Prior Authorization Criteria
2026 MCORE
Last Updated: 10/1/2026

# ABRYSVO

## Products Affected

- Abrysvo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | All indications: Vaccine is being used for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV). Immunization in age 60 years of age and older: Patient has not received an RSV vaccine (i.e., Abrysvo, Arexvy, MRESVIA) in their lifetime. Age greater than or equal to 60 years. Immunization in pregnancy: Patient has not received Abrysvo vaccine for the current pregnancy. Both of the following: 1) Will be used for active immunization of pregnant individuals at 32 through 36 weeks gestational age and 2) Will be used for the prevention of severe LRTD caused by RSV in infants from birth through 6 months of age. Immunization in age 18 through 59 years: Patient has not received an RSV vaccine (i.e., Abrysvo, Arexvy, MRESVIA) in their lifetime. Age 18 through 59 years. Patient is at increased risk for LRTD caused by RSV. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |

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| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ADALIMUMAB-AATY

## Products Affected

- Adalimumab-aaty 1-pen Kit INJ 80MG/0.8ML
- Adalimumab-aaty 2-pen Kit
- Adalimumab-aaty 2-syringe
- Adalimumab-aaty Cd/uc/hs Starter

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (Initial): Diagnosis (Dx) of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate (MTX), leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Dx of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (PsO) (Initial): Dx of moderate to severe chronic PSO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), C/I to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, OR calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Ankylosing Spondylitis (AS) (Initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Uveitis (UV) (Initial): Dx of non-infectious uveitis classified as intermediate, posterior, or panuveitis. |
| **Age Restrictions** | N/A |

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| **Prescriber Restrictions** | RA, AS, JIA: (Initial) Prescribed by or in consultation with a rheumatologist. PsA: (Initial) Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS: (Initial) Prescribed by or in consultation with a dermatologist. CD, UC: (Initial) Prescribed by or in consultation with a gastroenterologist. UV (initial): Prescribed by or in consultation with a rheumatologist or an ophthalmologist. |
| **Coverage Duration** | All uses (initial, reauth): plan year. |
| **Other Criteria** | Ulcerative Colitis (UC) (Initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. Hidradenitis suppurativa (HS) (Initial): Dx of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA, PsA, AS, PsO, CD, HS, UV, UC (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ADALIMUMAB-ADBM

## Products Affected

- Adalimumab-adbm

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (Initial): Diagnosis (Dx) of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate (MTX), leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Dx of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (PsO) (Initial): Dx of moderate to severe chronic PSO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), C/I to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, OR calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Ankylosing Spondylitis (AS) (Initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Uveitis (UV) (Initial): Dx of non-infectious uveitis classified as intermediate, posterior, or panuveitis. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | RA, AS, JIA: (Initial) Prescribed by or in consultation with a rheumatologist. PsA: (Initial) Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS: (Initial) Prescribed by or in consultation with a dermatologist. CD, UC: (Initial) Prescribed by or in consultation with a gastroenterologist. UV (initial): Prescribed by or in consultation with a rheumatologist or an ophthalmologist. |
| **Coverage Duration** | All uses (initial, reauth): plan year. |
| **Other Criteria** | Ulcerative Colitis (UC) (Initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. Hidradenitis suppurativa (HS) (Initial): Dx of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA, PsA, AS, PsO, CD, HS, UV, UC (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ADEMPAS

## Products Affected

- Adempas

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. Chronic thromboembolic pulmonary hypertension (CTEPH): One of the following: A) Both of the following: 1) Diagnosis of inoperable or persistent/recurrent CTEPH and 2) CTEPH is symptomatic OR B) Patient is currently on any therapy for the diagnosis of CTEPH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH, CTEPH: Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH, CTEPH: plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# AIMOVIG

## Products Affected

- Aimovig

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Episodic Migraines (EM) (initial): Diagnosis of EM. Patient has greater than or equal to 4 migraine days per month. Chronic Migraines (CM) (initial): Diagnosis of CM. Patient has greater than or equal to 8 migraine days per month.All Indications (initial): Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | EM, CM (initial, reauth): Plan year. |
| **Other Criteria** | EM, CM (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# AKEEGA

## Products Affected

- Akeega

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of prostate cancer. Disease is both of the following: a) metastatic and b) deleterious or suspected deleterious BRCA-mutated (BRCAm). Used in combination with prednisone. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ALECENSA

**Products Affected**

- Alecensa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is anaplastic lymphoma kinase (ALK)-positive. One of the following: 1) Disease is one of the following: a) Recurrent, b) Advanced, or c) Metastatic, or 2) Used as adjuvant treatment following tumor resection. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ALOSETRON

## Products Affected

- Alosetron Hydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Irritable bowel syndrome (IBS) (Initial): Exclude if patient is of the male gender. |
| **Required Medical Information** | IBS (Initial): Diagnosis of chronic severe diarrhea-predominant IBS. IBS (Reauthorization): Symptoms of IBS continue to persist. Patient demonstrates positive clinical response to therapy. |
| **Age Restrictions** | IBS (Initial): 18 years and older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | IBS (Initial): 12 weeks. IBS (Reauthorization): 6 months. |
| **Other Criteria** | IBS (initial): Trial and failure, contraindication, or intolerance to an anti-diarrheal agent [eg, loperamide]. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ALPHA - 1 PROTEINASE INHIBITORS

**Products Affected**

- Prolastin-c INJ 1000MG/20ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Alpha-1 antitrypsin (AAT) deficiency (initial): Diagnosis of congenital AAT deficiency. Diagnosis of emphysema. One of the following: Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous) or Other rare AAT disease genotypes associated with pre-treatment serum AAT level less than 11 µmol/L [eg, Pi(Malton, Malton), Pi(SZ)]. One of the following: 1) Circulating pre-treatment serum AAT level less than 11 µmol/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry), or 2) Patient has a concomitant diagnosis of necrotizing panniculitis. Continued conventional treatment for emphysema (eg, bronchodilators). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | AAT deficiency (initial, reauth): plan year |
| **Other Criteria** | AAT deficiency (reauth): Patient demonstrates positive clinical response to therapy. Continued conventional treatment for emphysema (e.g., bronchodilators). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ALUNBRIG

## Products Affected

- Alunbrig

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of metastatic, recurrent, or advanced NSCLC and tumor is anaplastic lymphoma kinase (ALK)-positive. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# AMBRISENTAN

## Products Affected

- Ambrisentan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH: Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# APREPITANT

## Products Affected

- Aprepitant

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Chemotherapy-induced Nausea and Vomiting (CINV): Patient is currently receiving moderately or highly emetogenic chemotherapy. Patient is concurrently on both corticosteroid [eg, Decadron (dexamethasone)] and 5-HT3 receptor antagonist [eg, Aloxi (palonosetron), Anzemet (dolasetron), Kytril (granisetron), Zofran (ondansetron)]. Delayed Chemotherapy-induced Nausea and Vomiting Prevention: Patient is currently receiving highly emetogenic chemotherapy and corticosteroid [eg, Decadron (dexamethasone)], or patient is receiving an anthracycline [eg, Adriamycin (doxorubicin), Ellence (epirubicin)] and Cytoxan (cyclophosphamide), or patient is currently receiving moderately emetogenic chemotherapy and was given aprepitant (oral or IV) on day 1 of chemotherapy. Postoperative Nausea and Vomiting (PONV): For the prevention of postoperative nausea and vomiting when administered prior to the induction of anesthesia. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Acute CINV, Delayed CINV: plan year. PONV: 1 month |
| **Other Criteria** | Subject to Part B vs. Part D review. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ARANESP

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Anemia due to Chronic Kidney Disease (CKD) (Initial): Diagnosis of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) within 30 days of request. The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. (Reauth): Diagnosis of CKD. Most recent or average (avg) Hct over 3 mo is 33% or less (Hgb 11 g/dL or less) for patients on dialysis, without ESRD OR Most recent or average (avg) Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis OR Most recent or average (avg) Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Patient demonstrates positive clinical response to therapy from pre-treatment level. Anemia w/ chemo (Initial): Other causes of anemia ruled out. Anemia w/ labs (Hct less than 30%, Hgb less than 10 g/dL) within prior 2 weeks of request. Cancer is non-myeloid malignancy. Patient is receiving chemo. (Reauth): Anemia by labs (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Patient demonstrates positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. Anemia in MDS (Init): Diagnosis of MDS. Serum erythropoietin 500 mU/mL or less, or transfusion dependent MDS. (Reauth): Most recent or avg Hct over 3 months was 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Patient demonstrates positive clinical response to therapy from pre-treatment level. |
| **Age Restrictions** | N/A |

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| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CKD(Init): 6 mo. CKD(reauth):plan yr. Chemo(init, reauth): 3 mo. MDS(init): 3 mo,(reauth): plan yr |
| **Other Criteria** | ESRD patients: Coverage is excluded under Medicare Part D for patients with ESRD on dialysis for any indication related or unrelated to treatment of ESRD since the payment for the drug is included in the ESRD PPS payment bundle. NON-ESRD PATIENTS for the following indications: Off-label uses (except Anemia in Myelodysplastic Syndrome (MDS): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.CKD (init, reauth), Chemo (init), MDS (init): Adequate iron stores confirmed by both of the following: a) Patient's ferritin level is greater than 100 mcg/L and b) Patient's transferrin saturation (TSAT) is greater than 20%. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ARCALYST

## Products Affected

- Arcalyst

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cryopyrin-Associated Period Syndromes (CAPS): Diagnosis of CAPS, Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS). Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA. Patient weighs at least 10 kg. Patient is currently in remission (e.g., no fever, skin rash, and bone pain/no radiological evidence of active bone lesions/C-reactive protein [CRP] less than 5 mg/L). Recurrent Pericarditis (initial): Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart. Trial and failure, contraindication, or intolerance (TF/C/I) to at least one of the following: nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen), colchicine, or corticosteroids (e.g., prednisone). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CAPS, DIRA: plan year. Recurrent Pericarditis (initial, reauth): plan year. |
| **Other Criteria** | Recurrent Pericarditis (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# AREXVY

## Products Affected

- Arexvy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Immunization in age 60 years of age and older: Vaccine is being used for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV). Patient has not received an RSV vaccine (i.e., Abrysvo, Arexvy, MRESVIA) in their lifetime. Age greater than or equal to 60 years. Immunization in age 18 through 59 years: Vaccine is being used for the prevention of LRTD caused by RSV. Patient has not received an RSV vaccine (i.e., Abrysvo, Arexvy, MRESVIA) in their lifetime. Age 18 through 59 years. Patient is at increased risk for LRTD caused by RSV. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ARIKAYCE

## Products Affected

- Arikayce

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Mycobacterium avium complex (MAC) lung disease: Diagnosis of Mycobacterium avium complex (MAC) lung disease. Used as part of a combination antibacterial drug regimen. Used in patients who do not achieve at least two negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy (e.g., a macrolide, a rifamycin, ethambutol, etc). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious disease specialist or pulmonologist. |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ARMODAFINIL

## Products Affected

- Armodafinil

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

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| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# AUGTYRO

**Products Affected**

- Augtyro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: a) advanced, b) metastatic, or c) recurrent. Disease is ROS1-positive. Solid Tumors: Diagnosis of solid tumors. Disease is positive for neutrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1). Disease is one of the following: a) Locally advanced, b) Metastatic, or c) Unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: a) Disease has progressed following treatment, or b) There is no satisfactory alternative therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year. |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# AUSTEDO

**Products Affected**

- Austedo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chorea associated with Huntington's disease: Diagnosis of Chorea associated with Huntington's disease. Tardive dyskinesia: Diagnosis of tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication or 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Huntington's disease chorea: Prescribed by or in consultation with a neurologist. Tardive dyskinesia: Prescribed by or in consultation with a neurologist or psychiatrist. |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# AVMAPKI FAKZYNJA

**Products Affected**

- Avmapki Fakzynja Co-pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of recurrent low-grade serous ovarian cancer (LGSOC). Tumor is KRAS-mutated. Patient has received prior systemic therapy (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# AVTOZMA SC

**Products Affected**

- Avtozma INJ 162MG/0.9ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), one formulary adalimumab product, Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinib), OR 2) for continuation of prior therapy if within the past 120 days. Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: 1) TF/C/I to two of the following: Enbrel (etanercept), one formulary adalimumab product, Rinvoq/Rinvoq LQ, Xeljanz (tofacitinib), OR 2) for continuation of prior therapy if within the past 120 days. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA, SJIA, PJIA, GCA (Initial): Prescribed by or in consultation with a rheumatologist. |
| **Coverage Duration** | RA, SJIA, PJIA, GCA (Initial, Reauth): Plan year. |
| **Other Criteria** | RA, SJIA, PJIA, GCA (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# AYVAKIT

## Products Affected

- Ayvakit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. One of the following: 1) Patient has unresectable, recurrent, or metastatic disease after progression on one approved therapy (e.g., imatinib, sunitinib, dasatinib, regorafenib, ripretinib) OR 2) Both of the following: a) Disease is one of the following: i) unresectable, ii) metastatic, iii) recurrent, iv) gross residual disease (R2 resection), v) residual disease with significant morbidity, vi) limited progression, or vii) resectable with significant morbidity AND b) Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Systemic Mastocytosis: Both of the following: 1) Diagnosis of one of the following: a) advanced systemic mastocytosis (AdvSM), b) aggressive systemic mastocytosis (ASM), c) systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or d) mast cell leukemia (MCL) AND 2) platelet count is greater than or equal to 50 x 10^9/L. Ayvakit 25 mg - Indolent Systemic Mastocytosis (ISM): Diagnosis of ISM. Platelet count is greater than or equal to 50 x 10^9/L. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# BALVERSA

## Products Affected

- Balversa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Urothelial Carcinoma: Diagnosis of urothelial carcinoma (UC). One of the following: Locally advanced or metastatic. Presence of fibroblast growth factor receptor (FGFR) 3 genetic alterations. Disease has progressed on or after at least one line of prior systemic therapy (e.g., chemotherapy). One of the following: 1) Patient has received prior systemic therapy containing an immune checkpoint inhibitor (e.g., pembrolizumab, nivolumab, avelumab) or 2) Patient is not eligible for immune checkpoint inhibitor therapy (e.g., pembrolizumab, nivolumab, avelumab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# BENLYSTA

## Products Affected

- Benlysta INJ 200MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Systemic Lupus Erythematosus (SLE) (Initial): Diagnosis of active SLE. Currently receiving at least one standard of care treatment for active SLE (eg, antimalarials [eg, Plaquenil (hydroxychloroquine)], corticosteroids [eg, prednisone], or immunosuppressants [eg, methotrexate, Imuran (azathioprine)]). Lupus Nephritis (Initial): Diagnosis of active lupus nephritis. Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide). SLE, Lupus Nephritis (Reauthorization): Patient demonstrates positive clinical response to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | SLE, Lupus Nephritis (initial, reauth): 6 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# BENZODIAZEPINES

## Products Affected

- Alprazolam TABS
- Clorazepate Dipotassium TABS
- Diazepam ORAL SOLN 5MG/5ML
- Diazepam TABS
- Diazepam Intensol

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The drug is being prescribed for a medically accepted indication. Prescriber acknowledges safety concerns (e.g., drowsiness, increased risk of falls, altered mental status) with the use of the prescribed benzodiazepine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# BESREMI

## Products Affected

- Besremi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of polycythemia vera. One of the following: a) Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women or b) Hematocrit greater than 49% for men or hematocrit greater than 48% for women. One of the following: a) Presence of JAK2 V617F or JAK2 exon 12 mutation or b) Patient has subnormal serum erythropoietin level. For high-risk polycythemia vera only (patient greater than or equal to 60 years old and/or prior thrombosis history), trial and inadequate response, contraindication or intolerance to hydroxyurea. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year. |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# BEXAROTENE

## Products Affected

- Bexarotene

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cutaneous T-cell lymphoma (CTCL): Diagnosis of cutaneous T-cell lymphoma (CTCL). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# BOSENTAN

## Products Affected

- Bosentan TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH: Prescribed by or in consultation with a pulmonologist or cardiologist |
| **Coverage Duration** | PAH: Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# BOSULIF

## Products Affected

- Bosulif
- Bosutinib TABS 400MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of chronic myelogenous/myeloid leukemia (CML). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# BRAFTOVI

**Products Affected**

- Braftovi CAPS 75MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Patient is positive for BRAF V600 mutation. Used in combination with Mektovi (binimetinib). Colorectal Cancer: One of the following diagnoses: Colon Cancer or Rectal Cancer. One of the following: 1) Unresectable or advanced disease or 2) Metastatic disease. Patient is positive for BRAF V600E mutation. Used in combination with one of the following: 1) Erbitux (cetuximab) or 2) Vectibix (panitumumab). Non-Small Cell Lung Cancer: Diagnosis of NSCLC. Disease is one of the following: recurrent, advanced, or metastatic. Patient is positive for BRAF V600 mutation. Used in combination with Mektovi (binimetinib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# BRIVIACT

## Products Affected

- Brivaracetam ORAL SOLN
- Brivaracetam TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Partial-onset seizures: Diagnosis of partial-onset seizures. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# BRUKINSA

**Products Affected**

- Brukinsa TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Mantle Cell Lymphoma (MCL): Diagnosis of MCL. Contraindication or intolerance to Calquence (acalabrutinib). Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. Disease is relapsed, refractory, or progressive. Patient has received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab). Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. Contraindication or intolerance to Calquence (acalabrutinib). Follicular Lymphoma (FL): Diagnosis of FL. Disease is relapsed or refractory. Used in combination with Gazyva (obinutuzumab). Patient has received at least two prior lines of systemic therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year. |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# BYLVAY

## Products Affected

- Bylvay
- Bylvay (pellets)

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Progressive familial intrahepatic cholestasis (PFIC) (initial): Diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1, 2, or 3, confirmed by one of the following: 1) Diagnostic test (e.g., liver function test, liver ultrasound and biopsy, bile analysis) or 2) Genetic testing. Alagille syndrome (ALGS) (initial): Diagnosis of Alagille Syndrome (ALGS). Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene. |
| **Age Restrictions** | PFIC (initial): Patient is 3 months of age or older |
| **Prescriber Restrictions** | PFIC, ALGS (initial): Prescribed by or in consultation with a hepatologist or gastroenterologist |
| **Coverage Duration** | PFIC, ALGS (initial): Plan Year. PFIC, ALGS (reauth): Plan year. |
| **Other Criteria** | PFIC, ALGS (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CABLIVI

**Products Affected**

- Cablivi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acquired thrombotic thrombocytopenic purpura (aTTP): Diagnosis of aTTP. First dose was/will be administered by a healthcare provider as a bolus intravenous injection. Used in combination with immunosuppressive therapy (e.g. rituximab, glucocorticoids). One of the following: 1) Used in combination with plasma exchange or 2) both of the following: patient has completed plasma exchange and less than 59 days have or will have elapsed beyond the last plasma exchange. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CABOMETYX

**Products Affected**

- Cabometyx

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Renal cell carcinoma (RCC): Diagnosis of one of the following: a) Advanced RCC, b) Relapsed RCC, or c) Hereditary leiomyomatosis and RCC (HLRCC). Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Used as subsequent-line systemic therapy. Differentiated Thyroid Cancer (DTC): Diagnosis of DTC. Disease is one of the following: a) locally advanced or b) metastatic. Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib]). Disease is radioactive iodine-refractory or ineligible. Pancreatic neuroendocrine tumors (pNET), Extra-pancreatic neuroendocrine tumors (epNET): Diagnosis of pNET or epNET. Disease is one of the following: a) unresectable, b) locally advanced, or c) metastatic. Tumors are well-differentiated. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# CALQUENCE

**Products Affected**

- Calquence TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Mantle Cell Lymphoma: Diagnosis of mantle cell lymphoma (MCL). One of the following: 1) All of the following: a) Patient has received no prior therapy for MCL (e.g., bortezomib, rituximab), b) Patient is ineligible for autologous hematopoietic stem cell transplantation (HSCT), and c) Used in combination with bendamustine and rituximab, or 2) Patient has received at least one prior therapy for MCL. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# CAMZYOS

## Products Affected

- Camzyos

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of obstructive hypertrophic cardiomyopathy (HCM). Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain). Patient has a left ventricular ejection fraction of greater than or equal to 55%. Patient has valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation. Trial and failure, contraindication, or intolerance to one of the following at a maximally tolerated dose: a) non-vasodilating beta blocker (e.g., bisoprolol, propranolol) or b) calcium channel blocker (e.g., verapamil, diltiazem). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial, Reauth: Prescribed by or in consultation with a cardiologist. |
| **Coverage Duration** | Initial: 6 months, Reauth: Plan Year |
| **Other Criteria** | Reauthorization: Patient demonstrates positive clinical response to therapy. Patient has a left ventricular ejection fraction of greater than or equal to 50%. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# CAYSTON

## Products Affected

- Cayston

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cystic Fibrosis (CF): Diagnosis of CF and lung infection with positive culture demonstrating Pseudomonas aeruginosa infection. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CHOLBAM

## Products Affected

- Cholbam

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of peroxisomal disorder, 2) patient exhibits at least one of the following: a) liver disease (eg, jaundice, elevated serum transaminases), OR b) steatorrhea, OR c) complications from decreased fat-soluble vitamin absorption (eg, poor growth), AND 3) Will be used as an adjunctive treatment. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by a hepatologist, medical geneticist, gastroenterologist, OR other specialist that treats inborn errors of metabolism. |
| **Coverage Duration** | Initial: 3 months Reauth: Plan year |
| **Other Criteria** | All uses (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CLOBAZAM

## Products Affected

- Clobazam SUSP 2.5MG/ML
- Clobazam TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Lennox-Gastaut syndrome: Diagnosis of Lennox-Gastaut syndrome. Used for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome. Dravet syndrome: Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with Diacomit. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CLONIDINE ER

**Products Affected**

- Clonidine Hydrochloride Er TB12

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of attention deficit hyperactivity disorder (ADHD). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# COBENFY

