World health Organization (WHO) Group I PAH (idiopathic PAH, PAH associated with connective tissue disorders, PAH associated with congenital heart defects, and all Group 1 subtypes). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Verzenio

**Products Affected**

- VERZENIO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vfend

**Products Affected**

- VFEND
- *voriconazole oral*

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual is currently transitioning from inpatient treatment (hospital/medical facility) with IV antifungal (voriconazole) to an outpatient (home) setting. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vibativ

**Products Affected**

- VIBATIV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 30 day supply/One time only |
| **Other Criteria** | Individual has started therapy in an inpatient setting and requires continued outpatient therapy for an organism susceptible to VIBATIV (telavancin). For hospital-acquired or ventilator-associated bacterial pneumonia (HABP or VABP), Individual has had a trial and an inadequate response or intolerance to or has a contraindication to at least one alternative antibiotic (such as but not limited to, intravenous vancomycin) (IDSA 2011, ATS/IDSA 2005). For complicated skin and skin structure infections (cSSSI), Individual has had an inadequate response to at least one alternative therapy (such as but not limited to, intravenous vancomycin) (IDSA 2014, 2011). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# VIBERZI

**Products Affected**

- VIBERZI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has a history of severe constipation or sequelae from constipation OR Biliary duct obstruction or sphincter of Oddi dysfunction OR History of pancreatitis or structural disease of the pancreas OR Excessive alcohol intake (more than 3 alcoholic beverages per day) OR Severe hepatic impairment (Child-Pugh Class C) OR Concomitant use with Lotronex (alosetron) OR history of cholecystectomy or absence of a gallbladder. |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 Year |
| **Other Criteria** | Individual is using for the treatment of irritable bowel syndrome with diarrhea (IBS-D) AND has had a trial and inadequate response or intolerance to two of the following medications or has a contraindication to all of the following medications: 1. Loperamide OR 2. Antispasmodics (such as dicyclomine) OR 3. Tricyclic antidepressants (AGA 2014). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vidaza

### Products Affected

- *azacitidine*
- VIDAZA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Viekira

**Products Affected**

- VIEKIRA PAK

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is requesting in concurrent therapy with alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergot derivatives, ethinyl estradiol-containing agents, St. Johns Wort, lovastatin, simvastatin, pimozide, efavirenz, Revatio (sildenafil), triazolam, and oral midazolam. Individual is using in combination with another NS3/4A protease inhibitor [such as but not limited to Olysio (simeprevir). Individual is using in combination with another non-nucleoside NS5B polymerase inhibitor. Individual is using in combination with another NS5A inhibitor (such as but not limited to, Harvoni [ledipasvir/sofosbuvir]. Individual is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of a serine NS3/4A protease inhibitor [such as but not limited to, Olysio (simeprevir), or paritaprevir] (AASLD/IDSA 2014). Individual is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of ombitasvir. Individual is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of a non-nucleoside NS5B polymerase inhibitor, such as dasabuvir or a regimen containing a nucleotide NS5B polymerase inhibitor, such as Sovaldi or Harvoni (AASLD/IDSA 2014). |

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance. Individual has had a prior trial and inadequate response to Harvoni (sofosbuvir/ledipasvir) OR individual is currently on and completing a course of therapy with the requested regimen OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni (ledipasvir/sofosbuvir) which is not also in Viekira OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni (sofosbuvir/ledipasvir). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vimizim

**Products Affected**

- VIMIZIM

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Confirmed diagnosis of Morquio A syndrome (Hendriksz 2015, Wood 2013) by documented reduced fibroblast or leukocyte N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity combined with normal enzyme activity level or another sulfatase or by genetic testing and Documented clinical signs and symptoms of Morquio A syndrome (for example, knee deformity, corneal opacity or pectus carinatum) (Hendriksz 2015, Wood 2013). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vimovo

**Products Affected**

- *naproxen-esomeprazole*
- VIMOVO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has had a trial and inadequate response or intolerance to one (1) oral generic prescription Non-Steroidal Anti-Inflammatory Drugs (NSAID) AND has had a trial and inadequate response or intolerance to one (1) of the following (Lanza 2009): (a) preferred proton pump inhibitor (PPI) OR (b) Generic misoprostol AND Individual has had an adequate response (pain relief and appropriate gastro protection) with a trial of naproxen and a proton pump inhibitor (such as esomeprazole) used at the same time AND Documentation has been provided for why the combination agent is clinically necessary and not for convenience. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Virazole