## Products Affected

- Cobenfy
- Cobenfy Starter Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of schizophrenia. Trial and failure, contraindication, or intolerance to one of the following: a) aripiprazole, b) asenapine, c) olanzapine, d) paliperidone, e) quetiapine (IR or ER), f) risperidone, or g) ziprasidone. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# COMETRIQ

## Products Affected

- Cometriq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# COPIKTRA

## Products Affected

- Copiktra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. Disease is relapsed or refractory. Trial and failure, contraindication, or intolerance to at least two prior therapies for CLL/SLL [e.g., Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), etc.]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# CORLANOR

## Products Affected

- Ivabradine Hydrochloride

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

| | |
|---|---|
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# COSENTYX

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance (TF/C/I) to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one non-steroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with signs of inflammation. Minimum duration of a one-month TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, naproxen) at maximally tolerated doses. Hidradenitis suppurativa (HS) (Initial): Diagnosis of moderate to severe HS. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Plaque psoriasis, HS (Initial): Prescribed by or in consultation with a dermatologist. Psoriatic Arthritis (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. AS, nr-axSpA, ERA (initial): Prescribed by or in consultation with a rheumatologist. |
| **Coverage Duration** | All uses (Initial, Reauth): plan year. |

| | |
|---|---|
| **Other Criteria** | Enthesitis-Related Arthritis (ERA) (Initial): Diagnosis of active ERA. Minimum duration of a one-month TF/C/I to two NSAIDs (eg, ibuprofen, naproxen) at maximally tolerated doses. All indications (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# COTELLIC

## Products Affected

- Cotellic

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma: Diagnosis of unresectable or metastatic melanoma. Disease is positive for BRAF V600E or V600K mutation. Used in combination with Zelboraf (vemurafenib). Histiocytic Neoplasm: Diagnosis of histiocytic neoplasm. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CRESEMBA ORAL

## Products Affected

- Cresemba CAPS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of invasive aspergillosis or invasive mucormycosis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CRINONE

## Products Affected

- Crinone GEL 8%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | All indications: Excluded if for fertility uses. |
| **Required Medical Information** | Secondary amenorrhea: Diagnosis of secondary amenorrhea (the absence of menses in women who have already started menstruation who are not pregnant, breastfeeding, or in menopause). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CTEXLI

## Products Affected

- Ctexli

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of cerebrotendinous xanthomatosis (cholestanol storage disease). Disease is confirmed by the presence of pathogenic variant(s) in the CYP27A1 gene. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with one of the following: a) Neurologist, b) Geneticist, c) Metabolic disease specialist, or d) endocrinologist. |
| **Coverage Duration** | Initial, Reauth: Plan year. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# DANZITEN

## Products Affected

- Danziten

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of chronic myeloid leukemia. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | For continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# DAURISMO

## Products Affected

- Daurismo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute myeloid leukemia (AML): Diagnosis of newly-diagnosed acute myeloid leukemia (AML) AND Daurismo therapy to be given in combination with low-dose cytarabine AND One of the following: 1) Patient is greater than or equal to 75 years old, or 2) Patient has significant comorbidities that preclude the use of intensive induction chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# DEFERASIROX

## Products Affected

- Deferasirox TABS
- Deferasirox TBSO

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Iron Overload due to Blood Transfusions (initial): Diagnosis of chronic iron overload (eg, sickle cell anemia, thalassemia, etc.) due to blood transfusion. Patient has blood transfusion of at least 100 mL/kg of packed red blood cells (eg, at least 20 units of packed red blood cells for a 40-kg person or more in individuals weighing more than 40 kg) prior to initiation of treatment with deferasirox. Patient has serum ferritin levels consistently greater than 1000 mcg/L prior to initiation of treatment with deferasirox. Chronic Overload in non-transfusion dependent thalassemia syndromes (initial): Diagnosis of chronic iron overload in non-transfusion dependent thalassemia syndrome. Patient has liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of treatment with deferasirox. Patient has serum ferritin levels consistently more than 300 mcg/L prior to initiation of treatment with deferasirox. Chronic Iron Overload due to Blood Transfusions, Chronic Overload in non-transfusion dependent thalassemia syndromes (reauthorization): Patient demonstrates positive clinical response to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by a hematologist/oncologist or hepatologist. |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# DEGARELIX

## Products Affected

- Firmagon INJ 120MG/VIAL, 80MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prostate Cancer: Diagnosis of prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# DICLOFENAC GEL 3%

**Products Affected**

- Diclofenac Sodium GEL 3%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Actinic Keratosis (initial): Diagnosis of Actinic Keratosis. Actinic Keratosis (reauthorization): Patient demonstrates positive clinical response to therapy. At least 30 days have elapsed since cessation of diclofenac sodium 3% topical gel therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 90 days |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# DICLOFENAC TOPICAL SOLUTION 1.5%

## Products Affected

- Diclofenac Sodium TOPICAL SOLN 1.5%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of osteoarthritis of the knee(s). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# DOPTELET

## Products Affected

- Doptelet

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Thrombocytopenia Prior to Planned Procedure (TPPP): Diagnosis (dx) of thrombocytopenia. Patient has chronic liver disease and is scheduled to undergo a procedure. Baseline platelet count is less than 50,000/mcL. Immune Thrombocytopenia (ITP) (initial): Diagnosis of chronic ITP, relapsed/refractory ITP, or pediatric patient with persistent ITP. Baseline platelet count is less than 30,000/mcL. Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | TPPP: 1 month. ITP (initial, reauth): Plan year |
| **Other Criteria** | ITP (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# DOPTELET SPRINKLE

## Products Affected

- Doptelet Sprinkle

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Immune Thrombocytopenia (ITP) (initial): Diagnosis of chronic ITP, relapsed/refractory ITP, or pediatric patient with persistent ITP. Baseline platelet count is less than 30,000/mcL. Trial, contraindication, or intolerance to at least one of the following: corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | ITP (initial, reauth): Plan year |
| **Other Criteria** | ITP (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# DRONABINOL

## Products Affected

- Dronabinol CAPS

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

# DROXIDOPA

## Products Affected

- Droxidopa

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

# DUPIXENT

## Products Affected

- Dupixent INJ 200MG/1.14ML, 300MG/2ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Eosinophilic Asthma (EA) (init): Dx of moderate to severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter. One of the following: 1) Patient (Pt) has had two or more asthma exacerbations requiring systemic corticosteroids (CS) (eg, prednisone) within the past 12 mo, or 2) Prior asthma-related hospitalization within the past 12 mo. Corticosteroid Dependent Asthma (CDA) (init): Dx of moderate to severe asthma. Pt is currently dependent on oral CS for the treatment of asthma. EA, CDA (init): One of the following: a) Pt is 6 years of age or older but less than 12 years of age AND Pt is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications: 1) Medium-dose inhaled corticosteroid (eg, greater than 100 - 200 mcg fluticasone propionate equivalent/day) and additional asthma controller medication (eg, leukotriene receptor antagonist [LTRA] [eg, montelukast], long-acting beta-2 agonist [LABA] [eg, salmeterol], long-acting muscarinic antagonist [LAMA] [eg, tiotropium]) OR 2) One medium dosed combination ICS/LABA product (eg, Wixela Inhub [fluticasone propionate 100mcg/ salmeterol 50mcg], budesonide 80mcg/ formoterol 4.5mcg, Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg]) OR b) Pt is 12 years of age or older AND Pt is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications: 1) High-dose ICS [eg, greater than 500 mcg fluticasone propionate equivalent/day] and additional asthma controller medication [eg, LTRA (eg, montelukast), LABA (eg, salmeterol), LAMA (eg, tiotropium)] OR 2) One max-dosed combination ICS/LABA product (eg, Wixela [fluticasone propionate 500mcg/salmeterol 50mcg], budesonide 160mcg/formoterol 4.5mcg, Breo Ellipta [fluticasone 200mcg/vilanterol 25mcg]). |

| | |
|---|---|
| **Age Restrictions** | AD (init): Pt is 6 months of age or older. EoE (init): Pt is 1 year of age or older. |
| **Prescriber Restrictions** | AD, PN, CSU, BP (init): Prescribed by or in consultation with a dermatologist or allergist/immunologist. Asthma (init): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. AFRS, CRSwNP (init): Prescribed by or in consultation with an otolaryngologist, allergist/immunologist, or pulmonologist. EoE (init): Prescribed by or in consultation with a gastroenterologist or allergist/immunologist. COPD (init): Prescribed by or in consultation with a pulmonologist. |
| **Coverage Duration** | AFRS, CRSwNP, EoE, Asthma, AD, PN, COPD, CSU, BP (Init/Reauth): Plan year. |

| | |
|---|---|
| **Other Criteria** | Atopic Dermatitis (AD) (init): Diagnosis (dx) of moderate-to-severe AD. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure, contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance to one of the following: Pimecrolimus cream or Tacrolimus ointment. Eosinophilic esophagitis (EoE) (init): Dx of EoE. Pt weighs at least 15 kg. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following: a) proton pump inhibitors (eg, pantoprazole, omeprazole) or b) topical (esophageal) CS (eg, budesonide, fluticasone). AD, EA, EoE, PN, CDA, COPD, CRSwNP, CSU, BP, AFRS (reauth): Pt demonstrates positive clinical response to therapy (Tx). Chronic rhinosinusitis with nasal polyposis (CRSwNP) (init): Dx of CRSwNP. Unless contraindicated, the pt has had an inadequate response to 2 mo of treatment with an intranasal corticosteroid (eg, fluticasone, mometasone). Used in combination with another agent for CRSwNP. Prurigo nodularis (PN) (init): Dx of PN. Chronic Obstructive Pulmonary Disease (COPD) (init): Dx of COPD. Presence of type 2 inflammation evidenced by blood eosinophils greater than or equal to 300 cells/mcL at baseline. Pt is receiving one of the following at maximally tolerated doses: triple Tx (ie, an ICS [eg, budesonide], a LAMA [eg, tiotropium, umeclidinium], and a LABA [eg, salmeterol, arformoterol, formoterol]) OR if contraindicated to ICS, a LAMA, and a LABA. Post-bronchodilator forced expiratory volume [FEV1] / forced vital capacity [FVC] ratio less than 0.70 while on Tx. Pt has had one of the following within the past 12 mo: At least two exacerbations where systemic CS [intramuscular, intravenous, or oral (eg, prednisone)] were required at least once OR COPD-related hospitalization. Chronic Spontaneous Urticaria (CSU) (init): Dx of CSU. Persistent symptoms (itching and hives) with a second generation H1 antihistamine (eg, cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines. Bullous pemphigoid (BP) (init): Dx of BP. Allergic Fungal Rhinosinusitis (AFRS) (init): Dx of AFRS. Pt has history of sino-nasal surgery. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# EBGLYSS

## Products Affected

- Ebglyss

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of moderate to severe atopic dermatitis. Patient weighs at least 40 kg. One of the following: a) Involvement of at least 10% body surface area (BSA) or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure, contraindication, or intolerance to one of the following: Pimecrolimus cream or Tacrolimus ointment. |
| **Age Restrictions** | Initial: Patient is 12 years of age or older. |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with a dermatologist or allergist/immunologist. |
| **Coverage Duration** | Initial, Reauth: Plan Year. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ELIGARD

## Products Affected

- Eligard

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prostate Cancer: Treatment of advanced prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# EMFLAZA

## Products Affected

- Deflazacort
- Jaythari SUSP
- Kymbee
- Pyquvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of Duchenne muscular dystrophy (DMD). Patient has received genetic testing for a mutation of the dystrophin gene. Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following: A) Documentation of a confirmed mutation of the dystrophin gene or B) Muscle biopsy confirmed an absence of dystrophin protein. Patient has had a trial and failure or intolerance to prednisone or prednisolone. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Initial, Reauth: Plan year |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# EMGALITY

## Products Affected

- Emgality

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Episodic Migraines (EM) (120 mg/mL strength only) (initial): Diagnosis of EM. Patient has greater than or equal to 4 migraine days per month. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. Chronic Migraines (CM) (120 mg/mL strength only) (initial): Diagnosis of CM. Patient has greater than or equal to 8 migraine days per month. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. Episodic Cluster Headaches (ECH) (100 mg/mL strength only) (initial): Diagnosis of ECH. Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months. Medication will not be used in combination with another injectable CGRP inhibitor. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | EM, CM, ECH (initial, reauth): Plan year. |
| **Other Criteria** | ECH, EM, CM (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ENBREL

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), C/I to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA, JIA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. Plaque Psoriasis (Initial): Prescribed by or in consultation with a dermatologist. |

| | |
|---|---|
| **Coverage Duration** | All indications (initial, reauth): plan year |
| **Other Criteria** | All indications (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ENDARI

## Products Affected

- L-glutamine PACK

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Sickle cell disease (initial): Diagnosis of sickle cell disease. Used to reduce acute complications of sickle cell disease. Patient has had 2 or more painful sickle cell crises within the past 12 months. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Sickle cell disease (initial, reauth): plan year |
| **Other Criteria** | Sickle cell disease (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ENSACOVE

## Products Affected

- Ensacove

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of non-small cell lung cancer (NSCLC). Tumor is anaplastic lymphoma kinase (ALK)-positive. Disease is one of the following: a) Advanced, b) Metastatic, or c) Recurrent. Patient has not previously received an ALK-inhibitor [e.g. Alecensa (alectinib), Alunbrig (brigatinib), Lorbrena (lorlatinib), Zykadia (ceritinib)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ENTYVIO SC

## Products Affected

- Entyvio Pen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Crohn's Disease (CD) (initial): Diagnosis of moderately to severely active CD. Ulcerative Colitis (UC) (initial): Diagnosis of moderately to severely active UC. CD, UC (initial): One of the following: a) Will be used as a maintenance dose following two doses of Entyvio IV for induction, or b) Patient is currently established on Entyvio IV. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | CD, UC (initial): 14 weeks. CD, UC (reauth): plan year. |
| **Other Criteria** | CD, UC (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# EPCLUSA

## Products Affected

- Sofosbuvir/velpatasvir

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C virus. Patient is not receiving sofosbuvir/velpatasvir in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]. ONE of the following: a) Trial, intolerance, or contraindication (eg, safety concerns, not indicated for patient's age/weight) to Mavyret (except patients with decompensated cirrhosis), OR b) for continuation of prior therapy if within the past 120 days. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 to 24 weeks. Criteria applied consistent with current AASLD/IDSA guideline |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# EPIDIOLEX

## Products Affected

- Epidiolex

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Lennox-Gastaut syndrome (LGS): Diagnosis of seizures associated with LGS. Trial of, contraindication, or intolerance to two formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate). Dravet syndrome (DS): Diagnosis of seizures associated with DS. Tuberous sclerosis complex (TSC): Diagnosis of seizures associated with TSC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# EPOETIN ALFA (PREFERRED)

**Products Affected**

- Procrit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Anemia due to Chronic Kidney Disease (CKD) (Initial): Diagnosis (dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) within 30 days of request. The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. (Reauth): Diagnosis of CKD. Most recent or average (avg) Hct over 3 months is 33% or less (Hgb 11 g/dL or less) for patients on dialysis, without ESRD OR Most recent or average (avg) Hct over 3 months is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis OR Most recent or average (avg) Hct over 3 months is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Patient demonstrates positive clinical response to therapy from pre-treatment level. Anemia w/ HIV (Initial): Anemia by labs (Hgb less than 12 g/dL or Hct less than 36%) within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Patient demonstrates positive clinical response to therapy from pre-treatment level. Anemia with chemo (Initial):Other causes of anemia ruled out. Anemia with labs (Hct less than 30%, Hgb less than 10 g/dL) within prior 2 weeks of request. Cancer is non-myeloid malignancy. Patient is receiving chemo. (Reauth): Anemia by labs (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 wks of request. Patient demonstrates positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CKD,HIV(Init):6mo.(reauth):plan yr.Chemo(init, reauth):3mo.MDS(init):3mo,(reauth):plan yr.Preop:1mo. |

| | |
|---|---|
| **Other Criteria** | Anemia in Myelodysplastic Syndrome (MDS) (Init): Diagnosis of MDS. Serum erythropoietin 500 mU/mL or less, or transfusion dependent MDS. (Reauth): Most recent or avg Hct over 3 months was 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Patient demonstrates positive clinical response to therapy from pre-treatment level. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. ESRD patients: Coverage is excluded under Medicare Part D for patients with ESRD on dialysis for any indication related or unrelated to treatment of ESRD since the payment for the drug is included in the ESRD PPS payment bundle. NON-ESRD PATIENTS for the following indications: Off-label uses (except Anemia in MDS and Hep C patients being treated with combo ribavirin and interferon/peginterferon): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.CKD (init, reauth), Chemo (init), preop, MDS (init): Adequate iron stores confirmed by both of the following: a) Patient's ferritin level is greater than 100 mcg/L and b) Patient's transferrin saturation (TSAT) is greater than 20%. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ERIVEDGE

## Products Affected

- Erivedge

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Metastatic basal cell carcinoma (BCC): Diagnosis of metastatic basal cell carcinoma. Advanced basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma. One of the following: Cancer has recurred following surgery, Patient is not a candidate for surgery, or Patient is not a candidate for radiation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ERLEADA

## Products Affected

- Erleada

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-metastatic castration-resistant prostate cancer (NM-CRPC): Diagnosis of non-metastatic, castration-resistant (chemical or surgical) or recurrent prostate cancer. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g., Zoladex [goserelin], Vantas [histrelin], Lupron [leuprolide], Trelstar [triptorelin], Firmagon [degarelix]) OR 2) Patient received a bilateral orchiectomy. Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of metastatic, castration-sensitive or naive prostate cancer. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron[leuprolide], Trelstar[triptorelin], Zoladex [goserelin], Vantas [histrelin], Firmagon [degarelix]) OR 2) Patient received bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ERLOTINIB

## Products Affected

- Erlotinib Hydrochloride TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-Small Cell Lung Cancer (NSCLC): 1) Diagnosis of NSCLC. Disease is one of the following: a) advanced, b) metastatic, or c) recurrent. Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletion mutations or exon 21 (L858R) substitution mutations or a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation). Pancreatic cancer: Diagnosis of locally advanced, unresectable or metastatic pancreatic cancer. Used in combination with Gemzar (gemcitabine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# EVEROLIMUS

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Neuroendocrine Tumors (NET): One of the following: 1) Both of the following: a) Diagnosis (Dx) of neuroendocrine tumors of gastrointestinal origin, lung origin, or thymic origin, and b) Disease is unresectable, locally advanced, or metastatic, OR 2) Diagnosis of neuroendocrine tumors of pancreatic origin, OR 3) All of the following: a) Diagnosis of well-differentiated, grade 3 neuroendocrine tumor, b) Disease is unresectable, locally advanced, or metastatic, and c) Tumor has favorable biology (e.g., relatively low Ki-67 [less than 55%], slow growing, positive SSTR-based PET imaging). Renal Cell Carcinoma/Kidney Cancer: Dx of renal cell cancer/kidney cancer. Disease is one of the following: (1) relapsed or (2) stage IV disease. Renal angiomyolipoma with tuberous sclerosis complex (TSC): Dx of renal angiomyolipoma and TSC. Subependymal Giant Cell Astrocytoma (SEGA) with tuberous sclerosis (TS): Dx of SEGA associated with TS. Breast Cancer: Dx of recurrent or metastatic breast cancer. One of the following: 1) Disease is hormone receptor positive (HR+) [i.e., estrogen-receptor-positive (ER+) or progesterone-receptor-positive (PR+)], 2) Breast cancer is considered inflammatory, OR 3) both of the following: disease is HR- and disease has clinical characteristics that predict a HR+ tumor. Disease is HER2-negative. One of the following: Patient is a postmenopausal woman, patient is a premenopausal woman being treated with ovarian ablation/suppression, or patient is male. One of the following: A) Both of the following: a) one of the following: 1) Disease progressed while on or within 12 months of non-steroidal aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole)] therapy or 2) patient was treated with tamoxifen at any time AND b) Used in combination with Aromasin (exemestane) OR B) Used in combination with Fulvestrant or Tamoxifen. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | All uses: Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# EVEROLIMUS SOLUTION

## Products Affected

- Everolimus TBSO

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Neuroendocrine Tumors (NET): One of the following: 1) Both of the following: a) Diagnosis (Dx) of neuroendocrine tumors of gastrointestinal origin, lung origin, or thymic origin, and b) Disease is unresectable, locally advanced, or metastatic, OR 2) Diagnosis of neuroendocrine tumors of pancreatic origin, OR 3) All of the following: a) Diagnosis of well-differentiated, grade 3 neuroendocrine tumor, b) Disease is unresectable, locally advanced, or metastatic, and c) Tumor has favorable biology (e.g., relatively low Ki-67 [less than 55%], slow growing, positive SSTR-based PET imaging). Renal Cell Carcinoma/Kidney Cancer: Dx of renal cell cancer/kidney cancer. Disease is one of the following: (1) relapsed or (2) stage IV disease. Renal angiomyolipoma with tuberous sclerosis complex (TSC): Dx of renal angiomyolipoma and TSC. Subependymal Giant Cell Astrocytoma (SEGA) with tuberous sclerosis (TS): Dx of SEGA associated with TS. Breast Cancer: Dx of recurrent or metastatic breast cancer. One of the following: 1) Disease is hormone receptor positive (HR+) [i.e., estrogen-receptor-positive (ER+) or progesterone-receptor-positive (PR+)], 2) Breast cancer is considered inflammatory, OR 3) both of the following: disease is HR- and disease has clinical characteristics that predict a HR+ tumor. Disease is HER2-negative. One of the following: Patient is a postmenopausal woman, patient is a premenopausal woman being treated with ovarian ablation/suppression, or patient is male. One of the following: A) Both of the following: a) one of the following: 1) Disease progressed while on or within 12 months of non-steroidal aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole)] therapy or 2) patient was treated with tamoxifen at any time AND b) Used in combination with Aromasin (exemestane) OR B) Used in combination with Fulvestrant or Tamoxifen. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

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|---|---|
| **Coverage Duration** | Plan year |
| **Other Criteria** | TSC Associated Partial-Onset Seizures: Dx of TSC associated partial-onset seizures. Used as adjunctive therapy. All uses: Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# FASENRA

## Products Affected

- Fasenra
- Fasenra Pen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Severe asthma (Initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: a) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months, OR b) Prior asthma-related hospitalization within the past 12 months. One of the following: 1) Both of the following: a) Patient is 6 years of age or older but less than 12 years of age, and b) Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: i) Medium-dose inhaled corticosteroid [ICS] (eg, greater than 100 - 200 mcg fluticasone propionate equivalent/day) AND Additional asthma controller medication (eg, leukotriene receptor antagonist [LTRA] [eg, montelukast], long-acting beta-2 agonist [LABA] [eg, salmeterol], long-acting muscarinic antagonist [LAMA] [eg, tiotropium]), OR ii) One medium dosed combination ICS/LABA product (eg, Wixela Inhub [fluticasone propionate 100mcg/salmeterol 50mcg], budesonide 80mcg/formoterol 4.5mcg, Breo Ellipta [fluticasone furoate 50 mcg/vilanterol 25 mcg]), OR 2) Both of the following: a) Patient is 12 years of age or older, and b) Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: 1) High-dose ICS (eg, greater than 500 mcg fluticasone propionate equivalent/day) and 2) additional asthma controller medication (e.g., LTRA [eg, montelukast], LABA [e.g., salmeterol], tiotropium) OR b) One maximally-dosed combination ICS/LABA product [e.g., Wixela (fluticasone propionate 500mcg/salmeterol 50mcg), budesonide 160mcg/formoterol 4.5mcg, Breo Ellipta (fluticasone 200mcg/vilanterol 25mcg)]. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | Severe Asthma (Initial): Prescribed by or in consultation with a pulmonologist or allergy/immunology specialist. EGPA (Initial): Prescribed by or in consultation with pulmonologist, rheumatologist, or allergist/immunologist. HES (Initial): Prescribed by or in consultation with an allergist/immunologist or hematologist. |
| **Coverage Duration** | All indications (Initial, Reauth): Plan year. |
| **Other Criteria** | Eosinophilic granulomatosis with polyangiitis (EGPA) (Initial): Diagnosis of EGPA. Patient's disease has relapsed or is refractory to standard of care therapy (ie, corticosteroid treatment with or without immunosuppressive therapy). Patient is currently receiving corticosteroid therapy (eg, prednisolone, prednisone) unless there is a contraindication or intolerance to corticosteroid therapy. Hypereosinophilic Syndrome (HES) (Initial): Diagnosis of HES. Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy). Patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative. Patient has pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter. Trial and failure, contraindication, or intolerance to corticosteroid therapy (e.g., prednisone) or cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib). EGPA, Severe asthma, HES (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# FINTEPLA

## Products Affected

- Fintepla

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | One of the following: 1) Diagnosis of seizures associated with Dravet syndrome, OR 2) Diagnosis of seizures associated with Lennox-Gastaut syndrome. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# FLUCYTOSINE

## Products Affected

- Flucytosine CAPS 250MG, 500MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of one of the following: a) candidal endocarditis, b) candidiasis, c) candidiasis of urogenital site, d) candida endophthalmitis, e) central nervous system candidiasis, f) cryptococcosis, g) cryptococcal meningitis – HIV infection, h) HIV infection – pulmonary cryptococcosis, i) peritoneal dialysis-associated peritonitis, Fungal. Used in combination with amphotericin B. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 weeks |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# FOTIVDA

## Products Affected

- Fotivda

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of advanced renal cell carcinoma. Disease is one of the following: relapsed or refractory. Patient has received two or more prior systemic therapies (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# FRUZAQLA

**Products Affected**

- Fruzaqla

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of colorectal cancer. Disease is one of the following: Advanced or Metastatic. Patient has been previously treated with both of the following: A) Fluoropyrimidine-, oxaliplatin-, irinotecan-based chemotherapy, and B) Anti-VEGF biological therapy (e.g., bevacizumab, ramucirumab). One of the following: A) Patient has RAS mutant tumors, OR B) Both of the following: a) Patient has RAS wild type tumors, AND b) Patient has been previously treated with an anti-EGFR biological therapy (e.g., panitumumab, cetuximab) |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# GAVRETO

## Products Affected

- Gavreto

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: recurrent, advanced, or metastatic. Presence of RET (rearranged during transfection) gene fusion-positive or RET rearrangement positive tumors. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is one of the following: advanced or metastatic. Disease is rearranged during transfection (RET) gene fusion-positive. Disease requires treatment with systemic therapy. One of the following: patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# GILOTRIF

**Products Affected**

- Gilotrif

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. One of the following: 1) Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by an FDA-approved test OR 2) squamous disease progressing after previous platinum-based chemotherapy (e.g., cisplatin, carboplatin) OR 3) tumors are positive for a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# GLYCOPYRROLATE

## Products Affected

- Glycopyrrolate TABS 1MG, 2MG

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

# GOMEKLI

## Products Affected

- Gomekli

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of neurofibromatosis type 1. Patient has plexiform neurofibromas that are inoperable. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# GROWTH HORMONES

## Products Affected

- Genotropin
- Genotropin Miniquick

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

| | |
|---|---|
| **Coverage Duration** | All indications (initial, reauth): Plan year |
| **Other Criteria** | AGHD(initial):dx of AGHD as a result of clin records supportng dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT],glucagon,macimorelin) to confirm adult GHD w/corresponding peak GH values ([ITT at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin at or below 2.8 ng/mL 30, 45, 60 and 90 mins after admin]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IGF-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab.<br>AGHD,IGHDA(reauth):evidence of ongoing monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level.<br>IGHDA(initial):doc GHD after 2 GH stim tests(ITT,glucagon,macimorelin) w/ 2 corresponding peak GH values [ITT at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin at or below 2.8 ng/mL 30,45,60,90 mins after admin]. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# HAEGARDA

## Products Affected

- Haegarda

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of hereditary angioedema (HAE). One of the following: 1) Diagnosis has been confirmed by both of the following: a) C4 level below the lower limit of normal, and b) C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following: i) C1-INH antigenic level below the lower limit of normal OR ii) C1-INH functional level below the lower limit of normal, OR 2) Diagnosis has been confirmed by both of the following: a) Both of the following: i) Normal C4 level AND ii) Normal C1-INH levels (HAE-nl-C1INH previously referred to as HAE Type III), and b) One of the following: i) Presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation OR ii) Patient has a confirmed family history of recurrent angioedema. For prophylaxis against HAE attacks. Not used in combination with other approved treatments for prophylaxis against HAE attacks. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with an immunologist or allergist. |
| **Coverage Duration** | Initial, Reauth: Plan year. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# HERNEXEOS

## Products Affected

- Hernexeos

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: a) unresectable, b) metastatic, c) recurrent, or d) advanced. Presence of HER2 (ERBB2) tyrosine kinase domain activating mutations. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# HYRNUO

## Products Affected

- Hyrnuo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: advanced, metastatic, recurrent, or unresectable. Presence of HER2 (ERBB2) tyrosine kinase domain activating mutations. Patient has received prior systemic therapy (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# IBRANCE

## Products Affected

- Ibrance CAPS 125MG
- Ibrance TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast cancer: Diagnosis of breast cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# IBTROZI

## Products Affected

- Ibtrozi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: 1) Advanced or 2) Metastatic. Tumor is ROS1 positive. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ICATIBANT

## Products Affected

- Icatibant Acetate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of hereditary angioedema (HAE). One of the following: 1) Diagnosis has been confirmed by both of the following: a) C4 level below the lower limit of normal, and b) C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following: i) C1-INH antigenic level below the lower limit of normal OR ii) C1-INH functional level below the lower limit of normal, OR 2) Diagnosis has been confirmed by both of the following: a) Both of the following: i) Normal C4 level AND ii) Normal C1-INH levels (HAE-nl-C1INH previously referred to as HAE Type III), and b) One of the following: i) Presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation OR ii) Patient has a confirmed family history of recurrent angioedema. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with an immunologist or allergist. |
| **Coverage Duration** | Initial, Reauth: Plan year. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ICLUSIG

## Products Affected

- Iclusig

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Myelogenous / Myeloid Leukemia (CML): Diagnosis of chronic myelogenous/myeloid leukemia (CML). One of the following: a) Both of the following: Disease is in the chronic phase AND patient is unable to take or has failed treatment with two or more alternative tyrosine kinase inhibitors (TKI) [eg, Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib)], b) confirmed documentation of T315I mutation, or c) Both of the following: Disease is in the accelerated or blast phase AND no other kinase inhibitors are indicated. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# IDHIFA

## Products Affected

- Idhifa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Myeloid Leukemia (AML): Diagnosis of AML. AML is isocitrate dehydrogenase-2 (IDH2) mutation-positive. One of the following: A) Disease is relapsed or refractory, B) Patient is not a candidate for or patient declines intensive induction therapy, C) Used for post induction therapy following response to low intensity induction therapy, or D) Used for consolidation therapy as continuation of low-intensity regimen used for induction. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# IMBRUVICA

## Products Affected

- Imbruvica CAPS
- Imbruvica SUSP
- Imbruvica TABS 140MG, 280MG, 420MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Chronic Graft Versus Host Disease (cGVHD): Diagnosis of cGVHD AND trial and failure of at least one other systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate, etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# IMKELDI

**Products Affected**

- Imkeldi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Myelogenous/Myeloid Leukemia (CML): Diagnosis of CML. Acute Lymphoblastic Leukemia (ALL): Diagnosis of Philadelphia chromosome positive/BCR ABL-positive (Ph+/BCR ABL+) ALL. Myelodysplastic/Myeloproliferative Disease (MDS/MPD): Diagnosis of MDS/MPD. One of the following: 1) Disease is associated with 5q32 translocations, 2) Disease is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements, or 3) disease is associated with a t(5:12) translocation associated with the ETV6-PDGFRbeta fusion gene. Aggressive Systemic Mastocytosis (ASM): Diagnosis of ASM. One of the following: a) Patient is without the D816V c-Kit mutation, b) c-Kit mutational status is unknown, c) Well-differentiated systemic mastocytosis (WDSM), or d) Eosinophilia is present with FIP1L1-PDGFRA fusion gene. Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL): Diagnosis of at least one of the following: HES or CEL. Dermatofibrosarcoma Protuberans (DFSP): Diagnosis of unresectable, recurrent, or metastatic DFSP. Gastrointestinal Stromal Tumors (GIST): Diagnosis of GIST. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# INBRIJA

## Products Affected

- Inbrija

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Parkinson's disease (PD) (initial): Diagnosis of PD. Patient is experiencing intermittent OFF episodes. Used in combination with carbidopa/levodopa. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | PD (initial, reauth): Plan year |
| **Other Criteria** | PD (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# INGREZZA

## Products Affected

- Ingrezza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Tardive Dyskinesia: Diagnosis of tardive dyskinesia. One of the following: a) patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication OR b) patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Chorea associated with Huntington's disease: Diagnosis of chorea in patients with Huntington's disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Tardive Dyskinesia: Prescribed by or in consultation with a neurologist or psychiatrist. Chorea associated with Huntington's disease: Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | All Indications: Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# INLURIYO

## Products Affected

- Inluriyo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of breast cancer. Breast cancer is all of the following: a) Estrogen receptor-positive (ER+), b) Human epidermal growth factor receptor 2-negative (HER2-), and c) Estrogen receptor 1 (ESR1)-mutated. Disease is advanced or metastatic. Disease progression has occurred following at least one line of endocrine therapy (e.g., fulvestrant, anastrozole, letrozole, exemestane). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# INLYTA

## Products Affected

- Inlyta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Advanced Renal Cell Carcinoma: Diagnosis of renal cell cancer. One of the following: (1) diagnosis of relapsed or stage IV disease, or (2) Both of the following: a) Disease is advanced, and b) One of the following: i) Patient has failed one prior systemic therapy (e.g., chemotherapy), or ii) Inlyta will be used in combination with Bavencio (avelumab) or Keytruda (pembrolizumab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# INQOVI

**Products Affected**

- Inqovi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Myelodysplastic syndrome (MDS): One of the following: 1) Both of the following: a) Diagnosis of MDS and b) Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS), OR 2) Diagnosis of chronic myelomonocytic leukemia (CMML). Acute Myeloid Leukemia (AML): Diagnosis of AML. Used in combination with venetoclax. One of the following: a) Patient is 75 years of age or older or b) Patient has comorbidities that preclude the use of intensive induction chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# INREBIC

## Products Affected

- Inrebic

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Myelofibrosis: Diagnosis of one of the following: primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# INSULIN - LIKE GROWTH FACTOR

**Products Affected**

- Increlex

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial therapy: IGF-1 deficiency: Diagnosis of severe primary IGF-1 deficiency. Height standard deviation score of -3.0 or less. Basal IGF-1 standard deviation score of -3.0 or less. Normal or elevated growth hormone (GH). GH gene deletion: Diagnosis of growth hormone gene deletion who have developed neutralizing antibodies to GH. Reauthorization: Patient demonstrates positive clinical response to therapy. Both of the following: (1) Expected adult height is not obtained and (2) Documentation of expected adult height goal |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Initial, reauth: plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# IRESSA

## Products Affected

- Gefitinib

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC, Disease is one of the following: a) advanced, b) recurrent, or c) metastatic, and One of the following: tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions or tumors are positive for EGFR exon 21 (L858R) substitution mutations or tumors are positive for a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ISOTRETINOIN

## Products Affected

- Accutane CAPS 10MG, 20MG, 40MG
- Amnesteem
- Claravis
- Isotretinoin CAPS
- Zenatane

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | (initial): Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy OR diagnosis of treatment resistant acne. Trial and failure, contraindication or intolerance to an adequate trial (at least 6 weeks) on two of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin)], b) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)], c) topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]. Retreatment (Reauthorization): After greater than or equal to 2 months off therapy, persistent or recurring severe recalcitrant nodular acne is still present. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months. Reauth: Retreatment - 6 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ITOVEBI

## Products Affected

- Itovebi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of breast cancer. Disease is one of the following: a) Locally advanced, or b) Metastatic. Disease is all of the following: a) PIK3CA-mutated, b) Hormone receptor (HR)-positive, and c) Human epidermal growth-factor receptor 2 (HER2)-negative. Used following recurrence on or after completing adjuvant endocrine therapy (e.g. Zoladex [goserelin], Arimidex [anastrozole], Nolvadex [tamoxifen]). Used in combination with both of the following: a) Ibrance (Palbociclib), and b) Fulvestrant. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ITRACONAZOLE (CAPSULES)

## Products Affected

- Itraconazole CAPS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Systemic Fungal Infections: Diagnosis of blastomycosis, histoplasmosis, or aspergillosis. Onychomycosis: Diagnosis of fingernail or toenail onychomycosis confirmed by one of the following: KOH test, fungal culture, or nail biopsy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Systemic Fungal infxns: plan year. Onychomycosis: (Fingernail) 2 mo. (Toenail) 3 mo. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# IVERMECTIN TABLETS

## Products Affected

- Ivermectin TABS 3MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Any medically accepted indication [e.g., Onchocerciasis due to nematode parasite, Pediculosis, Strongyloidiasis, Ascariasis, Scabies (including crusted scabies), Cutaneous larva migrans (hook worm disease), Enterobiasis, Filariasis, Trichuriasis, or Gnathostomiasis]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 month |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# IVIG (PREFERRED)

## Products Affected

- Gamunex-c INJ 1GM/10ML
- Octagam INJ 1GM/20ML, 2GM/20ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Primary immunodeficiency syndrome (PIS): patients with PIS. Idiopathic Thrombocytopenic Purpura (ITP): diagnosis (dx) of ITP. TF/C/I to corticosteroid therapy (e.g., prednisone, dexamethasone) OR platelet count of less than 30,000 cells/mm3. Kawasaki disease (KD): dx of KD. B-cell Chronic Lymphocytic Leukemia (CLL): dx of B-Cell CLL. Doc hypogammaglobulinemia (IgG less than 500mg/dL) or history of bacterial infections associated with B-cell CLL. Bone Marrow Transplant (BMT): Confirmed allogeneic BMT within the last 100 days. Doc severe hypogammaglobulinemia (IgG less than 400 mg/dL). HIV:dx of HIV. Doc hypogammaglobulinemia (IgG less than 400 mg/dL) or functional antibody deficiency demonstrated by poor specific antibody titers or recurrent bacterial infections. Guillain-Barre Syndrome (GBS) initial: dx of GBS. severe disease requiring aid to walk. Onset of neuropathic symptoms in the last 4 weeks. Myasthenia Gravis (MG): dx of generalized MG. Evidence of myasthenic exacerbation, defined by 1 of the following sxs in the last month: difficulty swallowing, acute respiratory failure, or major functional disability responsible for the discontinuation of physical activity. Dermatomyositis and Polymyositis (D/P) initial: dx of dermatomyositis or polymyositis. Trial and failure, contraindication or intolerance (TF/C/I) to immunosuppressive tx (eg corticosteroids, methotrexate, azathioprine, cyclophosphamide). Stiff person syndrome (SPS) initial:dx of SPS. TF/C/I to GABAergic medication (eg, baclofen). Lambert-Eaton myasthenic syndrome (LEMS) initial: dx of LEMS. TF/C/I to immunomodulator monotherapy (eg, azathioprine, corticosteroids). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | All uses: Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist). |

| | |
|---|---|
| **Coverage Duration** | KD: 1 mo. MG: 3 mo. ITP: 6 mo. CIDP,GBS (initial, reauth), other uses: plan year. |
| **Other Criteria** | Subject to Part B vs. Part D review. Pt does not meet criteria for Part B or patient is in a long-term care facility. PIS: Clinically significant functional deficiency of humoral immunity as evidenced by doc failure to produce antibodies to specific antigens or hx of significant recurrent infxns. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) initial: dx of CIDP confirmed by: 1) progressive sxs present for at least 2 mo, 2) symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor impairment of more than 1 limb, OR Progressive or relapsing sensory impairment of more than 1 limb, 3) Electrophysiologic findings when 1 of the following criteria are present: Partial conduction block of 1 or more motor nerve, Reduced conduction velocity of 2 or more motor nerves, Prolonged distal latency of 2 or more motor nerves, Prolonged F-wave latencies of 2 or more motor nerves, Absence of F waves of 2 or motor nerves, Abnormal Temporal Dispersion of 2 or more motor nerves, Distal compound muscle action potential (CMAP) duration increase of 1 or more motor nerves. Multifocal motor neuropathy (MMN) initial: dx of MMN confirmed by all of the following: 1) weakness with slowly progressive or stepwise progressive course over at least 1 month, 2) asymmetric involvement of 2 or more nerves, AND 3) absence of motor neuron signs and bulbar signs. CIDP, MMN reauth: documentation of positive clinical response to tx as measured by an objective scale [eg, Rankin, Modified Rankin, Medical Research Council (MRC) scale]. Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect. Relapsing remitting Multiple Sclerosis (MS) initial: dx of relapsing remitting form of MS (RRMS). Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin tx. TF/c/I to 1 of the following: teriflunomide, interferon beta-1b, interferon beta-1a, glatiramer acetate, natalizumab, dimethyl fumarate, fingolimod. RRMS reauth: The prescriber maintains and provides chart documentation of the patient's evaluation, including all of the following: findings of interval examination including neurological deficits incurred, and assessment of disability (eg, Expanded Disability Status Score [EDSS], Functional Systems Score [FSS], Multiple Sclerosis Functional Composite [MSFC], Disease Steps [DS]). Stable or improved disability score (eg, EDSS, FSS, MSFC, DS). Documentation of decreased number of relapses since starting immune globulin tx. Dx continues to be the relapsing-remitting form of MS. Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect. GBS, D/P, SPS, LEMS reauth: Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect. |

| | |
|---|---|
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# IWILFIN

## Products Affected

- Iwilfin

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of high-risk neuroblastoma (HRNB). Patient has shown at least a partial response to prior multiagent, multimodality therapy. Prior therapy included anti-GD2 immunotherapy (e.g., Danyelza [naxitamab-gqgk], Unituxin [dinutuximab]). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# JAKAFI

## Products Affected

- Jakafi
- Jakafi Xr

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Myelofibrosis: One of the following: Primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera and trial and failure, contraindication, or intolerance to one of the following: hydroxyurea or interferon therapy (e.g., Intron A, pegasys, etc.). Graft versus host disease (GVHD): One of the following: A) Both of the following: Diagnosis of acute (aGVHD). Disease is steroid-refractory, or B) Both of the following: Diagnosis of chronic graft versus host disease (cGVHD). Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# JAYPIRCA

## Products Affected

- Jaypirca

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Mantle Cell Lymphoma (MCL): Diagnosis of MCL. Disease is one of the following: a) relapsed, or b) refractory. Patient has received at least two prior systemic therapies [e.g., chemotherapy] for MCL, one of which is a Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Calquence (acalabrutinib), Imbruvica (ibrutinib)]. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of one of the following: a) CLL, or b) SLL. Patient has previously been treated with a covalent BTK inhibitor [e.g., Calquence (acalabrutinib), Imbruvica (ibrutinib)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# JAYTHARI

**Products Affected**

- Jaythari TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of Duchenne muscular dystrophy (DMD). Patient has received genetic testing for a mutation of the dystrophin gene. Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following: A) Documentation of a confirmed mutation of the dystrophin gene or B) Muscle biopsy confirmed an absence of dystrophin protein. Patient has had a trial and failure or intolerance to prednisone or prednisolone. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Initial, Reauth: Plan year |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# JYNARQUE