**Products Affected**

- *ribavirin inhalation*
- VIRAZOLE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual is hospitalized and will receive treatment in an inpatient setting. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vitrakvi

**Products Affected**

- VITRAKVI ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Written or verbal attestation to confirm genetic test results show the tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vizimpro

**Products Affected**

- VIZIMPRO ORAL TABLET 15 MG, 30 MG, 45 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | genetic mutations test result is confirmed by written or verbal attestation. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vosevi

**Products Affected**

- VOSEVI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has severe renal impairment (eGFR less than 30 mL/min/1.73m2), end stage renal disease, or requires dialysis OR Individual has moderate or severe hepatic impairment (Child-Pugh B or C). |
| **Required Medical Information** | Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a genotype and positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD/IDSA guidance. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance. For Genotype 1, 1a Individual has had a trial of and inadequate response to Harvoni (sofosbuvir/ledipasvir) OR Individual is currently on and completing a course of therapy with Vosevi OR has one of the following: (1) Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Harvoni(sofosbuvir/ledipasvir) which is not also in Vosevi OR (2) concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens OR (3) Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A inhibitor. For Genotype 4 Individual has had a trial of and inadequate response to Harvoni(sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) OR Individual is currently on and completing a course of therapy with Vosevi OR has one of the following: (1) Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Harvoni(sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) which is not also in Vosevi OR (2) concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens OR (3) Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A inhibitor. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# VOTRIENT

**Products Affected**

- VOTRIENT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vumerity

**Products Affected**

- VUMERITY
- VUMERITY (STARTER)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tecfidera and Tysabri). Individual with moderate or severe renal impairment (creatinine clearance less than 60 mL/min). Individual is using to treat non-active secondary progressive multiple sclerosis. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vyepti

**Products Affected**

- VYEPTI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is using concomitantly with botulinum toxin for migraine prophylaxis. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial 3 month, Continuation 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For Initial requests: Individual has dx of one of the following: (a)Episodic migraine defined as at least 4 and fewer than 15 migraine days per month and fewer than 15 headache days per month on average during the previous 3 month period OR (b) Chronic migraine defined as a headache occurring on 15 or more days per month for more than 3 months, which, on at least 8 days per month, has features of a migraine headache (ICHD-3). AND Individual has had a trial of and inadequate response or intolerance to two agents for migraine prophylaxis (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence, ICSI 2013, high quality evidence): (a) The following antidepressants: amitriptyline, venlafaxine or (b)One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol or (c) The following calcium channel blocker: verapamil or (d) One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin or (e) Botox (for chronic migraine). For Renewal requests: Individual has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month AND Individual has obtained clinical benefit deemed significant by individual or prescriber. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vyleesi

**Products Affected**

- VYLEESI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Treatment of HSDD in postmenopausal women. Treatment of HSDD in men. Enhancement of sexual performance. Individual has uncontrolled hypertension (systolic blood pressure greater than or equal to 140 mmHg, or diastolic blood pressure greater than or equal to 90 mmHg) (Clayton 2017 and ACC/AHA 2017). Individual has known cardiovascular disease (including, but not limited to, coronary heart disease, cerebrovascular disease, peripheral vascular disease, heart failure, and cardiomyopathies) (WHO 2019). Individuals who will be using Vyleesi (bremelanotide) in combination with Addyi (flibanserin). |
| **Required Medical Information** | |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) or acquired Female Sexual Interest Arousal Disorder (FSIAD) for at least 24 weeks characterized low sexual desire that causes marked distress or interpersonal difficulty. Individual is female AND is premenopausal AND it is confirmed that the diagnosis of HSDD or FSIAD is not caused by any of the following: (A) A co-existing psychiatric condition OR (B) A co-existing medical condition that could contribute to sexual dysfunction OR (C) Problems within a relationship OR (D) Other co-existing psychological conditions, such as loss of income or bereavement (NCT02333071, APA 2013). (E) Effects of a medication or other drug substance. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vyondys 53

**Products Affected**

- VYONDYS 53

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For initial therapy, individual has a confirmed diagnosis of Duchenne muscular dystrophy (DMD) AND a genetic mutation that is amendable to exon 53 skipping. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Continuation of therapy may be approved when initial therapy criteria are met and individual remains ambulatory with or without needing an assistive device, such as a cane or walker. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vytorin