**Products Affected**

- Tolvaptan TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Autosomal dominant polycystic kidney disease (ADPKD) (initial): Diagnosis of rapidly progressing ADPKD. One of the following: 1) Both of the following: A) Patient is new to therapy or has received tolvaptan (brand or generic Jynarque) for less than or equal to 18 months AND B) Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy OR 2) Both of the following: A) Patient has received tolvaptan (brand or generic Jynarque) for longer than 18 months AND B) ALT, AST, and bilirubin will be measured at least every 3 months. Patient does not have a history of significant liver impairment or injury, not including uncomplicated polycystic liver disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | ADPKD (reauth): Patient demonstrates positive clinical response to therapy. Patient does not have signs or symptoms consistent with hepatic injury, not including uncomplicated polycystic liver disease. One of the following: 1) Both of the following: A) Patient has received tolvaptan (brand or generic Jynarque) for less than or equal to 18 months AND B) Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy OR 2) Both of the following: A) Patient has received tolvaptan (brand or generic Jynarque) for longer than 18 months AND B) ALT, AST, and bilirubin will be measured at least every 3 months. |

| | |
|---|---|
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KALYDECO

## Products Affected

- Kalydeco

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Submission of laboratory records confirming patient has at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation. |
| **Age Restrictions** | CF (initial): Patient is 1 month of age or older. |
| **Prescriber Restrictions** | CF (initial, reauth): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist |
| **Coverage Duration** | CF (initial, reauth): plan year |
| **Other Criteria** | CF (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KERENDIA (SGLT2)

**Products Affected**

- Kerendia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic kidney disease (CKD) associated with type 2 diabetes (T2D) (Initial): Diagnosis of CKD associated with T2D. Patient has a urine albumin-to-creatinine ratio (UACR) greater than or equal to 30 mg/g. Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min/1.73 m2. Patient has a serum potassium level less than or equal to 5.0 mEq/L prior to initiating treatment. One of the following: 1) Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with one of the following: a) generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril), or b) generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan), OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs. Heart failure (HF) with Left Ventricular Ejection Fraction (LVEF) greater than or equal to 40% (Initial): Diagnosis of HF. Patient has LVEF greater than or equal to 40%. Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms. Patient has an eGFR greater than or equal to 25 mL/min/1.73 m2. Patient has a serum potassium level less than or equal to 5.0 mEq/L prior to initiating treatment. Patient is on diuretic treatment (e.g., bumetanide, furosemide) for the management of symptoms of heart failure for at least 30 days prior to initiating treatment. One of the following: 1) Patient is receiving drug in combination with an SGLT2 inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]), OR 2) Patient has a contraindication or intolerance to an SGLT2 inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | HF with LVEF greater than or equal to 40% (Initial): Prescribed by or in consultation with a cardiologist. |
| **Coverage Duration** | Initial, Reauth: Plan year |

| | |
|---|---|
| **Other Criteria** | CKD associated with T2D (Reauth): Patient demonstrates positive clinical response to therapy. One of the following: 1) Patient continues to be on a maximally tolerated dose of ACE inhibitor or ARB, OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs. HF with LVEF greater than or equal to 40% (Reauth): Patient demonstrates positive clinical response to therapy. One of the following: 1) Patient continues to be on an SGLT2 inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]), OR 2) Patient has a contraindication or intolerance to an SGLT2 inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]). |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# KINERET

## Products Affected

- Kineret

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), one Formulary adalimumab product, Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinib), OR for continuation of prior therapy if within the past 120 days. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID. Dx of NOMID confirmed by one of the following: 1) NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3-gene) (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation or 2) Both of the following: a) two of the following clinical symptoms: urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia), chronic aseptic meningitis, or skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing) AND b) elevated acute phase reactants (eg, erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA]). Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA (initial): Prescribed by or in consultation with a rheumatologist. NOMID (initial): Prescribed by or in consultation with an allergist/immunologist, pediatrician, or rheumatologist. |
| **Coverage Duration** | RA, NOMID (initial, reauth): plan year. DIRA: plan year. |
| **Other Criteria** | RA, NOMID (reauth): Patient demonstrates positive clinical response to therapy. |

| | |
|---|---|
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# KISQALI

**Products Affected**

- Kisqali

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Advanced or Metastatic Breast cancer: Diagnosis of advanced, recurrent, or metastatic breast cancer. Cancer is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: A) Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) or B) Used in combination with Faslodex (fulvestrant). Early Breast Cancer: Diagnosis of early breast cancer. Both of the following: A) Disease is HR-positive, and B) Disease is HER2-negative. Both of the following: A) Disease is stage II or stage III, and B) Patient is at high risk of recurrence. Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KOMZIFTI

## Products Affected

- Komzifti

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of acute myeloid leukemia (AML). Disease is relapsed or refractory. Positive for nucleophosmin 1 (NPM1) mutation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year. |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KORLYM

## Products Affected

- Mifepristone TABS 300MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | (Initial): Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Diagnosis of either type 2 diabetes mellitus or diagnosis of glucose intolerance. Patient has either failed surgery or patient is not a candidate for surgery. Patient is not pregnant. (Reauthorization): Documentation of one of the following: patient has improved glucose tolerance while on therapy or patient has stable glucose tolerance while on therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KOSELUGO

**Products Affected**

- Koselugo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Neurofibromatosis Type 1 (NF1): Diagnosis of NF1. Patient has plexiform neurofibromas that are both of the following: inoperable and causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment, bladder/bowel dysfunction). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KRAZATI

## Products Affected

- Krazati

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Presence of KRAS G12C mutation. Disease is recurrent, advanced, or metastatic. Patient has received at least one prior systemic therapy (e.g., chemotherapy). Colorectal Cancer (CRC): Diagnosis of CRC. Presence of KRAS G12C mutation. Disease is recurrent, advanced, or metastatic. Patient has received at least one prior systemic therapy (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LAPATINIB

## Products Affected

- Lapatinib Ditosylate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast Cancer: All of the following: A) Diagnosis of breast cancer, B) Disease is human epidermal growth factor receptor 2-positive (HER2+), AND C) One of the following: 1) All of the following: a) Disease is recurrent or stage IV breast cancer, b) Disease is hormone receptor positive (HR+), and c) Used in combination with an aromatase inhibitor [eg, Aromasin (exemestane), Femara (letrozole), Arimedex (anastrozole)], OR 2) Both of the following: a) One of the following: i) Disease is recurrent or stage IV breast cancer, or ii) Breast cancer is unresponsive to preoperative systemic therapy (e.g., chemotherapy), and b) Used in combination with trastuzumab or Xeloda (capecitabine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LAZCLUZE

## Products Affected

- Lazcluze

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: a) recurrent b) advanced c) metastatic. Disease is positive for one of the following: a) Epidermal growth factor receptor (EGFR) exon 19 deletion OR b) EGFR exon 21 L858R mutation. Used in combination with Rybrevant (amivantamab-vmjw). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LENALIDOMIDE

## Products Affected

- Lenalidomide

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple Myeloma (MM): Diagnosis of MM. Myelodysplastic syndrome (MDS): One of the following: A) Diagnosis of symptomatic anemia due to MDS associated with a deletion 5q, OR B) Both of the following: 1) Diagnosis of symptomatic anemia due to MDS without deletion 5q AND 2) One of the following: a) Both of the following: i) ring sideroblasts greater than or equal to 15% OR ring sideroblasts greater than or equal to 5% with an SF3B1 mutation AND ii) history of failure, contraindication, or intolerance to Rytelo (imetelstat) or Reblozyl (luspatercept-aamt) OR b) All of the following: i) ring sideroblasts less than 15% OR ring sideroblasts less than 5% with an SF3B1 mutation, ii) serum erythropoetin levels less than or equal to 500 mU/mL, AND iii) used in combination with an erythropoietin stimulating agent (ESA) [e.g., Epogen, Procrit, Retacrit (epoetin alfa)] or darbepoetin alfa, OR c) All of the following: i) ring sideroblasts less than 15% OR ring sideroblasts less than 5% with an SF3B1 mutation, ii) serum erythropoetin levels greater than 500 mU/mL, AND iii) history of failure, contraindication, intolerance, or a poor probability of responding to immunosuppressive therapy (e.g., azacitidine, decitabine), OR C) Both of the following: 1) Diagnosis of myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) overlap neoplasm AND 2) Patient has SF3B1 mutation and thrombocytosis OR patient has MDS/MPN with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T). Mantle Cell Lymphoma (MCL): Diagnosis of MCL. Follicular Lymphoma (FL): Diagnosis of FL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |

| | |
|---|---|
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LENVIMA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Differentiated thyroid cancer (DTC): Diagnosis of DTC. Renal cell carcinoma: Diagnosis of Renal cell carcinoma. Hepatocellular Carcinoma (HCC): Diagnosis of Hepatocellular Carcinoma or liver cell carcinoma. Endometrial Carcinoma: Diagnosis of endometrial carcinoma. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LEUPROLIDE ACETATE

**Products Affected**

- Leuprolide Acetate INJ 1MG/0.2ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prostate Cancer: Treatment of advanced prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Prostate Cancer: plan year |
| **Other Criteria** | Prostate Cancer: Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LIDOCAINE PATCH

## Products Affected

- Lidocaine PTCH 5%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Post-herpetic neuralgia: Diagnosis of post-herpetic neuralgia |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LIFYORLI

## Products Affected

- Lifyorli

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Disease is platinum resistant. Used in combination with nab-paclitaxel. Patient has received one prior bevacizumab-containing systemic treatment regimen. Patient has not received more than three prior systemic treatment regimens. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LIVTENCITY

## Products Affected

- Livtencity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of cytomegalovirus (CMV) infection/disease. Patient is a recipient of one of the following: a) Hematopoietic stem cell transplant OR b) Solid organ transplant. Trial and failure of a minimum 2 weeks duration, contraindication, or intolerance to one of the following therapies at an appropriately indicated dose: a) Intravenous (IV) ganciclovir, b) Oral valganciclovir, c) IV foscarnet, OR d) IV cidofovir. Patient weighs greater than or equal to 35 kg. |
| **Age Restrictions** | Patient is 12 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a provider who specializes in one of the following areas: transplant, oncology, or infectious disease. |
| **Coverage Duration** | 8 weeks |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LONSURF

**Products Affected**

- Lonsurf

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Colorectal cancer: Diagnosis of advanced or metastatic colorectal cancer. Trial and failure, contraindication, or intolerance to treatment with all of the following: fluoropyrimidine-based chemotherapy, oxaliplatin-based chemotherapy, irinotecan-based chemotherapy, and anti-VEGF biological therapy (e.g., bevacizumab). One of the following: a) tumor is RAS mutant-type or b) tumor is RAS wild-type and Trial and failure, contraindication, or intolerance to one anti-EGFR therapy (eg, Vectibix [panitumumab], Erbitux [cetuximab]). Gastric/Gastroesophageal Junction Adenocarcinoma: Diagnosis of one of the following: a) unresectable locally advanced, recurrent, or metastatic gastric cancer, or b) unresectable locally advanced, recurrent, or metastatic gastroesophageal junction adenocarcinoma. Trial and failure, contraindication, or intolerance to treatment with at least two prior lines of chemotherapy that consisted of the following agents: fluropyrimidine (e.g. fluorouracil), Platinum (e.g., carboplatin, cisplatin, oxaliplatin), Taxane (e.g., docetaxel, paclitaxel) or irinotecan, HER2/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LORBRENA

## Products Affected

- Lorbrena

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. One of the following: A) Disease is advanced, metastatic, or recurrent and anaplastic lymphoma kinase (ALK)-positive OR B) Both of the following: 1) Disease is both of the following: i) advanced, metastatic, or recurrent and ii) ROS proto-oncogene 1 (ROS1)-positive AND 2) Disease has progressed on at least one of the following therapies: Augtyro (repotrectinib), Xalkori (crizotinib), Rozlytrek (entrectinib), or Zykadia (ceritinib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LUMAKRAS

**Products Affected**

- Lumakras

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: a) recurrent, b) advanced or c) metastatic. Tumor is KRAS G12C-mutated. Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy). Metastatic Colorectal Cancer (mCRC): Diagnosis of metastatic colorectal cancer (mCRC). Tumor is KRAS G12C-mutated. Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LUMRYZ

## Products Affected

- Lumryz
- Lumryz Starter Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are present, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are absent, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present, AND One of the following: a) Patient is under 18 years of age, or b)Trial and failure, contraindication, or intolerance to both of the following: 1) modafinil, AND 2) methylphenidate-based stimulant. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 6 months. Reauth: plan year |
| **Other Criteria** | All indications (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LUPRON DEPOT

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prostate Cancer (7.5 mg, 22.5 mg, 30 mg, 45 mg): Treatment of advanced prostate cancer. Endometriosis (3.75 mg, 11.25 mg) (initial): Diagnosis of endometriosis. One of the following: a) Patient has had surgical ablation to prevent recurrence, or b) trial and failure, contraindication, or intolerance to one NSAID (e.g., diclofenac, ibuprofen, meloxicam, naproxen) and one oral contraceptive (e.g., norethindrone-ethinyl estradiol, estradiol and norethindrone). Endometriosis (3.75 mg, 11.25 mg) (reauthorization): Symptoms recur after one course. Used in combination with one of the following: norethindrone 5 mg daily, other "add -back" sex hormones (e.g., estrogen, medroxyprogesterone), or other bone-sparing agents (e.g., bisphosphonates such as alendronate, risedronate). Uterine Leiomyomata (3.75 mg, 11.25 mg) (fibroids): Either for use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) Or all of the following: treatment of anemia, anemia caused by uterine leiomyomata (fibroids), and use prior to surgery. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Prostate CA: plan yr. Endometrosis(all), Uterine leiomyomata (anemia): 6 mo. (fibroids): 4 mo. |
| **Other Criteria** | Prostate Cancer (7.5 mg, 22.5 mg, 30 mg, 45 mg): Approve for continuation of prior therapy if within the past 120 days. |

| | |
|---|---|
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LUPRON DEPOT PED

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Central Precocious Puberty (CPP) (initial): diagnosis of central precocious puberty (idiopathic or neurogenic). Onset of secondary sexual characteristics in one of the following: females less than age 8 or males less than age 9. Confirmation of diagnosis defined by one of the following: pubertal basal level of luteinizing hormone (based on laboratory reference ranges), a pubertal response to a GnRH stimulation test, or bone age advanced one year beyond the chronological age. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CPP (ini, reauth): plan yr. |
| **Other Criteria** | CPP (Reauthorization): Documentation of bone age monitoring (eg, radiographic imaging). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LYNKUET

## Products Affected

- Lynkuet

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Vasomotor symptoms (VMS) (initial): Diagnosis of moderate to severe VMS due to menopause. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | VMS (initial, reauth): 6 months. |
| **Other Criteria** | VMS (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LYNPARZA (TABLETS)

**Products Affected**

- Lynparza TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | High risk early breast cancer: Diagnosis of high risk early breast cancer. Presence of deleterious or suspected deleterious germline BRCA-mutations. Disease is human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) Disease is hormone receptor (HR)-negative, OR b) Both of the following: i) Disease is HR-positive AND ii) Patient is continuing concurrent treatment with endocrine therapy. Patient has been previously treated with neoadjuvant or adjuvant chemotherapy (e.g., anthracycline, taxane). Metastatic or recurrent breast cancer: Diagnosis of breast cancer. Disease is metastatic or recurrent. Presence of deleterious or suspected deleterious germline BRCA-mutations. Disease is human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) Disease is hormone receptor (HR) negative, or b) Disease is hormone receptor (HR)-positive and one of the following: i) disease has progressed on previous endocrine therapy or ii) provider attestation that treatment with endocrine therapy is inappropriate for the patient's disease. Pancreatic adenocarcinoma: Diagnosis of pancreatic adenocarcinoma. Disease is metastatic. Presence of deleterious or suspected deleterious germline BRCA-mutations. Disease has not progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen (e.g., FOLFIRINOX, FOLFOX, etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |

| | |
|---|---|
| **Other Criteria** | Ovarian cancer (Maintenance Therapy): Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Disease is one of the following: advanced or recurrent. One of the following: 1) Patient has had a complete or partial response to platinum-based chemotherapy (e.g., carboplatin, cisplatin), or 2) Both of the following: a) patient has had a complete or partial response to first-line platinum-based chemotherapy (e.g., carboplatin, cisplatin) AND b) one of the following: i) presence of deleterious or suspected deleterious germline or somatic BRCA-mutations OR ii) both of the following: cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation or genomic instability AND used in combination with bevacizumab (e.g., Avastin, Myvasi). Will be used as maintenance therapy. Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer. One of the following: 1) Both of the following: a) Presence of deleterious or suspected deleterious homologous recombination repair (HRR) gene mutations and b) Disease has progressed following prior treatment with one of the following: i) enzalutamide (Xtandi), or ii) abiraterone (e.g., Zytiga, Yonsa), OR 2) All of the following: a) Presence of deleterious or suspected deleterious BRCA-mutation, b) Used in combination with abiraterone (e.g., Zytiga, Yonsa), and c) Used in combination with prednisone or prednisolone. One of the following: 1) used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)], or 2) Patient has had bilateral orchiectomy. All indications: Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LYTGOBI

**Products Affected**

- Lytgobi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of cholangiocarcinoma (intrahepatic or extrahepatic). Disease is one of the following: a) unresectable, b) locally advanced, c) Resected gross residual (R2), or d) metastatic. Positive for fibroblast growth factor receptor 2 (FGFR2) fusions or other rearrangements. Used as second line or subsequent treatment. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# MAVYRET

## Products Affected

- Mavyret

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: 1) One of the following: a) Diagnosis of hepatitis C, or b) Patient was not infected with hepatitis C virus prior to receiving an organ transplant, and patient received a liver or non-liver organ transplant from a donor with a diagnosis of hepatitis C, 2) patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and 3) not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 8 to 16 weeks. Criteria applied consistent with current AASLD/IDSA guideline |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# MEKINIST

## Products Affected

- Mekinist

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma: Diagnosis of unresectable or metastatic melanoma AND cancer is BRAF V600 mutant type. Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type. Involvement of lymph nodes following complete resection. Used as adjuvant therapy. Medication is used in combination with Tafinlar (dabrafenib). Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of non-small cell lung cancer AND disease is one of the following: metastatic, advanced, or recurrent AND cancer is BRAF V600E mutant type AND medication is used in combination with Tafinlar (dabrafenib). Anaplastic Thyroid Cancer (ATC): Diagnosis of ATC. One of the following: 1) Disease is one of the following: metastatic, locally advanced, or unresectable OR 2) Prescribed as adjuvant therapy following resection. Cancer is BRAF V600E mutant type. Medication is used in combination with Tafinlar (dabrafenib). Solid tumors: Presence of solid tumor. Disease is unresectable or metastatic. Patient has progressed on or following prior systemic treatment (e.g., carboplatin, 5-fluorouracil, paclitaxel). Cancer is BRAF V600E mutant type. Medication is used in combination with Tafinlar (dabrafenib). Low-grade glioma: Diagnosis of low-grade glioma. Cancer is BRAF V600E mutant type. Medication is used in combination with Tafinlar (dabrafenib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |

| | |
|---|---|
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# MEKTOVI

## Products Affected

- Mektovi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. One of the following: 1) Both of the following: i) Patient is positive for BRAF V600 mutation and ii) Used in combination with Braftovi (encorafenib), OR 2) Both of the following: i) Patient is positive for NRAS mutation and ii) Progression after prior immune checkpoint inhibitor therapy (e.g., Keytruda). Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: recurrent, advanced, or metastatic. Patient is positive for BRAF V600 mutation. Used in combination with Braftovi (encorafenib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# MEMANTINE

## Products Affected

- Memantine Hydrochloride SOLN 2MG/ML
- Memantine Hydrochloride TABS
- Memantine Hydrochloride Er
- Memantine/donepezil Hydrochloride Er

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Age 41 or older, or diagnosis of moderate to severe dementia of the Alzheimer's type. |
| **Age Restrictions** | No Prior Authorization if patient is age 41 or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# MIGLUSTAT

## Products Affected

- Miglustat
- Yargesa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Gaucher disease: Diagnosis of mild to moderate Type 1 Gaucher disease. Patient is unable to receive enzyme replacement therapy due to one of the following conditions: allergy or hypersensitivity to enzyme replacement therapy, poor venous access, or unavailability of enzyme replacement therapy (e.g. Cerezyme, VPRIV). Niemann-Pick disease type C (NPC) (off-label) (initial): Diagnosis of NPC. Requested drug will be used in combination with Miplyffa (arimoclomol). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Niemann-Pick disease type C (NPC) (off-label) (initial): Prescribed by or in consultation with a specialist knowledgeable in the treatment of Niemann-Pick disease type C. |
| **Coverage Duration** | Gaucher disease: Plan year. NPC (initial): 6 months, (reauth): Plan year. |
| **Other Criteria** | Niemann-Pick disease type C (NPC) (off-label) (reauth): Patient demonstrates positive clinical response to therapy. Requested drug will be used in combination with Miplyffa (arimoclomol). |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# MODAFINIL

## Products Affected

- Modafinil TABS

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

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | OSA,SWD,Hypersomnia,Depression:Initial,Reauth:6 mo.Narcolepsy, MS Fatigue:Initial,Reauth:Plan Yr |
| **Other Criteria** | OSA, Narcolepsy, Idiopathic Hypersomnia, SWD, MS Fatigue (Reauth): Patient demonstrates positive clinical response to therapy. Depression (reauth): Patient demonstrates positive clinical response to therapy. Used as adjunctive therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# MODEYSO

## Products Affected

- Modeyso

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of one of the following: Diffuse midline glioma or high-grade glioma. Disease is positive for H3 K27M mutation. Disease is one of the following: recurrent or progessive. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# MOUNJARO

## Products Affected

- Mounjaro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Excluded if used for weight loss only. |
| **Required Medical Information** | Diabetes Mellitus (DM): Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 DM. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# MRESVIA