**Products Affected**

- *ezetimibe-simvastatin*
- VYTORIN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has had a trial of TWO generic statin (at any dose) and did not achieve LDL cholesterol goal OR Individual is currently on an agent that interacts with both preferred generics. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Vyvanse

**Products Affected**

- VYVANSE

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual is using for weight loss. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual has diagnosis of binge-eating disorder OR has a diagnosis of attention deficit hyperactivity disorder (ADHD) AND Individual has had a trial of and insufficient response or intolerance to one of the following: (1) Methylphenidate extended-release or (2) Extended-release amphetamine/dextroamphetamine salt combination OR Individual has been diagnosed with coexisting ADHD and substance use disorder. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Wakix

**Products Affected**

- WAKIX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has severe hepatic impairment. Individual has a risk factor for prolonged QT interval. Is using with another drug that increases the QT interval. |
| **Required Medical Information** | For Narcolepsy type 1 confirmed by the following (ICSD-3): (1) Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following: (a) Clear cataplexy (defined as more than one episode of generally brief [less than 2 min]) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND (b) Multiple Sleep Latency Test (MSLT) with one of the following: (i) Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) OR (ii) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR (c) Cerebrospinal fluid hypocretin-1 deficiency (less than 100 pg/mL or less than one-third of the normative values with the same standardized assay). Narcolepsy type 2 confirmed by the following (ICSD-3): (1) Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months AND (2) Multiple sleep latency test (MSLT) with one of the following: (a) MSLT of less than 8 minutes and evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014) OR (b) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) AND (3) The absence of cataplexy AND (4) Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam, and PSG. |
| **Age Restrictions** | Individual is 18 years of age or older |
| **Prescriber Restrictions** | |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xalkori

**Products Affected**

- XALKORI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Documentation is provided that tumor is anaplastic lymphoma kinase (ALK)-positive or c-ros oncogene 1 (ROS1) positive. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xeljanz PDP

**Products Affected**

- XELJANZ
- XELJANZ XR

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Using in combination with, other JAK inhibitors (such as Olumiant), biologic disease-modifying antirheumatic drug (DMARDs) (such as but not limited to, TNF agents, anti-CD20 monoclonal antibodies, IL-1R antagonists, selective co-stimulation modulators) or potent immunosuppressants such as azathioprine and cyclosporine. At initiation of therapy, absolute neutrophil count (ANC) less than 1000 cells/mm3, lymphocyte count less than 500 cells/mm3, or hemoglobin less than 9 g/dL. Tuberculosis or other active serious infections or a history of recurrent infections. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis prior to initiating Xeljanz. Individual has severe hepatic impairment (Child Pugh class C). |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For RA and PsA, Individual had an inadequate response to, is intolerant of, or has a contraindication ONE conventional therapy [nonbiologic DMARDS (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] AND individual has had a trial of and an inadequate response or is intolerant to: Humira(adalimumab) OR the TNF agent (Humira (adalimumab)) tried and failed is not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Xeljanz or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis. For UC, Individual has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as 6-mercaptopurine, azathioprine, oral aminosalicylates, or oral corticosteroids) AND has had a trial of and an inadequate response or is intolerant to Humira (adalimumab) OR Humira (adalimumab) is not acceptable due to concomitant clinical conditions, such as but not limited to any of the following listed above (a-d) |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# XENAZINE

**Products Affected**

- *tetrabenazine oral tablet 12.5 mg, 25 mg*
- XENAZINE ORAL TABLET 12.5 MG, 25 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xermelo

**Products Affected**

- XERMELO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial: 3 months. Continuation: 1 year |
| **Other Criteria** | For initial therapy: Individual is using in combination with somtostatin analog (SSA) therapy (such as but not limited to, lanreotide(Somatuline Depot), cotreotide (Sandostatin)) AND individual has had an inadequate response on a stable dose of SSA monotherapy for at least 3 months. For continuation therapy: Individual has previously met the initiation criteria AND if clinically significant improvements are confirmed after 12 weeks pf treatment with Xermelo (telotristat ethyl) when added to SSA therapy |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xgeva

**Products Affected**

- XGEVA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Skeletally mature adolescent is defined by at least one mature long bone [for example, closed epiphyseal growth plate of the humerus]. Hypercalcemia of malignancy is defined as an albumin corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xiaflex