## Products Affected

- Mresvia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Vaccine is being used for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV). Patient has not received an RSV vaccine (i.e., Abrysvo, Arexvy, MRESVIA) in their lifetime. One of the following: a) Age greater than or equal to 60 years, or b) Both of the following: 1) Age 18 through 59 years, and 2) Patient is at increased risk for LRTD caused by RSV. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NAYZILAM

## Products Affected

- Nayzilam

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Epilepsy: Diagnosis of epilepsy. Frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NERLYNX

**Products Affected**

- Nerlynx

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Early Stage or Node-Positive Breast Cancer: One of the following: 1) All of the following: a) Diagnosis (dx) of early stage breast cancer, b) Disease is human epidermal growth factor receptor 2 (HER2)-positive, and c) Patient has received adjuvant trastuzumab based therapy (e.g., Herceptin, Kanjinti, etc.), OR 2) All of the following: a) Dx of node positive breast cancer, b) Disease is both of the following: 1) Hormone receptor (HR)-positive and 2) HER2-positive, and c) Used as extended adjuvant therapy following adjuvant trastuzumab-containing therapy (e.g., Herceptin, Kanjinti). Advanced or Metastatic Breast Cancer: 1) All of the following: a) Dx of advanced or metastatic breast cancer, b) Disease is human epidermal growth factor receptor 2 (HER2)-positive, c) Patient has received two or more prior anti-HER2 based regimens (e.g., trastuzumab + pertuzumab + docetaxel, ado-trastuzumab emtansine, etc.), and d) Used in combination with capecitabine, OR 2) Both of the following: a) Diagnosis of Stage IV (M1) breast cancer, and b) One of the following: i) Hormone receptor-positive, (HER2)-negative disease in patients who have already received a CDK4/6 inhibitor therapy, or ii) Triple negative disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# NINLARO

## Products Affected

- Ninlaro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple myeloma: Diagnosis of multiple myeloma. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NUBEQA

**Products Affected**

- Nubeqa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-metastatic castration-resistant or castration-recurrent prostate cancer (NM-CRPC): Diagnosis of non-metastatic castration-resistant (chemical or surgical) or castration-recurrent prostate cancer. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g., Zoladex [goserelin], Vantas [histrelin], Lupron [leuprolide], Trelstar [triptorelin], Firmagon [degarelix]) OR 2) Patient received bilateral orchiectomy. Metastatic castration-sensitive prostate cancer (mCSPC): Diagnosis of mCSPC [also known as metastatic hormone-sensitive prostate cancer (mHSPC)]. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g., Zoladex [goserelin], Vantas [histrelin], Lupron [leuprolide], Trelstar [triptorelin], Firmagon [degarelix]) OR 2) Patient received bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | NM-CRPC, mCSPC: Plan year |
| **Other Criteria** | NM-CRPC, mCSPC: Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NUCALA

## Products Affected

- Nucala

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Severe eosinophilic asthma (initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level is greater than or equal to 150 cells/microliter. Patient has had two or more asthma exacerbations requiring systemic corticosteroids (eg, prednisone) within the past 12 months or Patient has had a prior asthma-related hospitalization within the past 12 months. One of the following: 1) Patient is 6 years of age or older but less than 12 years of age AND Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: both a medium-dose inhaled corticosteroid (ICS) (eg, greater than 100 - 200 mcg fluticasone propionate equivalent/day) and additional asthma controller medication (eg, leukotriene receptor antagonist [LTRA] [eg, montelukast], long-acting beta-2 agonist [LABA] [eg, salmeterol], long-acting muscarinic antagonist [LAMA] [eg, tiotropium]), OR one medium dosed combination ICS/LABA product (eg, Wixela Inhub [fluticasone propionate 100mcg/ salmeterol 50mcg], budesonide 80mcg/ formoterol 4.5mcg, Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg]), OR 2) Patient is 12 years of age or older AND Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: both a high dose ICS (eg, greater than 500 mcg fluticasone propionate equivalent/day) and additional asthma controller medication [eg, LTRA (e.g., montelukast), LABA (eg, salmeterol), LAMA (eg, tiotropium], OR one maximally-dosed combination ICS/ LABA product (eg, Wixela [fluticasone propionate 500 mcg/ salmeterol 50 mcg], budesonide 160 mcg/ formoterol 4.5 mcg, Breo Ellipta [fluticasone 200 mcg/vilanterol 25 mcg]). |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | Severe asthma (init): Prescribed by or in consultation with a pulmonologist or allergy/immunology specialist. CRSwNP (init): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist. EGPA (init): Prescribed by or in consultation with a pulmonologist, rheumatologist or allergist/immunologist. HES (init): Prescribed by or in consultation with an allergist/immunologist or hematologist. COPD: Prescribed by or in consultation with a pulmonologist. |
| **Coverage Duration** | COPD (init): 6 mo, (reauth): plan year. Asthma, CRSwNP, EGPA, HES (Init, reauth): plan year. |
| **Other Criteria** | Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (init): Diagnosis (dx) of CRSwNP. Unless contraindicated (CI), the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (CS) (eg, fluticasone, mometasone). Used in combination with another agent for CRSwNP. Eosinophilic Granulomatosis with Polyangiitis (EGPA) (init): Dx of EGPA. Patient's disease has relapsed or is refractory to standard of care therapy (ie, CS treatment with or without immunosuppressive therapy). Pt is currently receiving CS therapy (eg, prednisolone, prednisone) unless there is a CI or intolerance to CS therapy. Hypereosinophilic Syndrome (HES) (init): Dx of HES. Patient has been diagnosed for at least 6 months. Verification that other non-hematologic secondary causes have been ruled out (eg, drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy). Patient is FIP1L1-PDGFRA-negative. Patient has uncontrolled HES defined as both of the following: a) History of 2 or more flares within the past 12 months AND b) Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter. Trial and failure, CI, or intolerance to CS therapy (eg, prednisone) or cytotoxic/immunosuppressive therapy (eg, hydroxyurea, cyclosporine, imatinib). COPD, CRSwNP, EGPA, HES, Severe asthma (reauth): Pt demonstrates positive clinical response to therapy. Chronic Obstructive Pulmonary Disease (COPD) (init): Dx of COPD. Presence of Type 2 inflammation evidenced by blood eosinophils greater than or equal to 150 cells/microliter at baseline or greater than or equal to 300 cells/microliter in the last 12 months. Pt is receiving one of the following at max tolerated doses: 1) Triple therapy (ie, an ICS, a LAMA, and a LABA) OR 2) if CI to ICS, a LAMA and a LABA. Post-bronchodilator forced expiratory volume [FEV1] / forced vital capacity [FVC] ratio less than 0.70 while on therapy. Pt has had one of the following within the past 12 months: 1) At least 2 exacerbations where systemic CS [intramuscular, intravenous, or oral (e.g., prednisone)] were required at least once OR 2) COPD-related hospitalization. |

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| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# NUEDEXTA

## Products Affected

- Nuedexta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pseudobulbar affect (PBA) (initial): Diagnosis of PBA secondary to a brain injury or neurologic disease (e.g., amyotrophic lateral sclerosis, multiple sclerosis, Parkinson's disease, stroke, or traumatic brain injury). Diagnosis is confirmed by one of the following: 1) Physician attestation that a baseline Center for Neurologic Studies Lability Scale (CNS-LS) score has been assessed OR 2) Patient attestation that patient has experienced involuntary, sudden, or frequent episodes of laughing and/or crying. Patient does not have any of the following contraindications: a) Concomitant use with other drugs containing quinidine, quinine, or mefloquine, b) History of Nuedexta, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression, or lupus-like syndrome, c) Known hypersensitivity to dextromethorphan (e.g., rash, hives), d) Taking monoamine oxidase inhibitors (MAOIs) (e.g., phenelzine, selegiline, tranylcypromine) or have taken MAOIs within the preceding 14 days, e) Has prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, or has heart failure, f) Receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), g) Has complete atrioventricular (AV) block without implanted pacemakers, or at high risk of complete AV block. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PBA (initial/reauth): Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist. |
| **Coverage Duration** | PBA (initial/reauth): plan year |

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|---|---|
| **Other Criteria** | PBA (reauth): One of the following: 1) Physician attestation that the patient's CNS-LS score has improved since baseline OR 2) Physician attestation that frequency of laughing and/or crying episodes has decreased since baseline. Diagnosis of PBA secondary to a brain injury or neurologic disease (e.g., amyotrophic lateral sclerosis, multiple sclerosis, Parkinson's disease, stroke, or traumatic brain injury). Patient does not have any of the following contraindications: a) Concomitant use with other drugs containing quinidine, quinine, or mefloquine, b) History of Nuedexta, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression, or lupus-like syndrome, c) Known hypersensitivity to dextromethorphan (e.g., rash, hives), d) Taking monoamine oxidase inhibitors (MAOIs) (e.g., phenelzine, selegiline, tranylcypromine) or have taken MAOIs within the preceding 14 days, e) Has prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, or has heart failure, f) Receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), g) Has complete atrioventricular (AV) block without implanted pacemakers, or at high risk of complete AV block. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NUPLAZID

## Products Affected

- Nuplazid CAPS
- Nuplazid TABS 10MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NURTEC

## Products Affected

- Nurtec

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Treatment of Migraine (initial): Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines. Preventive Treatment of Episodic Migraine (EM) (initial): Diagnosis of EM. Patient has greater than or equal to 4 migraine days per month. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All Indications (initial, reauth): Plan year |
| **Other Criteria** | All Indications (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# NUZYRA (IV)

**Products Affected**

- Nuzyra INJ

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Community-acquired bacterial pneumonia (CABP): Diagnosis of CABP caused by one of the following: methicillin-susceptible Staphylococcus aureus (MSSA), Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, or Chlamydophila pneumoniae. Acute bacterial skin and skin structure infection (ABSSSI): Patient is unable to take oral Nuzyra tablets AND one of the following: 1) Diagnosis of ABSSSI caused by methicillin-resistant Staphylococcus aureus (MRSA) OR empirical treatment of patients with ABSSSI where presence of MRSA infection is likely. OR 2) Diagnosis of ABSSSI caused by one of the following: MSSA, Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, S. constellatus), Enterococcus faecalis, Enterobacter cloacae, or Klebsiella pneumoniae. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CABP, ABSSSI: 14 days |
| **Other Criteria** | CABP: Approve for continuation of Nuzyra therapy upon hospital discharge (patients who are transitioning from the hospital are allowed to continue use of the drug and other prior authorization requirements do not apply) when patient is unable to take oral Nuzyra tablets. ABSSSI: Approve for continuation of Nuzyra therapy upon hospital discharge (patients who are transitioning from the hospital are allowed to continue use of the drug and other prior authorization requirements do not apply). |

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|---|---|
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# NUZYRA (ORAL)

**Products Affected**

- Nuzyra TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Community-acquired bacterial pneumonia (CABP): Diagnosis of CABP caused by one of the following: methicillin-susceptible Staphylococcus aureus (MSSA), Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, or Chlamydophila pneumoniae. Acute bacterial skin and skin structure infection (ABSSSI): One of the following: 1) Diagnosis of ABSSSI caused by methicillin-resistant Staphylococcus aureus (MRSA) OR empirical treatment of patients with ABSSSI where presence of MRSA infection is likely. OR 2) Diagnosis of ABSSSI caused by one of the following: MSSA, Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, S. constellatus), Enterococcus faecalis, Enterobacter cloacae, or Klebsiella pneumoniae. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CABP, ABSSSI: 14 days |
| **Other Criteria** | CABP: Approve for continuation of Nuzyra therapy upon hospital discharge (patients who are transitioning from the hospital are allowed to continue use of the drug and other prior authorization requirements do not apply). ABSSSI: Approve for continuation of Nuzyra therapy upon hospital discharge or as continuation of therapy when transitioning from intravenous antibiotics given in the hospital for the requested indication (e.g., daptomycin, vancomycin, linezolid) (patients who are transitioning from the hospital or from intravenous antibiotics given in the hospital are allowed to continue use of the drug and other prior authorization requirements do not apply). |

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|---|---|
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# OCTREOTIDE

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acromegaly (initial): Diagnosis of acromegaly confirmed by one of the following: serum GH level greater than 1 ng/mL after a 2-hour oral glucose tolerance test at the time of diagnosis, or elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at the time of diagnosis. One of the following: A) Inadequate response to surgery, radiotherapy, or dopamine agonist (e.g., bromocriptine, cabergoline) therapy, or B) Not a candidate for any of the following: surgery, radiotherapy, dopamine agonist (e.g., bromocriptine, cabergoline) therapy. HIV/AIDS-Related Diarrhea (initial): Diagnosis of HIV/AIDS-related diarrhea. Carcinoid tumors, symptomatic treatment of diarrhea or flushing (initial): diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes. Vasoactive Intestinal Peptide Tumors, symptomatic treatment of diarrhea (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea. Cancer Chemotherapy- and/or Radiation- Induced Diarrhea (initial): Diagnosis of complicated diarrhea due to concurrent cancer chemotherapy and/or radiation or uncomplicated diarrhea due to concurrent cancer chemotherapy and/or radiation. Carcinoid tumor: diagnosis of carcinoid tumor. Reauthorization (all except carcinoid tumor): Patient demonstrates positive clinical response to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All Indications: Plan Year |

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|---|---|
| **Other Criteria** | Uncomplicated diarrhea due to concurrent cancer chemotherapy and/or radiation (initial): Trial and failure, contraindication, or intolerance (TF/C/I) to standard therapy (e.g., loperamide). HIV/AIDS-related Diarrhea (initial): TF/C/I to standard therapy (e.g., loperamide, diphenoxylate with atropine). Carcinoid tumor: Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ODOMZO

## Products Affected

- Odomzo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Advanced basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma. One of the following: cancer that has recurred following surgery or radiation therapy, or patient is not a candidate for surgery or radiation therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# OFEV

## Products Affected

- Nintedanib Esylate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF, defined as exclusion of other known causes of interstitial lung disease and either the presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF in patients not subjected to lung biopsy, or HRCT and surgical lung biopsy pattern revealing IPF or probable IPF in patients subjected to a lung biopsy. Systemic Sclerosis-associated interstitial lung disease (SSc-ILD) (initial): Diagnosis of SSc-ILD, defined as exclusion of other known causes of interstitial lung disease (ILD) and either the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on HRCT revealing SSc-ILD or probable SSc-ILD in patients not subjected to surgical lung biopsy, or HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD in patients subjected to a lung biopsy. Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (initial): Diagnosis of chronic fibrosing ILDs. Patient has a high-resolution computed tomography (HRCT) showing at least 10% of lung volume with fibrotic features. Disease has a progressive phenotype as observed by one of the following: decline of forced vital capacity (FVC), worsening of respiratory symptoms, or increased extent of fibrosis seen on imaging. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | (initial): Prescribed by or in consultation with a pulmonologist or rheumatologist. |
| **Coverage Duration** | (initial, reauth): plan year |
| **Other Criteria** | IPF, SSc-ILD, Chronic Fibrosing ILDs with a progressive phenotype (reauth): Patient demonstrates positive clinical response to therapy. |

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|---|---|
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# OGSIVEO

**Products Affected**

- Ogsiveo TABS 100MG, 150MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of desmoid tumor. Patient requires systemic treatment. Disease is progressive. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# OJEMDA

## Products Affected

- Ojemda

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of pediatric low-grade glioma. Disease is relapsed or refractory. Disease has a BRAF fusion or rearrangement, or BRAF V600 mutation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# OJJAARA

**Products Affected**

- Ojjaara

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | One of the following: A) Diagnosis of symptomatic lower-risk myelofibrosis, OR B) All of the following: 1) Diagnosis of higher risk myelofibrosis, 2) Presence of symptomatic splenomegaly and/or constitutional symptoms, and 3) One of the following: a) Used as continued therapy near the start of conditioning therapy in a transplant candidate or b) Patient is not a transplant candidate or transplant not currently feasible, OR C) Diagnosis of myelofibrosis-associated anemia, OR D) Both of the following: 1) Diagnosis of accelerated/blast phase myeloproliferative neoplasm and 2) One of the following: a) Used for the improvement of splenomegaly or other disease-related symptoms or b) Continued treatment as a single agent near to the start of conditioning therapy in transplant candidates for the improvement of splenomegaly and other disease-related symptoms. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ONUREG

## Products Affected

- Onureg

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Myeloid Leukemia (AML): Diagnosis of acute myeloid leukemia (AML). Patient has received previous treatment with an intensive induction chemotherapy regimen (e.g., cytarabine + daunorubicin, cytarabine + idarubicin). Patient has achieved one of the following: a) first complete remission (CR) or b) complete remission with incomplete blood count recovery (CRi). Patient is not a candidate for intensive curative therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# OPIPZA

## Products Affected

- Opipza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Schizophrenia: Diagnosis of Schizophrenia. Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: a) aripiprazole (failure or contraindication are not required), b) olanzapine, c) quetiapine IR/ER, d) risperidone, e) clozapine, f) ziprasidone, g) paliperidone, or h) asenapine. Major Depressive Disorder (MDD): Diagnosis of MDD. Both of the following: a) TF/C/I to quetiapine IR/ER and b) trial of or intolerance to aripiprazole. Autism: Diagnosis of irritability associated with autistic disorder. Both of the following: a) Trial and failure, contraindication (e.g., age), or intolerance to risperidone and b) trial of or intolerance to aripiprazole. Tourette's Syndrome: Diagnosis of Tourette's Syndrome. Trial of or intolerance to aripiprazole. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# OPSUMIT

## Products Affected

- Macitentan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH: Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ORENITRAM

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH: Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ORGOVYX

## Products Affected

- Orgovyx

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prostate Cancer: Diagnosis of prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ORKAMBI

## Products Affected

- Orkambi TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cystic fibrosis (initial): Diagnosis of cystic fibrosis (CF). Submission of laboratory records confirming the patient is homozygous for the F508del mutation in the CFTR gene. |
| **Age Restrictions** | Patient is greater than or equal to 6 years of age |
| **Prescriber Restrictions** | CF (initial, reauthorization): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist |
| **Coverage Duration** | CF (initial, reauth): plan year |
| **Other Criteria** | CF (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ORKAMBI GRANULES

**Products Affected**

- Orkambi PACK

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cystic fibrosis (initial): Diagnosis of cystic fibrosis (CF). Submission of laboratory records confirming the patient is homozygous for the F508del mutation in the CFTR gene. One of the following: A) Patient is 1 through 5 years of age, OR B) Both of the following: Patient is 6 years of age or greater AND Patient is unable to swallow oral tablets. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | CF (initial, reauthorization): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist |
| **Coverage Duration** | CF (initial, reauth): plan year |
| **Other Criteria** | CF (Reauthorization): Patient demonstrates positive clinical response to therapy. One of the following: A) Patient is 1 through 5 years of age, OR B) Both of the following: Patient is 6 years of age or greater AND Patient is unable to swallow oral tablets. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ORSERDU

## Products Affected

- Orserdu

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of breast cancer. Disease is advanced or metastatic. One of the following: a) Patient is male, b) Patient is a postmenopausal woman, or c) Patient is a premenopausal woman treated with ovarian ablation/suppression. Disease is estrogen receptor (ER)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Presence of estrogen receptor (ESR1) mutation(s). Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# OSPHENA

## Products Affected

- Osphena

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Dyspareunia: Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause. Vaginal dryness: Diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# OTEZLA

## Products Affected

- Otezla

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Psoriatic arthritis (PsA, initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Diagnosis of plaque psoriasis. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Oral ulcers associated with Behcet's Disease (initial): Diagnosis of Behcet's Disease. Patient has active oral ulcers. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PsA (init): Prescribed by or in consultation with one of the following specialists: dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist. |
| **Coverage Duration** | All uses (initial, reauth): plan year. |
| **Other Criteria** | All indications (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# OTEZLA XR

## Products Affected

- Otezla Xr
- Otezla/otezla Xr 28 Day Treatment Initiation Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Psoriatic arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Diagnosis of plaque psoriasis. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Oral ulcers associated with Behcet's Disease (initial): Diagnosis of Behcet's Disease. Patient has active oral ulcers. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PsA (initial): Prescribed by or in consultation with one of the following specialists: dermatologist or rheumatologist. Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. |
| **Coverage Duration** | All uses (initial, reauth): plan year. |
| **Other Criteria** | All uses (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# OZEMPIC

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Excluded if used for weight loss only. |
| **Required Medical Information** | Diabetes Mellitus (DM): Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 DM. Nonalcoholic steatohepatitis (NASH)/Metabolic dysfunction-associated steatohepatitis (MASH) (Initial): Diagnosis of MASH, formerly known as nonalcoholic steatohepatitis (NASH). Patient does not have cirrhosis (e.g., decompensated cirrhosis). Submission of medical records (e.g., chart notes) confirming disease is fibrosis stage F2 or F3 as confirmed by one of the following: 1) Both of the following: A) Serum biomarker [e.g., enhanced liver fibrosis (ELF) test, fibrosis-4 index (FIB-4)], and B) Imaging biormarker [e.g., FibroScan, magnetic resonance imaging-proton density fat fraction (MRI-PDFF)], or 2) One of the following: A) FibroScan aspartate aminotransferase (FAST), B) MRI-aspartate aminotransferase (MAST), C) Magnetic Resonance Elastography combined with fibrosis-4-index (MEFIB), or D) liver biopsy within the past 12 months. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MASH (Initial): Prescribed by or in consultation with a gastroenterologist or hepatologist. |
| **Coverage Duration** | Plan year |
| **Other Criteria** | MASH (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# OZEMPIC TABLET

## Products Affected

- Ozempic TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Excluded if used for weight loss only. |
| **Required Medical Information** | Diabetes Mellitus (DM): Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 DM. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# PANRETIN

## Products Affected

- Panretin

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Kaposi's sarcoma lesions: Diagnosis of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma (KS). Not used when systemic anti-KS therapy is required (e.g., more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# PEGFILGRASTIM PREFERRED

## Products Affected

- Neulasta INJ 6MG/0.6ML
- Udenyca

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Neutropenia Associated with Dose Dense Chemotherapy (NDDC): Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, or a dose-dense chemotherapy regimen for which the incidence of febrile neutropenia is unknown. Chemotherapy-Induced Febrile Neutropenia (CFN): Patient is receiving a chemotherapy regimen associated with greater than 20% incidence of febrile neutropenia, or patient is receiving chemotherapy regimen associated with 10-20% incidence of febrile neutropenia and has 1 or more risk factors associated with chemotherapy-induced infection, febrile neutropenia or neutropenia. Secondary prophylaxis of FN: For patients who are receiving myelosuppressive anticancer drugs associated with neutropenia. Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist/oncologist. |
| **Coverage Duration** | ARS: 1 mo. CFN, NDDC, FN (prophylaxis): 3 mo or duration of tx. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# PEGINTERFERON ALFA - 2A

## Products Affected

- Pegasys

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Hepatitis B: Diagnosis of chronic hepatitis B infection. Chronic Hepatitis C: Diagnosis of chronic hepatitis C infection. Patient has compensated liver disease. One of the following: a) Used in combination with one other hepatitis C virus (HCV) antiviral drug (e.g., Mavyret [glecaprevir-pibrentasvir], ribavirin) OR b) Both of the following: Used as monotherapy AND contraindication or intolerance to all other HCV antiviral drugs (e.g., Mavyret [glecaprevir-pibrentasvir], ribavirin). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | HepB, HepC: 48 wks. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# PEMAZYRE

## Products Affected

- Pemazyre

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is one of the following: unresectable locally advanced, resected gross residual (R2), or metastatic. Presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement. Patient has been previously treated. Myeloid/Lymphoid neoplasms: Diagnosis of myeloid/lymphoid neoplasm (MLNs). Presence of a fibroblast growth factor receptor 1 (FGFR1) rearrangement. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# PHYRAGO

## Products Affected

- Phyrago

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Myeloid Leukemia (CML): Diagnosis of CML. Trial or intolerance to generic dasatinib. Acute Lymphoblastic Leukemia (ALL): Diagnosis of ALL. Trial or intolerance to generic dasatinib. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# PIQRAY

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast Cancer (BC): Diagnosis of advanced or metastatic BC. Disease is hormone receptor (HR)-positive, and human epidermal growth factor receptor 2 (HER2)-negative. Presence of one or more PIK3CA mutations. Used in combination with fulvestrant. Disease has progressed on or after an endocrine-based regimen. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# PIRFENIDONE

## Products Affected

- Pirfenidone CAPS
- Pirfenidone TABS 267MG, 801MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF, defined as exclusion of other known causes of interstitial lung disease and either the presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF in patients not subjected to lung biopsy, or HRCT and surgical lung biopsy pattern revealing IPF or probable IPF in patients subjected to a lung biopsy. IPF (reauth): Patient demonstrates positive clinical response to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | (initial): Prescribed by or in consultation with a pulmonologist. |
| **Coverage Duration** | (initial, reauth): plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# POLYPHARMACY-ACH

## Products Affected

- Amitriptyline Hydrochloride TABS
- Amoxapine
- Benztropine Mesylate TABS
- Chlorpromazine Hydrochloride CONC
- Chlorpromazine Hydrochloride TABS
- Clomipramine Hydrochloride
- Clozapine TABS 100MG, 200MG, 25MG, 50MG
- Clozapine Odt
- Cyclobenzaprine Hydrochloride TABS 10MG, 5MG
- Desipramine Hydrochloride
- Dicyclomine Hcl SOLN
- Dicyclomine Hydrochloride CAPS
- Dicyclomine Hydrochloride TABS 20MG
- Diphenoxylate Hydrochloride/atropine Sulfate
- Doxepin Hcl CAPS 75MG
- Doxepin Hcl CONC
- Doxepin Hydrochloride CAPS 100MG, 10MG, 150MG, 25MG, 50MG
- Hydroxyzine Hcl TABS 50MG
- Hydroxyzine Hydrochloride SYRP 10MG/5ML
- Hydroxyzine Hydrochloride TABS 10MG, 25MG
- Hydroxyzine Pamoate CAPS
- Meclizine Hcl TABS 12.5MG
- Meclizine Hydrochloride TABS 25MG
- Nortriptyline Hcl CAPS 25MG, 75MG
- Nortriptyline Hcl SOLN
- Nortriptyline Hydrochloride CAPS 10MG, 50MG
- Olanzapine TABS
- Olanzapine Odt
- Oxybutynin Chloride SOLN
- Oxybutynin Chloride TABS 5MG
- Oxybutynin Chloride Er
- Perphenazine TABS
- Prochlorperazine SUPP 25MG
- Prochlorperazine Maleate TABS
- Scopolamine PT72 1MG/3DAYS
- Solifenacin Succinate
- Trihexyphenidyl Hydrochloride
- Versacloz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prescriber acknowledges anticholinergic risks (e.g., confusion, dry mouth, blurry vision, constipation, urinary retention) and will consider lowering the dose or discontinuing medication(s) that are no longer clinically warranted for the patient. |
| **Age Restrictions** | PA applies to patients 65 years or older. |

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# POMALYST

## Products Affected

- Pomalidomide

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple myeloma (MM): Diagnosis of MM. One of the following: 1) Trial, contraindication, or intolerance to one of the following: a) immunomodulatory agent [eg, Revlimid (lenalidomide)], b) proteasome inhibitor [eg, Velcade (bortezomib)], or c) anti CD-38 therapy [eg, Darzalex (daratumumab), Sarclisa (isatuximab)], OR 2) Induction therapy for the management of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome. Kaposi sarcoma (KS): One of the following: 1) Both of the following: a) Diagnosis of AIDS-related KS and b) Patient is currently being treated with antiretroviral therapy (ART), OR 2) Both of the following: a) Diagnosis of KS and b) Patient is HIV-negative, OR 3) Diagnosis of KS herpesvirus (KSHV)-Associated Inflammatory Cytokine Syndrome (KICS). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# POSACONAZOLE ORAL

## Products Affected

- Posaconazole Dr

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prophylaxis of Invasive Fungal Infections (IFI): Used as prophylaxis of invasive fungal infections caused by Aspergillus or Candida for one of the following conditions: 1) Patient is at high risk of infections due to severe immunosuppression from hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD) or hematologic malignancies with prolonged neutropenia from chemotherapy [eg, acute myeloid leukemia (AML), myelodysplastic syndrome (MDS)], OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Treatment of IFI: Used as treatment of invasive fungal infections caused by Aspergillus. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Prophylaxis of IFI: plan year. Treatment of IFI: 3 months. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# PREVYMIS ORAL

## Products Affected

- Prevymis PACK
- Prevymis TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cytomegalovirus (CMV) Prophylaxis in Hematopoietic Stem Cell Transplant (HSCT): Used for prophylaxis of CMV infection and disease AND patient is a CMV-seropositive recipient [R+] of an allogeneic HSCT. CMV Prophylaxis in Kidney Transplant: Used for prophylaxis CMV infection and disease. Patient is a CMV-seronegative recipient [R-]. Patient is receiving a kidney transplant from a CMV-seropositive donor [D+]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | CMV Prophylaxis in HSCT: Prescribed by or in consultation with an oncologist, hematologist, physician experienced in the management of transplant patients, or infectious disease specialist. CMV Prophylaxis in Kidney Transplant: Prescribed by or in consultation with a nephrologist, physician experienced in the management of transplant patients, or infectious disease specialist. |
| **Coverage Duration** | CMV Prophylaxis in HSCT: 7 months. CMV Prophylaxis in Kidney Transplant: 7 months. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# PROMACTA

## Products Affected

- Eltrombopag Olamine

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Idiopathic thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: persistent ITP, chronic ITP or relapsed/refractory ITP. Baseline platelet count is less than 30,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. ITP (reauthorization): Patient demonstrates positive clinical response to therapy. Chronic Hepatitis C-associated thrombocytopenia (initial): Diagnosis of chronic hepatitis C-associated thrombocytopenia. One of the following: planning to initiate and maintain interferon-based treatment or currently receiving interferon-based treatment. First-line for severe aplastic anemia (SAA): Diagnosis of SAA. Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy with any equine antithymocyte globulin plus cyclosporine, alemtuzumab, or high dose cyclophosphamide). Used in combination with standard immunosuppressive therapy (e.g., Atgam [antithymocyte globulin equine] and cyclosporine). Patient meets at least two of the following: 1) absolute neutrophil count less than 500/mcL, 2) platelet count less than 20,000/mcL, 3) absolute reticulocyte count less than 60,000/mcL. Refractory SAA (initial): Diagnosis of refractory SAA. Patient has a platelet count less than 30,000/mcL. Refractory SAA (reauthorization): Patient demonstrates positive clinical response to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1stline SAA:6mo.HepC (init):3mo.RefractSAA(init):16wk.ITP,HepC(reauth),RefractSAA(reauth):plan yr |

| | |
|---|---|
| **Other Criteria** | ITP (initial): Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Chronic Hepatitis C-associated thrombocytopenia (Reauthorization): Patient currently on antiviral interferon therapy for treatment of chronic hepatitis C. Refractory SAA (initial): Trial and failure, contraindication, or intolerance to at least one course of immunosuppressive therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# PURIXAN

## Products Affected

- Mercaptopurine SUSP

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | One of the following: History of contraindication or intolerance to generic mercaptopurine tablets OR patient is unable to swallow tablets. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# PYRUKYND

## Products Affected

- Pyrukynd
- Pyrukynd Taper Pack

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

# QINLOCK

**Products Affected**

- Qinlock

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Gastrointestinal Stromal Tumor (GIST): Diagnosis of gastrointestinal stromal tumor (GIST). One of the following: a) gross residual disease (R2 resection), b) tumor rupture, c) unresectable primary disease, or d) recurrent/metastatic. One of the following: a) Trial and failure, contraindication, or intolerance to all of the following: imatinib (Gleevec), sunitinib (Sutent), and regorafenib (Stivarga), b) Both of the following: history of progression on imatinib (Gleevec), and history of intolerance to sunitinib (Sutent), or c) All of the following: PDGFRA exon 18 mutations that are insensitive to imatinib (Gleevec) (including PDGFRA D842V), history of progression on avapritinib (Ayvakit), and history of progression on dasatinib (Sprycel). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# QUININE

## Products Affected

- Quinine Sulfate CAPS 324MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis (dx) of uncomplicated malaria and one of the following: treatment in areas of chloroquine-sensitive malaria or treatment in areas of chloroquine-resistant malaria. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 7 days |
| **Other Criteria** | Chloroquine-sensitive malaria: Failure, contraindication or intolerance to chloroquine or hydroxychloroquine. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# QULIPTA

**Products Affected**

- Qulipta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Episodic Migraine (EM) (initial): Diagnosis of EM. Patient has greater than or equal to 4 migraine days per month. Chronic Migraines (CM) (initial): Diagnosis of CM. Patient has greater than or equal to 8 migraine days per month. All Indications (initial): Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | EM, CM (initial, reauth): Plan year |
| **Other Criteria** | EM, CM (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# RADICAVA ORS

## Products Affected

- Radicava Ors Starter Kit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Amyotrophic lateral sclerosis (ALS) (initial): Documentation of the most recent ALS Functional Rating Scale-Revised (ALSFRS-R) score confirming that the patient scores greater than or equal to 2 in all items of the ALSFRS-R criteria at the start of treatment. Documentation confirming that the patient has a % forced vital capacity (%FVC) greater than or equal to 80% at the start of treatment. Diagnosis of "definite" or "probable" amyotrophic lateral sclerosis (ALS) per the revised EL Escorial diagnostic criteria. Radicava dosing for ALS is in accordance with the United States Food and Drug Administration approved labeling. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | ALS (initial): Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | ALS (initial, reauth): 6 months |
| **Other Criteria** | ALS (reauthorization): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# RETEVMO

## Products Affected

- Retevmo TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-Small Cell Lung cancer: Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: a) recurrent, b) advanced, or c) metastatic. Presence of RET gene fusion-positive or RET rearrangement positive tumor(s). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is advanced or metastatic. Disease has presence of RET gene mutation. Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is advanced or metastatic. Disease is RET gene fusion-positive. Disease requires treatment with systemic therapy. Patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate. Solid Tumors: Presence of RET gene fusion-positive solid tumor. Disease is recurrent, advanced, or metastatic. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Non-Small Cell Lung Cancer, MTC, Thyroid Cancer, Solid Tumors: Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# REVCOVI

## Products Affected

- Revcovi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# REVUFORJ

## Products Affected

- Revuforj

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsed or refractory acute leukemia: Diagnosis of acute leukemia. Disease is relapsed or refractory. Positive for lysine methyltransferase 2A gene (KMT2A) translocation. Relapsed or refractory acute myeloid leukemia: Diagnosis of acute myeloid leukemia (AML). Disease is relapsed or refractory. Positive for nucleophosmin 1 (NPM1) mutation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# REZDIFFRA (I)

## Products Affected

- Rezdiffra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH), [formerly known as nonalcoholic steatohepatitis (NASH)]. Patient does not have cirrhosis (e.g., decompensated cirrhosis).Submission of medical records (e.g., chart notes) documenting disease is fibrosis stage F2 or F3 as confirmed by one of the following: 1) Both of the following: A) Serum biomarker [e.g., enhanced liver fibrosis (ELF) test, fibrosis-4 index (FIB-4)], and B) Imaging biomarker [e.g., FibroScan, magnetic resonance imaging-proton density fat fraction (MRI-PDFF)], or 2) One of the following: A) FibroScan aspartate aminotransferase (FAST), B) MRI-aspartate aminotransferase (MAST), C) Magnetic Resonance Elastography combined with fibrosis-4 index (MEFIB), or D) Liver biopsy within the past 12 months. Presence of one metabolic risk factor (e.g., Type 2 diabetes, hypertension, obesity). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with a gastroenterologist or hepatologist. |
| **Coverage Duration** | Initial, Reauth: Plan Year. |
| **Other Criteria** | Reauth: Patient demonstrates positive response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# REZLIDHIA

## Products Affected

- Rezlidhia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of acute myeloid leukemia (AML). Disease is relapsed or refractory. Positive for a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (e.g., R132C, R132H, R132G, R132S, R132L). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# RINVOQ

## Products Affected

- Rinvoq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid arthritis (RA) (init): Diagnosis (Dx) of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Psoriatic arthritis (PsA) (init): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing spondylitis (AS) (init): Dx of active AS. Non-radiographic axial spondyloarthritis (NRAS) (init): Dx of active NRAS. Patient has signs of inflammation. Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, certolizumab pegol). AS, NRAS (init): Minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Atopic dermatitis (AD) (init): Dx of moderate to severe AD. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. TF/C/I to one of the following: Pimecrolimus cream or Tacrolimus ointment. One of the following: 1) TF/C/I to one systemic AD product from: Adbry, Dupixent or Ebglyss, OR 2) Provider attests that treatment is inadvisable for one systemic product. Not used in combination with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine). |
| **Age Restrictions** | AD (initial): Patient is 12 years of age or older. |
| **Prescriber Restrictions** | RA, PJIA, AS, NRAS, GCA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. AD (initial): Prescribed by or in consultation with a dermatologist or allergist/immunologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. |

| | |
|---|---|
| **Coverage Duration** | RA, PJIA, PsA, AS, NRAS, AD, CD, UC, GCA (initial, reauth): Plan year. |
| **Other Criteria** | Polyarticular juvenile idiopathic arthritis (PJIA) (init): Dx of active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide. RA, PJIA, PsA, AS (init): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, etanercept, adalimumab). Giant cell arteritis (GCA) (init): Dx of GCA. RA, PJIA, PsA, AS, NRAS, GCA (init, reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). Crohn's disease (CD) (init): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Ulcerative colitis (UC) (init): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. CD/UC (init): One of the following: a) Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab), or b) If treatment is inadvisable with a TNF inhibitor (ie, contraindication), patient has had a trial of a systemic therapy approved for CD or UC (eg, guselkumab, risankizumab-rzaa, ustekinumab). Not used in combination with other JAK inhibitors, biological therapies for CD/UC, or potent immunosuppressants (eg, azathioprine, cyclosporine). All indications (reauth): Patient demonstrates positive clinical response to therapy. AD (reauth): Not used in combination with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine). CD/UC (reauth): Not used in combination with other JAK inhibitors, biological therapies for CD/UC, or potent immunosuppressants (eg, azathioprine, cyclosporine). |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# RINVOQ LQ

**Products Affected**

- Rinvoq Lq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Polyarticular juvenile idiopathic arthritis (PJIA) (init): Diagnosis of active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide. Psoriatic arthritis (PsA) (init): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. PJIA, PsA (init): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept). PJIA, PsA (init, reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PJIA (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. |
| **Coverage Duration** | PJIA, PsA (init, reauth): Plan year. |
| **Other Criteria** | PJIA, PsA (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ROFLUMILAST

## Products Affected

- Roflumilast

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

# ROMVIMZA

## Products Affected

- Romvimza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of tenosynovial giant cell tumor (TGCT). Surgical resection will potentially cause worsening functional limitation or severe morbidity. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ROZLYTREK

## Products Affected

- Rozlytrek

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of metastatic non-small cell lung cancer (NSCLC). Patient has ROS1 rearrangement positive tumor(s). Solid Tumors: Patient has solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.). Disease is without a known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions). Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# RUBRACA

## Products Affected

- Rubraca

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Presence of deleterious BRCA mutation. Metastatic castration-resistant prostate cancer (mCRPC): Diagnosis of mCRPC. Presence of deleterious BRCA mutation. History of failure, contraindication, or intolerance to androgen receptor-directed therapy [e.g., Erleada (apalutamide), Xtandi (enzalutamide), Zytiga (abiraterone)]. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)], OR 2) Patient received bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# RYDAPT

## Products Affected

- Rydapt

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Myeloid Leukemia (AML): Diagnosis of acute myeloid leukemia (AML), AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive, Rydapt will be used in combination with standard induction and consolidation therapy. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), Mast Cell Leukemia (MCL): Diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SCEMBLIX

## Products Affected

- Scemblix

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of chronic myelogenous/myeloid leukemia (CML). Disease is Philadelphia chromosome-positive (Ph+) or BCR::ABL1-positive. Disease is in chronic phase or disease is in accelerated phase. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SHINGRIX

## Products Affected

- Shingrix

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Vaccine is being used for prevention of herpes zoster (shingles). One of the following: A) Age greater than or equal to 50 years OR B) Both of the following: 1) Age 18 to 49 years and 2) Patient is or will be at increased risk of herpes zoster due to immunodeficiency or immunosuppression caused by known disease or therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 6 months (2 injections per lifetime) |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SIGNIFOR

## Products Affected

- Signifor

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cushing's disease: Diagnosis of endogenous Cushing's disease (i.e, hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Either pituitary surgery has not been curative for the patient OR patient is not a candidate for pituitary surgery. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SILDENAFIL

## Products Affected

- Sildenafil Citrate TABS 20MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH: Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SIRTURO

## Products Affected

- Sirturo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of pulmonary multidrug resistant tuberculosis (MDR-TB) and adverse reactions or resistance to standard drugs used to treat MDR-TB. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 24 weeks |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# SKYCLARYS

## Products Affected

- Skyclarys

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of Friedreich's ataxia confirmed via genetic testing demonstrating mutation in the FXN gene. Patient has a B-type natriuretic peptide value less than or equal to 200 pg/mL. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with one of the following: Neurologist, Neurogeneticist, or Physiatrist (Physical Medicine and Rehabilitation Specialist). |
| **Coverage Duration** | Initial, Reauth: Plan Year. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SKYRIZI (I)

## Products Affected

- Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML, 55MG/0.37ML
- Skyrizi Pen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Plaque Psoriasis (initial): Diagnosis of chronic moderate to severe plaque psoriasis. One of the following: at least 3% body surface area involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active CD. Will be used as a maintenance dose following the intravenous induction doses. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction doses. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | All uses (initial, reauth): plan year. |
| **Other Criteria** | All indications (Reauth): Patient demonstrates positive clinical response to therapy. |

| | |
|---|---|
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# SOMAVERT

## Products Affected

- Somavert

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acromegaly (Initial): Diagnosis of acromegaly by one of the following: serum growth hormone (GH) level greater than 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis, or elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis. Inadequate response to one of the following: surgery, radiotherapy, or dopamine agonist (e.g., bromocriptine, cabergoline) therapy or not a candidate for surgery, radiotherapy or dopamine agonist (eg, bromocriptine, cabergoline) therapy. One of the following: 1) Inadequate response, contraindication, or intolerance to a somatostatin analog (e.g., octreotide, lanreotide) or 2) Clinical rationale provided for preferred treatment with pegvisomant (e.g., comorbid diabetes mellitus is present with acromegaly, IGF-1 levels greater than 900 ng/mL). Acromegaly (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Acromegaly (Initial, Reauth): plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# SORAFENIB

## Products Affected

- Sorafenib Tosylate TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Renal cell carcinoma (RCC): Diagnosis of RCC. Hepatocellular carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or both of the following: a) patient is not a transplant candidate, and b) disease is unresectable. Differentiated thyroid carcinoma (DTC): Diagnosis of one of the following: a) follicular carcinoma, b) oncocytic carcinoma, or c) papillary carcinoma. One of the following: metastatic disease, unresectable recurrent disease, or persistent locoregional disease. One of the following: patient has symptomatic disease or patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SOTYKTU

## Products Affected

- Sotyktu

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Plaque Psoriasis (PsO) (initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. PsO, PsA (initial, reauth): Not used in combination with other potent immunosuppressants (eg, azathioprine, cyclosporine, biologic disease-modifying antirheumatic drugs [DMARDs]). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PsO (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. |
| **Coverage Duration** | All uses (initial, reauth): plan year. |
| **Other Criteria** | PsO, PsA (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# SPRYCEL