**Products Affected**

- XIAFLEX

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Repeat injection of a previously treated cord within one year of a prior course for treating Dupuytren's contracture. |
| **Required Medical Information** | For Peyronie disease, stable disease as define by symptoms (that is, penile curvature and pain) for at least 6 months and Penile curvature greater than or equal to 30 and less than or equal to 90 degrees and Intact erectile function with or without use of medications and Palpable penile plaque. For Dupuytren's contracture, there is documented impairment to the individual's functional activities which measures either: 20 degrees or more at the metacarpophalangeal (MP) joint or 20 degrees or more at the proximal interphalangeal (PIP) joint. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xifaxan - HE

**Products Affected**

- XIFAXAN ORAL TABLET 550 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xifaxan 200mg

**Products Affected**

- AEMCOLO
- XIFAXAN ORAL TABLET 200 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | For Xifaxan 200mg, travelers diarrhea (TD) caused by noninvasive strains of Escherichia coli AND Individual has already been started on Xifaxan and needs to complete treatment OR Individual has had a trial and inadequate response or intolerance to one of the following medications or has contraindications to all of the following medications (CDC, 2018): (1)Generic Fluoroquinolone OR(2)Azithromycin. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xolair

**Products Affected**

- XOLAIR SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- XOLAIR SUBCUTANEOUS SOLUTION RECONSTITUTED

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has Moderate to Severe Persistent Asthma AND has a positive skin test or in vitro reactivity to a perennial aeroallergen, AND individual has an FEV1 less than 80% predicted AND IgE level is equal to or greater than 30 IU/ml. Severe asthma as defined by the National Heart, Lung, and Blood Institute: Severe Persistent Asthma: symptoms throughout the day, extremely limited normal activity. Nocturnal symptoms are frequent, FEV1 or PEF is less than or equal to 60% predicted. Moderate Persistent Asthma as defined by the National Heart, Lung, and Blood Institute: Daily symptoms, daily use of inhaled short-acting beta2-agonist, somewhat limited activity, Nocturnal symptoms occur greater than 1 time per week, FEV1 or PEF is greater than 60% and less than 80% predicted, FEV1 FVC is reduced 5 percent or exacerbations requiring oral systemic corticosteroids use for more than or equal to 2 times per year. |
| **Age Restrictions** | Patient is 12 years of age or older for urticaria and 6 years of age or older for moderate to severe persistent asthma |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For moderate to severe persistent asthma, individual has had a minimum of 3 month trial and inadequate response or intolerance to ONE combination controller therapy (medium to high doses of inhaled corticosteroids plus long acting beta-2 agonists or Leukotriene modifiers)(GINA 2018). Continued treatment beyond 12 months is allowed when treatment has resulted in clinical improvement as documented by one or more of the following: Decreased utilization of rescue medications OR Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids) OR Increase in percent predicted FEV1 from pretreatment baseline OR Reduction in reported asthma-related symptoms, such as, but not limited to, wheezing, shortness of breath, coughing, fatigue, sleep disturbance, or asthmatic symptoms upon awakening. For chronic idiopathic urticaria, individual has had trial and inadequate response or intolerance to ONE potent antihistamine (AAAAI/ACAAI 2014). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xospata

**Products Affected**

- XOSPATA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Individual has confirmed FMS-like tyrosine kinase 3 (FLT3) mutation (written or verbal attestation is acceptable). |
| **Age Restrictions** | 18 years of age and older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xpovio

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xpovio

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xtandi

**Products Affected**

- XTANDI

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xuriden

**Products Affected**

- XURIDEN

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Xyrem

**Products Affected**

- XYREM
- XYWAV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For initial tx of Narcolepsy type 1 (narcolepsy with cataplexy) confirmed by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following: (1) Clear cataplexy (defined as more than one episode of generally brief [less than 2 min]) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND (2) Multiple Sleep Latency Test (MSLT) showing one of the following: (a) MSLT of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014) or (b) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR (3) Cerebrospinal fluid hypocretin-1 deficiency (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial Request 3 months, Renewal is 6 months. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For initial tx, of Narcolepsy type 2 (narcolepsy without cataplexy) confirmed by the following: (1) Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months AND (2) MSLT showing one of the following: (a) MSLT of less than 8 minutes with evidence of two SOREMPs (ICSD-3, 2014) or (b) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight PSG AND (3) absence of cataplexy AND (4) Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and PSG. AND (5) Mbr has had a previous trial of and inadequate response or intolerance to TWO of the following medications: (A) One of the following wakefulness promoting medications: (i) Modafinil or (ii) Nuvigil (armodafinil) AND (B) One of the following stimulants: (i) Methylphenidate (ii) Dextroamphetamine or (iii) Amphetamine/dextroamphetamine salt immediate-release OR (6) Trials of wakefulness promoting agents and stimulant agents are not acceptable due to concomitant clinical situations including but not limited to the following: (1) Cardiovascular disease or (2) Drug interactions. For Renewal of Narcolepsy type I or II, Xyrem (sodium oxybate) use has resulted in a reduction in frequency of cataplexy attacks OR use has resulted in a reduction in excessive daytime sleepiness (EDS) as measured by improvement in Epworth Sleepiness Scale (ESS) measurements or Maintenance of Wakefulness Test (MWT). For continuation, use has resulted in a reduction in frequency of cataplexy attacks compared to baseline OR use has resulted in a reduction in excessive daytime sleepiness (EDS) as measured by improvement in Epworth Sleepiness Scale (ESS) measurements or Maintenance of Wakefulness Test (MWT) compared to baseline |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Yervoy

**Products Affected**

- YERVOY

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individual has autoimmune disease which requires treatment with immunosuppressant drugs. |
| **Required Medical Information** | For small cell lung cancer, unresectable or metastatic melanoma (cutaneous or uveal), colorectal cancer, renal cell carcinoma, or first line treatment of stage IV/recurrent NSCLC, individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For the treatment of unresectable or metastatic melanoma (cutaneous and uveal): Used in combination with nivolumab (Opdivo) as: (a) First-line therapy or (b) Second-line or subsequent therapy for disease progression if nivolumab was not previously used or Ipilimumab is used as a single agent for one of the following: (a) First line therapy as a single course of 4 treatments or (b) Second-line or subsequent lines of therapy as a single course of 4 treatments or (c) Retreatment, consisting of a 4-dose limit, for an individual who had no significant systemic toxicity during prior ipilimumab therapy, and whose disease progressed after being stable for greater than 6 months following completion of a prior course of ipilimumab, and for whom no intervening therapy has been administered. OR used for the adjuvant treatment of cutaneous melanoma in individuals with pathologic involvement of regional lymph nodes of more than 1 millimeter who have undergone complete resection, including lymphadenetomy. For the treatment of small cell lung cancer (SCLC): Yervoy is used in combination with nivolumab (Opdivo) as subsequent therapy for one of the following: 1) demonstrated disease relapse within 6 months following complete or partial response or stable disease with initial treatment, OR 2) no response with initial treatment, OR 3) primary progressive disease. For colorectal cancer AND meets one of the following criteria: (a) Primary tx used in combination with nivolumab for unresectable metachronous metastases (defective mismatch repair/high microsatellite instability [dMMR/MSIH] only) and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months or (b) Ipilimumab is used in combination with nivolumab as subsequent therapy for unresectable advanced or metastatic colorectal cancer with defective mismatch repair (dMMR) or high microsatellite instability (MSIH) mutations that has progressed following treatment with fluoropyrimidine and oxaliplatin or irinotecan. For Renal cell |

| PA Criteria | Criteria Details |
|---|---|
| | carcinoma, when: (a) used in combination with nivolumab, as first-line therapy for previously untreated RCC or (b) used in subsequent therapy with nivolumab if no checkpoint blockade (PD-1, PD-L1, or CTLA-4) antibody treatment has been previously administered and (c)Histologic confirmation of RCC with clear-cell component. For stage IV/recurrent NSCLC when: used in combination with nivolumab and Cytologically confirmed stage IV or recurrent NSCLC and High tumor mutation burden (greater than or equal to 10 mutations per megabase) and No sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) translocations in nonsquamous carcinoma and Has not received prior systemic therapy as primary therapy for advanced or metastatic NSCLC, prior adjuvant or neoadjuvant chemotherapy is permitted as long as the last administration of the prior regimen occurred at least 6 months prior. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Yonsa

**Products Affected**

- YONSA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zaltrap

**Products Affected**

- ZALTRAP

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Diagnosis of metastatic anal adenocarcinoma or metastatic appendicle adenocarcinoma or metastatic small bowel adenocarcinoma or metastatic colorectal cancer AND used in combination with an irinotecan based regimen AND individual is resistant to or has disease progression following treatment with an oxaliplatin containing regimen AND Zaltrap will be used in a single line of therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zarxio