## Products Affected

- Dasatinib

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Myeloid Leukemia (CML): Diagnosis of chronic myeloid leukemia (CML). Acute Lymphoblastic Leukemia (ALL): Diagnosis of acute lymphoblastic leukemia (ALL). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# STARJEMZA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial regardless of dose): One of the following: at least 3% body surface area involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial regardless of dose): One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (initial): Diagnosis of moderately to severely active Crohn's disease. Will be used as a maintenance dose following the intravenous induction dose. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD and UC (initial): Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | All indications (initial, reauth): plan year. |

| | |
|---|---|
| **Other Criteria** | Ulcerative colitis (UC) (initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction dose. All indications (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# STEQEYMA

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial regardless of dose): One of the following: at least 3% body surface area involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial regardless of dose): One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (initial): Diagnosis of moderately to severely active Crohn's disease. Will be used as a maintenance dose following the intravenous induction dose. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD and UC (initial): Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | All indications (initial, reauth):  plan year. |

| | |
|---|---|
| **Other Criteria** | Ulcerative colitis (UC) (initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction dose. All indications (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# STIVARGA

## Products Affected

- Stivarga

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Colorectal Cancer (CRC): Diagnosis of advanced or metastatic colorectal cancer. Trial and failure, contraindication, or intolerance to treatment with all the following: oxaliplatin-based chemotherapy, irinotecan-based chemotherapy, fluoropyrimidine-based chemotherapy, and anti-VEGF therapy-based chemotherapy. One of the following: 1) Tumor is RAS mutant-type OR 2) Tumor is RAS wild-type and trial and failure, contraindication, or intolerance to anti-EGFR therapy [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]. Gastrointestinal stromal tumor (GIST): Diagnosis of gross residual (R2 resection), unresectable primary, tumor rupture, or recurrent/metastatic GIST. One of the following: 1) Patient has succinate dehydrogenase (SDH) deficient GIST or 2) Trial and failure, contraindication, or intolerance to imatinib mesylate and one of the following: sunitinib malate or Qinlock (ripretinib). Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Used as subsequent-line therapy for disease progression. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# SUNITINIB

## Products Affected

- Sunitinib Malate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. One of the following: 1) History of disease progression on, contraindication, or intolerance to Gleevec (imatinib), Stivarga (regorafenib), or standard dose Qinlock (ripretinib) or 2) Succinate dehydrogenase (SDH)-deficient GIST. Renal Cell Carcinoma (RCC): Diagnosis of RCC. One of the following: 1) Disease has relapsed, 2) Both of the following: used in adjuvant setting and patient has a high risk of recurrence following nephrectomy, or 3) Disease is advanced. Islet Cell Tumors/Pancreatic Neuroendocrine Tumors (pNET): Diagnosis of islet cell tumors/progressive pNET. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# SYMPAZAN

## Products Affected

- Sympazan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Lennox-Gastaut syndrome: Diagnosis of Lennox-Gastaut syndrome. Used for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome. Dravet syndrome: Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with Diacomit. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TABLOID

## Products Affected

- Tabloid

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of acute myeloid leukemia. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TABRECTA

## Products Affected

- Tabrecta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of non-small cell lung cancer (NSCLC). One of the following: a) Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors or b) High level MET amplification in lung cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TADALAFIL (BPH)

**Products Affected**

- Tadalafil TABS 2.5MG, 5MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Excluded if used for the treatment of erectile dysfunction only. |
| **Required Medical Information** | Benign prostatic hyperplasia (BPH): Diagnosis of BPH. Male Gender. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | BPH: plan year |
| **Other Criteria** | BPH: Trial and failure, contraindication, or intolerance to two formulary alpha blockers (e.g., tamsulosin, alfuzosin). 2.5mg strength: Patient has renal insufficiency. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TADALAFIL (PAH)

## Products Affected

- Alyq
- Tadalafil TABS 20MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH: Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TAFAMIDIS

## Products Affected

- Vyndamax

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) (initial): Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM). One of the following: 1) Presence of a transthyretin (TTR) mutation (e.g., V122I), 2) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits, OR 3) Both of the following: i) cardiac magnetic resonance imaging or scintigraphy scan suggestive of amyloidosis, and ii) absence of light-chain amyloidosis. Documentation that patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist |
| **Coverage Duration** | ATTR-CM (initial, reauth): Plan year |
| **Other Criteria** | ATTR-CM (reauth): Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TAFINLAR

**Products Affected**

- Tafinlar

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma AND cancer is BRAFV600 mutant type. Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type. Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Mekinist (trametinib). Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of non-small cell lung cancer AND disease is one of the following: metastatic, advanced, or recurrent AND cancer is BRAF V600E mutant type AND medication is used in combination with Mekinist (trametinib). Anaplastic Thyroid Cancer (ATC): Diagnosis of anaplastic thyroid cancer. One of the following: 1) Disease is one of the following: metastatic, locally advanced, or unresectable OR 2) Prescribed as adjuvant therapy following resection. Cancer is BRAF V600E mutant type. Medication is used in combination with Mekinist (trametinib). Solid tumors: Presence of solid tumor. Disease is unresectable or metastatic. Patient has progressed on or following prior systemic treatment (e.g., carboplatin, 5-fluorouracil, paclitaxel). Cancer is BRAF V600E mutant type. Medication is used in combination with Mekinist (trametinib). Low-grade glioma: Diagnosis of low-grade glioma. Cancer is BRAF V600E mutant type. Medication is used in combination with Mekinist (trametinib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |

| | |
|---|---|
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TAGRISSO

**Products Affected**

- Tagrisso

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is positive for at least one of the following EGFR mutations: 1) Exon 19, 2) Exon 21 L858R, 3) S7671, 4) L861Q, 5) G719X, 6) T790M. One of the following: 1) Disease is one of the following: a) advanced, b) recurrent, or c) metastatic, OR 2) Both of the following: A) One of the following: a) Disease is stage IB, II, IIIA, or IIIB (T3, N2) or b) Patient has undergone complete resection, and B) Patient has received previous adjuvant chemotherapy (e.g., cisplatin + pemetrexed, cisplatin + gemcitabine, cisplatin + docetaxel) or ineligible to receive platinum-based chemotherapy (e.g., cisplatin, carboplatin), OR 3) All of the following: a) Disease is stage II-III, b) Disease is locally advanced or unresectable, and c) No disease progression during or following concurrent or sequential chemoradiation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TALZENNA

## Products Affected

- Talzenna

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) locally advanced or b) metastatic. Presence of a germline BRCA-mutation. Prostate cancer: Diagnosis of prostate cancer. Disease is HRR gene-mutated. Disease is metastatic castration-resistant. Taken in combination with Xtandi (enzalutamide). Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] OR Patient has had bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TASIGNA

## Products Affected

- Nilotinib Hydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of chronic myeloid leukemia. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TASIMELTEON CAPSULE

**Products Affected**

- Tasimelteon

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-24-hour sleep-wake disorder: Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome). Smith-Magenis Syndrome (SMS): Diagnosis of Smith-Magenis Syndrome (SMS). Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking). |
| **Age Restrictions** | SMS: 16 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Non-24, SMS: 6 months |
| **Other Criteria** | Non-24: Patient is totally blind (has no light perception). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TAZAROTENE

## Products Affected

- Tazarotene CREA 0.1%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | All indications: Excluded if treatment for cosmetic purposes. |
| **Required Medical Information** | Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne). Psoriasis: Diagnosis of psoriasis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TEPMETKO

## Products Affected

- Tepmetko

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: recurrent, advanced, or metastatic. One of the following: 1) Mesenchymal-epithelial transition (MET) exon 14 skipping mutation positive tumor(s) or 2) High level MET amplification. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TERIPARATIDE

## Products Affected

- Bonsity
- Teriparatide

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

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

# TETRABENAZINE

## Products Affected

- Tetrabenazine

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Huntington's Disease: Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia: Diagnosis of tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication or 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Tourette's syndrome: Patient has tics associated with Tourette's syndrome. Trial and failure, contraindication, or intolerance to Haldol (haloperidol). |
| **Age Restrictions** | Tardive dyskinesia: Age greater than or equal to 18 years. |
| **Prescriber Restrictions** | Huntington's: Prescribed by or in consultation with a neurologist. Tardive dyskinesia, Tourette's: Prescribed by or in consultation with a neurologist or psychiatrist. |
| **Coverage Duration** | Plan year. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TEZSPIRE

## Products Affected

- Tezspire

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Asthma (Initial): Diagnosis of severe asthma. One of the following: 1) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months, OR 2) Prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) (i.e., greater than 500 mcg fluticasone propionate equivalent/day) and ii) Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium), OR b) One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], budesonide/formoterol, Breo Ellipta [fluticasone/vilanterol]). Chronic rhinosinusitis with nasal polyps (CRSwNP) (Initial): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone). Used in combination with another agent for CRSwNP. |
| **Age Restrictions** | Asthma (Initial): Patient is 12 years of age or older. |
| **Prescriber Restrictions** | Asthma (Initial): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (Initial): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist. |
| **Coverage Duration** | All indications (Initial, Reauth): Plan year. |

| | |
|---|---|
| **Other Criteria** | Asthma (Reauth): Patient demonstrates positive clinical response to therapy. Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. CRSwNP (Reauth): Patient demonstrates positive clinical response to therapy. Used in combination with another agent for CRSwNP. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# THALOMID

## Products Affected

- Thalomid CAPS 100MG, 50MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Erythema Nodosum Leprosum (ENL): Diagnosis (Dx) of moderate to severe ENL. One of the following: used for acute treatment OR used as maintenance therapy for prevention & suppression of cutaneous manifestations of ENL recurrence. Multiple Myeloma (MM): Dx of multiple myeloma. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TIBSOVO

## Products Affected

- Tibsovo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsed or refractory Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. AML is isocitrate dehydrogenase-1 (IDH1) mutation-positive. Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. AML is isocitrate dehydrogenase-1 (IDH1) mutation-positive. One of the following: 1) Patient is greater than or equal to 75 years old OR 2) Patient has comorbidities that preclude the use of intensive induction chemotherapy OR 3) Patient is not a candidate for or declines intensive induction therapy OR 4) Patient is receiving post-induction therapy following response to previous lower intensity therapy. Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is locally advanced, unresectable, or metastatic. Cholangiocarcinoma is IDH1 mutation-positive. Disease has progressed on or after systemic treatment. Myelodysplastic Syndromes (MDS): Diagnosis of MDS. Disease is one of the following: relapsed or refractory. MDS is IDH1 mutation-positive. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TOBI PODHALER

## Products Affected

- Tobi Podhaler

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TOLVAPTAN (SAMSCA)

## Products Affected

- Tolvaptan TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of significant hyponatremia (euvolemic or hypervolemic). Treatment has been initiated or re-initiated in a hospital setting prior to discharge within the past 30 days. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Length of authorization: 30 days |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TOPICAL RETINOIDS

## Products Affected

- Tretinoin CREA
- Tretinoin GEL 0.01%, 0.025%
- Tretinoin Microsphere GEL 0.1%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | All indications: Excluded if treatment for cosmetic purposes. |
| **Required Medical Information** | Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TORPENZ

## Products Affected

- Torpenz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Neuroendocrine Tumors (NET): One of the following: 1) Both of the following: a) Diagnosis (Dx) of neuroendocrine tumors of gastrointestinal origin, lung origin, or thymic origin, and b) Disease is unresectable, locally advanced, or metastatic, OR 2) Diagnosis of neuroendocrine tumors of pancreatic origin, OR 3) All of the following: a) Diagnosis of well-differentiated, grade 3 neuroendocrine tumor, b) Disease is unresectable, locally advanced, or metastatic, and c) Tumor has favorable biology (e.g., relatively low Ki-67 [less than 55%], slow growing, positive SSTR-based PET imaging). Renal Cell Carcinoma/Kidney Cancer: Dx of renal cell cancer/kidney cancer. Disease is one of the following: (1) relapsed or (2) stage IV disease. Renal angiomyolipoma with tuberous sclerosis complex (TSC): Dx of renal angiomyolipoma and TSC. Subependymal Giant Cell Astrocytoma (SEGA) with tuberous sclerosis (TS): Dx of SEGA associated with TS. Breast Cancer: Dx of recurrent or metastatic breast cancer. One of the following: 1) Disease is hormone receptor positive (HR+) [i.e., estrogen-receptor-positive (ER+) or progesterone-receptor-positive (PR+)], 2) Breast cancer is considered inflammatory, OR 3) both of the following: disease is HR- and disease has clinical characteristics that predict a HR+ tumor. Disease is HER2-negative. One of the following: Patient is a postmenopausal woman, patient is a premenopausal woman being treated with ovarian ablation/suppression, or patient is male. One of the following: A) Both of the following: a) one of the following: 1) Disease progressed while on or within 12 months of non-steroidal aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole)] therapy or 2) patient was treated with tamoxifen at any time AND b) Used in combination with Aromasin (exemestane) OR B) Used in combination with Fulvestrant or Tamoxifen. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | Plan year |
| **Other Criteria** | All uses: Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TREMFYA (I)

## Products Affected

- Tremfya INJ 100MG/ML, 200MG/2ML
- Tremfya Induction Pack For Crohns Disease/ulcerative Colitis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Plaque Psoriasis (initial): Diagnosis of chronic moderate-to-severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: 1) Will be used as a maintenance dose, OR 2) Both of the following: a) Will be used as induction dosing, and b) One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. Crohn's Disease (CD) (initial) in Other Criteria element. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | All indications (initial, reauth): plan year |

| | |
|---|---|
| **Other Criteria** | Crohn's Disease (CD) (initial): Diagnosis of moderately to severely active CD. One of the following: 1) Will be used as a maintenance dose, OR 2) Both of the following: a) Will be used as induction dosing, and b) One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), or CD Activity Index (CDAI) greater than 220. All indications (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TRIENTINE

## Products Affected

- Trientine Hydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TRIKAFTA

**Products Affected**

- Trikafta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of cystic fibrosis. Submission of medical records (e.g., chart notes) or laboratory results confirming the presence of at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. One of the following: 1) CFTR mutation is responsive based on clinical or in vitro data OR 2) CFTR mutation results in the production of CFTR protein. |
| **Age Restrictions** | Initial: For granule packets: patient is at least 2 to less than 6 years of age. For tablets: patient is 6 years of age or older |
| **Prescriber Restrictions** | Initial/Reauth: Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center |
| **Coverage Duration** | Initial, Reauth: Plan Year. |
| **Other Criteria** | Reauthorization: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TRULICITY

## Products Affected

- Trulicity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Excluded if used for weight loss only. |
| **Required Medical Information** | Diabetes Mellitus (DM): Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 DM. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TRUQAP

## Products Affected

- Truqap TABS 200MG
- Truqap TBPK 160MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of breast cancer. Disease is one of the following: locally advanced, recurrent unresectable (local or regional), or metastatic. Used in combination with fulvestrant. Disease is hormone receptor (HR)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Presence of one or more PIK3CA/AKT1/PTEN-alterations. One of the following: A) Has progressed on at least one endocrine-based regimen in the metastatic setting (e.g., anastrozole, letrozole, exemestane, tamoxifen) OR B) Recurrence on or within 12 months of completing adjuvant therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TUKYSA

## Products Affected

- Tukysa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) advanced unresectable or b) metastatic. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Used in combination with trastuzumab and capecitabine. Patient has been previously treated with an anti-HER2-based regimen (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine) in the metastatic setting. Colorectal cancer: Diagnosis of colorectal cancer (HER2-amplified and RAS and BRAF wild-type). Disease is HER2-positive. Disease is one of the following: a) advanced, b) unresectable, c) metastatic. One of the following: a) patient has previously been treated with one of the following regimens: i) fluoropyrimidine-based chemotherapy, ii) oxaliplatin-based chemotherapy, iii) irinotecan-based chemotherapy or b) patient is not appropriate for intensive therapy. Used in combination with trastuzumab. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TURALIO

## Products Affected

- Turalio CAPS 125MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Tenosynovial Giant Cell Tumor (TGCT): Diagnosis of TGCT. Patient is symptomatic. Patient is not a candidate for surgery due to worsening functional limitation or severe morbidity with surgical removal. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TYENNE SC

**Products Affected**

- Tyenne INJ 162MG/0.9ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), one formulary adalimumab product, Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinib), OR 2) for continuation of prior therapy if within the past 120 days. Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: 1) TF/C/I to two of the following: Enbrel (etanercept), one formulary adalimumab product, Rinvoq/Rinvoq LQ, Xeljanz (tofacitinib), OR 2) for continuation of prior therapy if within the past 120 days. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA, SJIA, PJIA, GCA (Initial): Prescribed by or in consultation with a rheumatologist. |
| **Coverage Duration** | RA, SJIA, PJIA, GCA (Initial, Reauth): Plan year |
| **Other Criteria** | RA, SJIA, PJIA, GCA (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TYMLOS

**Products Affected**

- Tymlos

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

| | |
|---|---|
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# UBRELVY

## Products Affected

- Ubrelvy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, Reauth: Plan year |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# VALCHLOR

## Products Affected

- Valchlor

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL): Both of the following: 1) diagnosis of Stage IA MF-CTCL OR diagnosis of Stage IB MF-CTCL AND 2) patient has received at least one prior skin-directed therapy (e.g., topical corticosteroids, bexarotene topical gel [Targretin topical gel], etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# VALTOCO

## Products Affected

- Valtoco 10 Mg Dose
- Valtoco 15 Mg Dose
- Valtoco 20 Mg Dose
- Valtoco 5 Mg Dose

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Epilepsy: Diagnosis of epilepsy. Frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VANDETANIB

## Products Affected

- Caprelsa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Thyroid Cancer: Diagnosis of medullary thyroid cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VANFLYTA

## Products Affected

- Vanflyta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is FLT3 internal tandem duplication (ITD) positive. Vanflyta will be used in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VAXCHORA

## Products Affected

- Vaxchora

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Vaccine is being used for active immunization against disease caused by Vibrio cholerae serogroup O1. Patient is traveling to a cholera-affected area. Age 2 through 64 years. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VENCLEXTA

## Products Affected

- Venclexta
- Venclexta Starting Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL. Acute Myeloid Leukemia (AML): One of the following: 1) Diagnosis of newly diagnosed AML. Used in combination with one of the following: azacitidine, decitabine, cladribine, fludarabine, idarubicin, or cytarabine. One of the following: a) used as treatment for induction therapy, b) used as follow-up after induction therapy, or c) used as consolidation therapy as continuation of lower-intensity regimen used for induction, 2) Diagnosis of relapsed/refractory acute myeloid leukemia (AML). Venclexta therapy to be given in combination with the patients previous initial successful induction regimen (e.g., azacitidine, decitabine, low-dose cytarabine, etc.), or 3) Diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) - acute myeloid leukemia (AML). Venclexta therapy will be given in combination with azactidine, decitabine, or low-dose cytarabine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VEOZAH

## Products Affected

- Veozah

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of moderate to severe vasomotor symptoms due to menopause. Prescriber attests that baseline serum alanine aminotransferase (ALT), serum aspartate aminotransferase (AST) and total bilirubin levels are less than 2 times the upper limit of normal (ULN) prior to initiating Veozah. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, Reauth: 6 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. One of the following within the past 3 months: a) For patients with total bilirubin levels less than or equal to 2 times the ULN, transaminase elevations do not exceed 5 times the ULN, or b) For patients with total bilirubin levels greater than 2 times the ULN, transaminase elevations do not exceed 3 times the ULN. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VERQUVO

## Products Affected

- Verquvo

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

# VERZENIO

## Products Affected

- Verzenio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Advanced, Recurrent, or Metastatic Breast Cancer: Diagnosis of advanced, recurrent, or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane), OR b) used in combination with Faslodex (fulvestrant) OR c) used as monotherapy and disease has progressed following endocrine therapy and patient has already received at least one prior chemotherapy regimen. Early Breast Cancer: Diagnosis of early breast cancer at high risk of recurrence. Disease is hormone receptor (HR)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Used in combination with one of the following endocrine therapies: 1) tamoxifen or 2) aromatase inhibitor (e.g., anastrozole, letrozole, exemestane). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# VIGABATRIN

## Products Affected

- Vigabatrin

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Complex Partial Seizures (CPS): For use as adjunctive therapy. Infantile Spasms (IS): Diagnosis of infantile spasms. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. CPS: Trial and failure, contraindication, or intolerance (TF/C/I) to two formulary anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)]. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# VIGAFYDE

## Products Affected

- Vigafyde

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of infantile spasms. Trial or intolerance to generic vigabatrin. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# VITRAKVI

## Products Affected

- Vitrakvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Presence of solid tumors. Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.). Disease is without a known acquired resistance mutation [e.g., TRKA G595R, G623R, G696A, F617L]. Disease is one of the following: metastatic or unresectable. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VONJO

**Products Affected**

- Vonjo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Patient has been diagnosed with one of the following: a) Primary myelofibrosis, b) Post-polycythemia vera myelofibrosis, c) Post-essential thrombocythemia myelofibrosis, OR d) Accelerated/blast phase myeloproliferative neoplasm. 1) One of the following: A) Both of the following: i) Patient has symptomatic lower-risk myelofibrosis AND ii) Patient has a platelet count below 50 x 10^9/L, or B) All of the following: i) Patient has higher-risk myelofibrosis and ii) Patient is not a transplant candidate or transplant not currently feasible and iii) One of the following: a) Patient has a platelet count less than 50 x 10^9/L or b) Both of the following: i) Patient has symptomatic splenomegaly and/or constitutional symptoms and ii) Patient has a platelet count greater than or equal to 50 x 10^9/L, or C) Used for treatment of myelofibrosis-associated anemia, or D) Used for splenomegaly and other disease-related symptoms in one of the following: i) Continued near the start of conditioning therapy of transplant candidates, or ii) Palliation in combination with hypomethylating agents (e.g., azacitidine or decitabine) as bridging therapy prior to transplant, or if not a candidate for transplant. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VOQUEZNA