**Products Affected**

- ZARXIO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Febrile neutropenic individuals who are at risk for infection-associated complications or have any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10to the power of 9/L) neutropenia, Age greater than 65 years, Pneumonia or other clinically documented infection, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, prior episode of FN, or Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have other patient specific risk factors for FN including any of the following: Individual age greater than 65 years, Poor performance status (ECOG status 3-4), prior chemotherapy or radiation therapy, Bone marrow involvement by tumor producing cytopenias, persistent neutropenia (ANC less than 1500mm3), poor renal function (GFR less than 60mL/min) , liver dysfunction (liver function tests at least 2x upper limit of normal) or recent surgery and/or presence of open wounds. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Using for adjunctive tx for FN and has been prophylactic therapy with GCSF agent or has not received prophylactic therapy with a GCSF and who are at high risk for infection-associated complications. Use in acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy. Use in individuals with acute myeloid leukemia (AML) shortly after the completion of induction or repeat induction chemotherapy, or after the completion of consolidation chemotherapy for AML. For tx of moderate to severe aplastic anemia. Tx of severe neutropenia in individuals with hairy cell leukemia. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm3 or experiencing recurrent infection. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. For tx of (non-chemotherapy) drug-induced neutropenia. For tx of low neutrophil counts in individuals with glycogen storage disease type 1b. For tx of neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected. After accidental or intentional total body radiation of myleosuppressive doses (greater than 2 Grays [Gy] (such as Hematopoietic Syndrome of Acute Radiation Syndrome). After hematopoietic progenitor stem cell transplant (HPCT/HSCT) |

| PA Criteria | Criteria Details |
|---|---|
| | to promote myeloid reconstitution or when engraftment is delayed or has failed. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT). Use as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zavesca

**Products Affected**

- *miglustat*
- ZAVESCA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | May not be approved for use in conjunction with Cerdelga (eliglustat) or enzyme replacement therapy (ERT) agents (Cerezyme, Elelyso or Vpriv). Severe Type 1 Gaucher disease (hemoglobin less than 9 g/dL, platelet count less than 50,000 mm3 or those at risk developing new bone complications) (Weinreb et al. 2005). Individual has severe renal impairment (less than 30 mL/min/1.73 m2). Individual has mild, moderate or severe hepatic impairment or cirrhosis. |
| **Required Medical Information** | Presence of type 1 Gaucher disease is confirmed by either of the following (Weinreb et al. 2004, Wang et al. 2011): Glucocerebrosidase activity in the white blood cells or skin fibroblasts less than or equal to 30% of normal activity, OR genotype testing indicating mutation of two alleles of the glucocerebrosidase genome. And patient has clinically significant manifestations of gauchers disease including any of the following: skeletal disease (demonstrated by radiologic evidence of ANY of the following (Weineb et al. 2004):: avascular necrosis, erlenmeyer flask deformity, lytic disease, marrow infiltration, osteopenia, osteosclerosis, pathological fracture, joint deterioration or replacement) OR patient presents with at least 2 of the following (Weinreb et al. 2004, Mistry et al. 2015): clinically significant hepatomegaly as confirmed by medical imaging (such as but limited to, volumetric MRI), clinically significant splenomegaly as confirmed by medical imaging (such as but limited to, volumetric MRI), hgb less than or equal to 11.5 grams per dl for females or 12.5 grams per deciliter for males or 1 gram per deciliter below lower limit for normal for age and sex, platelet counts less than or equal to 120,000 mm3. |
| **Age Restrictions** | Individual is 18 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Enzyme replacement therapy with Cerezyme, ELELYSO or VPRIV is not a therapeutic option for reasons such as but limited to any of the following (Label, Weinreb et al. 2005): (a) Medically unmanageable hypersensitivity or (b) Development of therapy-limiting inhibitory antibodies or (c) Poor peripheral or central venous access. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zejula

**Products Affected**

- ZEJULA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | In the last 8 weeks, the individual has had a complete or partial response to a platinum-based chemotherapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zelboraf

**Products Affected**

- ZELBORAF

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Individuals with wild-type BRAF melanoma. |
| **Required Medical Information** | Individual has BRAF mutation and a copy of the BRAF test results must be provided. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zepatier