## Products Affected

- Voquezna
- Voquezna Dual Pak
- Voquezna Triple Pak

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Helicobacter pylori (H. pylori) (Voquezna Dual Pak, Voquezna Triple Pak): Diagnosis of H. pylori infection. Trial and failure, contraindication, or intolerance to bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI]). H. pylori (Voquezna): Diagnosis of H. pylori infection. One of the following: a) Used in combination with amoxicillin and clarithromycin for the treatment of H. pylori infection, or b) Used in combination with amoxicillin for the treatment of H. pylori infecion. Trial and failure, contraindication, or intolerance to bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI]). Healing and Relief of Heartburn associated with Erosive Esophagitis (HRH) (Voquezna): Diagnosis of erosive esophagitis. Used for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis. Trial and failure, contraindication, or intolerance to TWO of the following: a) generic omeprazole, b) generic oral pantoprazole tablet, or c) generic esomeprazole granules. Maintenance of Healing and Relief of Heartburn associated with Erosive Esophagitis (MHRH) (Voquezna): Used to maintain healing and relief of heartburn associated with erosive esophagitis. Trial and failure, contraindication, or intolerance to TWO of the following: a) generic omeprazole, b) generic oral pantoprazole tablet, or c) generic esomeprazole granules. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | H. pylori, NERD: 1 mo. HRH: 8 wks. MHRH: 6 mos. |

| | |
|---|---|
| **Other Criteria** | Relief of Heartburn associated with non-erosive Gastroesophageal Reflux Disease (NERD) (Voquezna): Diagnosis of non-erosive Gastroesophageal Reflux Disease. Both of the following: a) Patient has history of heartburn for at least 6 months and b) Heartburn symptoms are present for at least 4 days during any consecutive 7-day period. Trial and failure, contraindication, or intolerance to TWO of the following: a) generic omeprazole, b) generic oral pantoprazole tablet, or c) generic esomeprazole granules. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# VORANIGO

**Products Affected**

- Voranigo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of Astrocytoma or Oligodendroglioma. Presence of an isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation. History of one of the following: a) Biopsy, b) Sub-total resection, or c) Gross total resection. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VORICONAZOLE INJECTION

**Products Affected**

- Voriconazole INJ 200MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Invasive aspergillosis: Diagnosis of invasive aspergillosis (IA). Candidemia: Diagnosis of candidemia. One of the following: (1) patient is non-neutropenic or (2) infection is located in skin, abdomen, kidney, bladder wall, or wounds. Esophageal Candidiasis: Diagnosis of esophageal candidiasis. Mycosis: Diagnosis of fungal infection caused by Scedosporium apiospermum (asexual form of Pseudallescheria boydii) or Fusarium spp. including Fusarium solani. For fusariosis: Patient is intolerant of, or refractory to, other therapy (e.g., liposomal amphotericin B, amphotericin B lipid complex). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 weeks |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VOSEVI

## Products Affected

- Vosevi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and patient is not receiving Vosevi in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VOTRIENT

## Products Affected

- Pazopanib Hydrochloride TABS 200MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Renal Cell Carcinoma (RCC): Diagnosis of RCC. Soft tissue sarcoma (STS): Diagnosis of advanced STS. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VOWST

## Products Affected

- Vowst

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

# WELIREG

## Products Affected

- Welireg

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | von Hippel-Lindau (VHL) disease: Diagnosis of von Hippel-Lindau (VHL) disease. Patient requires therapy for one of the following: a) renal cell carcinoma (RCC), b) central nervous system (CNS) hemangioblastoma, or c) pancreatic neuroendocrine tumor (pNET). Patient does not require immediate surgery. Advanced Renal Cell Carcinoma (RCC): Diagnosis of advanced renal cell carcinoma. Disease has progressed after treatment with both of the following: a) Programmed death receptor 1 (PD-1) or programmed death ligand 1 (PD-L1) checkpoint inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab)] and b) Vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) [e.g., Inlyta (axitinib), Lenvima (lenvatinib), Cabometyx (cabozantinib]. Pheochromocytoma or Paraganglioma (PPGL): Diagnosis of Pheochromocytoma or Paraganglioma (PPGL). Disease is one of the following: a) advanced, b) unresectable, or c) metastatic. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# WINREVAIR

## Products Affected

- Winrevair

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. Patient is currently on at least two therapies indicated for the treatment of PAH from the following different mechanisms of action, unless there is a contraindication or intolerance: a) Endothelin receptor antagonists (i.e., Bosentan, ambrisentan or macitentan) and b) Phosphodiesterase 5 inhibitors (i.e., Tadalafil or sildenafil). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# XALKORI

## Products Affected

- Xalkori

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Anaplastic Large Cell Lymphoma (ALCL): Diagnosis of systemic ALCL. Disease is relapsed or refractory. Tumor is anaplastic lymphoma kinase (ALK)-positive. Inflammatory Myofibroblastic Tumor (IMT): Diagnosis of IMT. Tumor is anaplastic lymphoma kinase (ALK)-positive. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# XATMEP

## Products Affected

- Xatmep

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute lymphoblastic leukemia (ALL): Diagnosis of acute lymphoblastic leukemia (ALL). Polyarticular juvenile idiopathic arthritis (pJIA) (initial): Diagnosis of active polyarticular juvenile idiopathic arthritis. Trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (e.g., diclofenac, ibuprofen, meloxicam, naproxen). |
| **Age Restrictions** | ALL: Patient is 18 years of age or younger. pJIA (initial): Patient is 18 years of age or younger. |
| **Prescriber Restrictions** | pJIA (initial): Prescribed by or in consultation with a rheumatologist. |
| **Coverage Duration** | ALL: plan year. pJIA (initial, reauth): plan year |
| **Other Criteria** | Subject to Part B vs. Part D review. ALL: Approve for continuation of prior therapy if within the past 120 days. pJIA (reauth): Patient demonstrates positive clinical response to therapy |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# XELJANZ

## Products Affected

- Tofacitinib Citrate SOLN
- Tofacitinib Citrate TABS
- Tofacitinib Citrate Er

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

| | |
|---|---|
| **Coverage Duration** | RA, PJIA, PsA, AS, UC (initial, reauth): plan year. |
| **Other Criteria** | Tofacitinib: Polyarticular course juvenile idiopathic arthritis (PJIA) (Initial): Diagnosis of active polyarticular course juvenile idiopathic arthritis. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept). RA, PsA, AS, PJIA (Initial, Reauth): Not used in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (eg, azathioprine, cyclosporine). All indications (Reauth): Patient demonstrates positive clinical response to therapy. UC (Reauth): Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine). |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# XERMELO

## Products Affected

- Xermelo

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

# XIFAXAN

**Products Affected**

- Xifaxan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Traveler's Diarrhea (TD): Diagnosis of traveler's diarrhea. Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin). Prophylaxis of Hepatic Encephalopathy (HE): Used for the prophylaxis of hepatic encephalopathy recurrence. One of the following: 1) Trial and failure, contraindication, or intolerance to lactulose OR 2) Add-on treatment to lactulose. Treatment of HE: Diagnosis of HE. Used for the treatment of HE. One of the following: 1) Trial and failure, contraindiation, or intolerance to lactulose OR 2) Add-on treatment to lactulose. Irritable Bowel Syndrome with Diarrhea (Initial): Diagnosis of irritable bowel syndrome with diarrhea (IBS-D). Trial and failure, contraindication or intolerance to an antidiarrheal agent (e.g., loperamide). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | TD: 14 days (one treatment course). HE (Prophylaxis, Tx): plan year. IBS-D (initial/reauth): 2 wks |
| **Other Criteria** | IBS-D Reauthorization: Patient experiences IBS-D symptom recurrence. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# XOLAIR

## Products Affected

- Xolair

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Asthma (Initial): Diagnosis of moderate to severe persistent allergic asthma. One of the following: A) All of the following: a) Patient is 6 years of age or older but less than 12 years of age, b) pre-treatment serum IgE level between 30 to 1300 IU/mL, c) Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: 1) Medium-dose inhaled corticosteroid (eg, greater than 100 - 200 mcg fluticasone propionate equivalent/day) AND Additional asthma controller medication (eg, leukotriene receptor antagonist [LTRA] [eg, montelukast], long-acting beta-2 agonist [LABA] [eg, salmeterol], long-acting muscarinic antagonist [LAMA] [eg, tiotropium]), OR 2) One medium dosed combination ICS/LABA product (eg, Wixela Inhub [fluticasone propionate 100mcg/ salmeterol 50mcg], budesonide 80mcg/ formoterol 4.5mcg, Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg]), OR B) All of the following: a) Patient is 12 years of age or older, b) Pre-treatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL, c) Patient is currently being treated with one of the following, unless there is a contraindication or intolerance to these medications: 1) one maximally-dosed combination ICS/LABA [eg, Wixela (fluticasone propionate 500 mcg/salmeterol 50 mcg), budesonide 160mcg/formoterol 4.5 mcg, Breo Ellipta (fluticasone 200 mcg/vilanterol 25mcg)] or 2) Both of the following: a) high-dose ICS [eg, greater than 500 mcg fluticasone propionate equivalent/day] and b) additional asthma controller medication {e.g., LTRA, LABA, LAMA [eg, tiotropium]}. Positive skin test or in vitro reactivity to a perennial aeroallergen. One of the following: a) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months, OR b) Prior asthma-related hospitalization within the past 12 months. |
| **Age Restrictions** | N/A |

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|---|---|
| **Prescriber Restrictions** | Asthma (Init): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CSU (Init): Prescribed by or in consultation with an allergist/immunologist, or dermatologist. CRSwNP (Init): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist. IgE-Mediated Food Allergy (Init): Prescribed by or in consultation with an allergist/immunologist |
| **Coverage Duration** | Asthma, CSU, Allergy (Init, Reauth): PlanYr. CRSwNP: PlanYr. |
| **Other Criteria** | Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (Previously Nasal Polyps) (Initial): Diagnosis of CRSwNP (previously nasal polyps). Unless contraindicated, the patient has had an inadequate response to an intranasal corticosteroid (e.g., fluticasone, mometasone). CRSwNP (Reauthorization): Patient demonstrates positive clinical response to therapy. CRSwNP (Initial): Used in combination with another agent for chronic rhinosinusitis with nasal polyps. Asthma (Reauthorization): Patient demonstrates positive clinical response to therapy. CSU (Reauthorization): Patient demonstrates positive clinical response to therapy. IgE-Mediated Food Allergy (Initial): One of the following: A) Both of the following: 1) Diagnosis of IgE Mediated Food Allergy as evidenced by one of the following: a) Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food, b) Positive food specific IgE, c) Positive oral food challenge, defined as experiencing dose-limiting symptoms at a single dose of less than or equal to 300 mg of food protein, AND 2) Clinical history of IgE Mediated Food Allergy, OR B) Provider attestation that patient has a history of severe allergic response, including anaphylaxis, following exposure to one or more foods. Used in conjunction with food allergen avoidance. Baseline (pre-Xolair treatment) serum total IgE level is greater than or equal to 30 IU/mL and less than or equal to 1850 IU/mL. Dosing is according to serum total IgE levels and body weight. IgE-Mediated Food Allergy (Reauth): Patient demonstrates positive clinical response to therapy. Chronic Spontaneous Urticaria (CSU) (Previously Chronic Idiopathic Urticaria) (Initial): Diagnosis of CSU (previously chronic idiopathic urticaria). Persistent symptoms (itching and hives) with a second generation H1 antihistamine (eg, cetirizine, fexofenadine), unless there is a history of contraindication or intolerance to H1 antihistamines. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# XOLREMDI

## Products Affected

- Xolremdi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome. Patient has genotype confirmed variant of CXCR4. Patient has an absolute neutrophil count (ANC) less than or equal to 500 cells/μL. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with one of the following: dermatologist, immunologist, hematologist, geneticist, or allergist. |
| **Coverage Duration** | Initial: 6 months, Reauth: Plan Year |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# XOSPATA

**Products Affected**

- Xospata

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of acute myeloid leukemia (AML). AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive. One of the following: a) Used as low-intensity treatment induction when not a candidate for intensive induction therapy, b) Follow-up after induction therapy with response to previous lower intensity therapy with the same regimen, c) Post-allogeneic hematopoietic cell transplantation and in remission, d) Disease is relapsed or refractory, or e) Consolidation therapy as continuation of low-intensity regimen used for induction in patients with poor-risk AML. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# XPOVIO

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple Myeloma (MM): Diagnosis of multiple myeloma. Patient has received at least one prior therapy (e.g., lenalidomide, bortezomib, daratumumab, pomalidomide). Used in combination with one of the following: bortezomib and dexamethasone, daratumumab and dexamethasone, or carfilzomib and dexamethasone. Relapsed/Refractory Multiple Myeloma (RRMM): Diagnosis of relapsed or refractory multiple myeloma (RRMM). Patient has received at least four prior therapies (e.g., lenalidomide, bortezomib, daratumumab, pomalidomide). Disease is refractory to all of the following: 1) Two proteasome inhibitors (e.g., bortezomib, carfilzomib), 2) Two immunomodulatory agents (e.g., lenalidomide, thalidomide), and 3) An anti-CD38 monoclonal antibody (e.g. daratumumab). Used in combination with dexamethasone. Diffuse large B-cell lymphoma (DLBCL): Diagnosis of one of the following: 1) Relapsed or refractory DLBCL not otherwise specified OR 2) Relapsed or refractory DLBCL arising from follicular lymphoma. Patient has previously received at least two lines of systemic therapy (e.g., CHOP: cyclophosphamide, doxorubicin, vincristine, and prednisone plus rituximab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |

| | |
|---|---|
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# XTANDI

**Products Affected**

- Xtandi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prostate cancer (PC): Diagnosis of prostate cancer. One of the following: 1) Disease is castration-resistant, 2) Disease is both of the following: a) Metastatic, and b) Castration-sensitive, or 3) Disease is all of the following: a) Non-metastatic, b) Castration-sensitive, c) Recurrent, and d) High risk of metastasis. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] or 2) Patient has had bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# YESINTEK

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial regardless of dose): One of the following: at least 3% body surface area involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial regardless of dose): One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (initial): Diagnosis of moderately to severely active Crohn's disease. Will be used as a maintenance dose following the intravenous induction dose. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD and UC (initial): Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | All indications (initial, reauth):  plan year. |

| | |
|---|---|
| **Other Criteria** | Ulcerative colitis (UC) (initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction dose. All indications (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ZEJULA

**Products Affected**

- Zejula TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Ovarian cancer: Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: I) One of the following: A) Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin), or B) Used for recurrence therapy for platinum-sensitive disease in combination with bevacizumab, or II) Both of the following: A) Used for the maintenance treatment for those who are in complete or partial response after first-line platinum and B) Disease is homologous recombination deficient (HRD) defined by a deleterious or suspected deleterious BRCA mutation and/or genomic instability. Disease is stage II-IV. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ZELBORAF

## Products Affected

- Zelboraf

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma: Diagnosis of unresectable or metastatic melanoma. Patient is positive for BRAF V600 mutation. Erdheim-Chester Disease: Diagnosis of Erdheim-Chester disease AND Disease is BRAFV600 mutant type (MT). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ZOKINVY

## Products Affected

- Zokinvy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | One of the following: 1) Diagnosis of Hutchinson-Gilford Progeria Syndrome, OR 2) For treatment of processing-deficient Progeroid Laminopathies with one of the following: i) Heterozygous LMNA mutation with progerin-like protein accumulation OR ii) Homozygous or compound heterozygous ZMPSTE24 mutations. Patient has a body surface area of 0.39 m^2 and above. |
| **Age Restrictions** | Patient is 12 months of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ZOLINZA

## Products Affected

- Zolinza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Patient has progressive, persistent, or recurrent disease on or following two systemic therapies [e.g., Adcetris (brentuximab vedotin), bexarotene, interferon gamma-1b, methotrexate, Poteligeo (mogamulizumab), romidepsin]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ZORYVE

## Products Affected

- Zoryve CREA

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Zoryve 0.3% Plaque psoriasis (PsO) (Initial): Diagnosis of plaque psoriasis. One of the following: a) Minimum duration of a 4 week trial and failure, contraindication, or intolerance (TF/C/I) to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), or a topical combination therapy [e.g., vitamin D analog/corticosteroid (eg, Enstilar, Taclonex), or Duobrii (halobetasol/tazarotene)]. Zoryve 0.15%, 0.05% Atopic dermatitis (AD) (Initial): Diagnosis of mild to moderate AD. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following: Medium or higher potency topical corticosteroid, Elidel (pimecrolimus) cream, or Tacrolimus ointment. |
| **Age Restrictions** | AD 0.15% (initial): Patient is 6 years of age or older. AD 0.05% (initial): Patient is between 2 and 5 years of age. |
| **Prescriber Restrictions** | PsO (Initial): Prescribed by or in consultation with a dermatologist. AD (Initial): Prescribed by or in consultation with a dermatologist or allergist/immunologist. |
| **Coverage Duration** | PsO, AD (Initial): 6 months, Reauth: Plan Year |
| **Other Criteria** | PsO, AD (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ZORYVE FOAM

**Products Affected**

- Zoryve FOAM

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Seborrheic Dermatitis (SD) (Initial): Diagnosis of SD. Minimum duration of a 4-week trial and failure, contraindication, or intolerance (TF/C/I) to one of the following generic topical therapies: corticosteroids (eg, betamethasone, clobetasol), antifungals (eg, ciclopirox, ketoconazole), or calcineurin inhibitors (eg, tacrolimus). Plaque Psoriasis (PsO) (Initial): Diagnosis of plaque psoriasis. Minimum duration of a 4-week TF/C/I to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), or one of the following topical combination therapies: vitamin D analog/corticosteroid (eg, Enstilar, Taclonex) or Duobrii (halobetasol/tazarotene). |
| **Age Restrictions** | SD (Initial): Patient is 9 years of age or older. |
| **Prescriber Restrictions** | SD, PsO (Initial): Prescribed by or in consultation with a dermatologist. |
| **Coverage Duration** | SD, PsO (Initial): 6 months, (Reauth): Plan Year. |
| **Other Criteria** | SD, PsO (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ZTALMY

## Products Affected

- Ztalmy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD). Patient has a mutation in the CDKL5 gene. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ZURZUVAE

## Products Affected

- Zurzuvae

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Postpartum Depression (PPD): Diagnosis of PPD. Onset of symptoms in the third trimester or within 4 weeks of delivery. Prescriber attests that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 12 hours after taking each dose of Zurzuvae for the duration of the 14-day treatment course and that patients are informed that they may not be able to assess their own driving competence or the degree of driving impairment caused by Zurzuvae. |
| **Age Restrictions** | PPD: Patient is 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 14 days |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ZYKADIA

## Products Affected

- Zykadia TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of metastatic, recurrent, or advanced non-small cell lung cancer (NSCLC), tumor is anaplastic lymphoma kinase (ALK)-positive. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Plan year |
| **Other Criteria** | Approve for continuation of prior therapy if within the past 120 days. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# PART B VERSUS PART D

## Products Affected

- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Amphotericin B INJ
- Amphotericin B Liposome
- Arformoterol Tartrate
- Astagraf XL
- Azathioprine TABS 50MG
- Budesonide SUSP
- Calcitriol CAPS
- Calcitriol ORAL SOLN
- Calcium Acetate CAPS
- Calcium Acetate TABS 667MG
- Cinacalcet Hydrochloride
- Clinolipid
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclophosphamide TABS 50MG
- Cyclosporine CAPS
- Cyclosporine Modified
- Doxercalciferol CAPS
- Engerix-b
- Envarsus Xr
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Gengraf CAPS 100MG, 25MG
- Granisetron Hydrochloride TABS
- Heparin Sodium INJ 10000UNIT/ML, 1000UNIT/ML, 20000UNIT/ML, 5000UNIT/ML
- Heplisav-b
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/100ML, 30GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU 0.31MG/3ML, 1.25MG/3ML
- Levalbuterol Hydrochloride NEBU 0.63MG/3ML
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nutrilipid
- Ondansetron Hcl SOLN 4MG/5ML
- Ondansetron Hydrochloride TABS
- Ondansetron Odt TBDP 4MG, 8MG
- Paricalcitol CAPS
- Pentamidine Isethionate INHALATION SOLR
- Plenamine INJ 147.4MEQ/L; 2.17GM/100ML; 1.47GM/100ML; 434MG/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 749MG/100ML; 1.04GM/100ML; 1.18GM/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 592MG/100ML; 749MG/100ML; 250MG/100ML; 39MG/100ML; 960MG/100ML
- Premasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 492MG/100ML; 526MG/100ML; 356MG/100ML; 356MG/100ML; 390MG/100ML; 34MG/100ML; 152MG/100ML
- Prograf PACK
- Prosol
- Pulmozyme SOLN 2.5MG/2.5ML
- Rabavert
- Recombivax Hb
- Sevelamer Carbonate
- Sirolimus SOLN
- Sirolimus TABS

- Tacrolimus CAPS
- Tobramycin NEBU 300MG/5ML
- Travasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 492MG/100ML; 526MG/100ML; 356MG/100ML; 500MG/100ML; 356MG/100ML; 390MG/100ML; 34MG/100ML; 152MG/100ML
- Trophamine INJ 0.54GM/100ML; 1.2GM/100ML; 0.32GM/100ML; 0; 0; 0.5GM/100ML; 0.36GM/100ML; 0.48GM/100ML; 0.82GM/100ML; 1.4GM/100ML; 1.2GM/100ML; 0.34GM/100ML; 0.48GM/100ML; 0.68GM/100ML; 0.38GM/100ML; 5MEQ/L; 0.025GM/100ML; 0.42GM/100ML; 0.2GM/100ML; 0.24GM/100ML; 0.78GM/100ML

## Details

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

Plans are insured through UnitedHealthcare Insurance Company or one of its affiliated companies, a Medicare Advantage organization with a Medicare contract and a Medicare-approved Part D sponsor. Enrollment in the plan depends on the plan's contract renewal with Medicare.

[<OVEX3386715_000>]
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