**Products Affected**

- ZEPATIER

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a genotype and positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2017). |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD/IDSA guidance. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, Individual has had a prior trial and inadequate response to Harvoni (sofosbuvir/ledipasvir) OR individual is currently on and completing a course of therapy with the requested regimen OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni (ledipasvir/sofosbuvir) which is not also in Zepatier OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni (sofosbuvir/ledipasvir) OR Individual has concomitant severe or end-stage CKD or requires dialysis. For GT 4, individual has had a prior trial and inadequate response to Harvoni (sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) OR individual is currently on and completing a course of therapy with the requested regimen OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni(sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) which is not also in Zepatier OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni(sofosbuvir/ledipasvir) or Epclusa(sofosbuvir/velpatasvir) OR Individual has concomitant severe or end-stage CKD or requires dialysis. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zeposia

**Products Affected**

- ZEPOSIA
- ZEPOSIA 7-DAY STARTER PACK
- ZEPOSIA STARTER KIT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tecfidera, Tysabri and Vumerity). Individual has had a recent (within the past 6 months) occurrence of one of the following: (a) Myocardial infarction OR (b) Unstable angina OR (c) Stroke OR (d) Transient ischemic attack (TIA) OR (e) Decompensated heart failure requiring hospitalization OR (f) Class III/IV heart failure. Individual has history or presence of Mobitz Type II second- or third-degree atrioventricular (AV) block, sick sinus syndrome or sino-atrial block, unless individual has a functioning pacemaker. Individual has severe untreated sleep apnea. Concurrent use with a monoamine oxidase (MAO) inhibitor (including but not limited to selegiline, phenelzine and linezolid). Individual is using to treat non-active secondary progressive multiple sclerosis. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |

# Zinplava

**Products Affected**

- ZINPLAVA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual has confirmed Clostridium difficile infection when the following are met: (a) Passage of three or more loose stools within 24 hours or less AND (b) Positive stool test for toxigenic Clostridium difficile from a stool sample collected not more than 7 days prior to scheduled infusion AND (c) currently receiving antibacterial therapy for Clostridium difficile infection AND (d) Individual is at high risk of Clostridium difficile infection recurrence meeting any one of the following: (1) Individual 65 years of age or older,or (2) history of Clostridium difficile infection in the past 6 months or (3) Immunocompromised state or (4) Severe Clostridium difficile infection at presentation or (4 5) Clostridium difficile ribotype 027. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zolinza

**Products Affected**

- ZOLINZA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zometa

**Products Affected**

- *zoledronic acid intravenous concentrate*
- *zoledronic acid intravenous solution 4 mg/100ml*
- ZOMETA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Bone metastases documented on imaging or bone pain associated with imaging-documented metastases from breast, prostate, lung, kidney, thyroid, or other solid tumors. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For Breast cancer, prevention of bone loss secondary to adjuvant hormone therapy OR for early stage, premenopausal breast cancer, prevention of bone loss secondary to ovarian dysfunction induced by adjuvant chemotherapy therapy OR Hypercalcemia of malignancy, treatment or Multiple myeloma OR Prevention of osteoporosis during androgen deprivation therapy in prostate cancer. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zulresso

**Products Affected**

- ZULRESSO

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year. |
| **Other Criteria** | Individual is 6 months postpartum or less AND has a diagnosis of moderate to severe postpartum depression consistent with qualifying score using a standardized screening tool for depression (such as, but not limited to, Hamilton Rating Scale for Depression [HAM-D], Patient Health Questionnaire [PHQ-9], Beck Depression Inventory [BDI], Montgomery-Asberg Depression Rating Scale [MADRS], Edinburgh Postnatal Depression Scale [EPDS]). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zydelig

**Products Affected**

- ZYDELIG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zykadia

**Products Affected**

- ZYKADIA

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zytiga

**Products Affected**

- *abiraterone acetate*
- ZYTIGA ORAL TABLET 250 MG, 500 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

# Zyvox

**Products Affected**

- *linezolid oral suspension reconstituted*
- *linezolid oral tablet*
- ZYVOX ORAL SUSPENSION RECONSTITUTED
- ZYVOX ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Confirmed vancomycin-resistant enterococcus faecium (VRE) infection. Confirmed methicillin-resistant S. aureus (MRSA) infection AND individual has had a trial and inadequate response or intolerance to or has contraindications to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: vancomycin, TMP-SMX, clindamycin, doxycycline, tetracycline (Based on 2011 IDSA MRSA guideline recommendations)). Individual started treatment with Zyvox in the hospital and requires continued outpatient therapy. Isolates of MRSA have a vancomycin minimum inhibitory concentration (MIC) of greater than 2. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 30 days |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

**Index**