# ACTIMMUNE (S)

## Products Affected

- Actimmune INJ 100MCG/0.5ML

| 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: 1) Chronic granulomatous disease (CGD), or 2) severe malignant osteopetrosis (SMO). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ADALIMUMAB-AATY (S)

## Products Affected

- Adalimumab-aaty 1-pen Kit
- 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 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 TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque Psoriasis (PsO) (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. 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). Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. |
| **Age Restrictions** | N/A |

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| **Prescriber Restrictions** | RA, AS, PJIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. PsO, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist. |
| **Coverage Duration** | UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo. |
| **Other Criteria** | Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. Hidradenitis Suppurativa (HS) (Initial): Diagnosis of moderate to severe HS (ie, Hurley Stage II or III). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. HS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the abscess and inflammatory nodule count from baseline, reduced formation of new sinus tracts and scarring, improvement in symptoms (eg, pain, suppuration) from baseline. Uveitis (Reauth): Patient demonstrates positive clinical response to therapy. PsO (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |

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

# ADALIMUMAB-ADBM (S)

## Products Affected

- Adalimumab-adbm
- Adalimumab-adbm Crohns/uc/hs Starter
- Adalimumab-adbm Psoriasis/uveitis Starter
- Adalimumab-adbm Starter Package For Crohns Disease/uc/hs
- Adalimumab-adbm Starter Package For Psoriasis/uveitis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |

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| **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 TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque Psoriasis (PsO) (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. 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). Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA, AS, PJIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. PsO, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist. |
| **Coverage Duration** | UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo. |

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|---|---|
| **Other Criteria** | Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. Hidradenitis Suppurativa (HS) (Initial): Diagnosis of moderate to severe HS (ie, Hurley Stage II or III). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. HS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the abscess and inflammatory nodule count from baseline, reduced formation of new sinus tracts and scarring, improvement in symptoms (eg, pain, suppuration) from baseline. Uveitis (Reauth): Patient demonstrates positive clinical response to therapy. PsO (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ADBRY (S)

**Products Affected**

- Adbry

| 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. 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 of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least two of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) 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: 6 months. Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ADCIRCA (S)

## 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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | PAH (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ADEMPAS (S)

**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) (Initial): 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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH, CTEPH: Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | PAH, CTEPH (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# AFINITOR (S)

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. Renal cell carcinoma: Diagnosis of advanced renal cell carcinoma AND trial and failure, contraindication, or intolerance to SUTENT (sunitinib) or NEXAVAR (sorafenib). Neuroendocrine tumors of pancreatic origin (pNET): Diagnosis of progressive pNET that are unresectable, locally advanced, or metastatic. Renal angiomyolipoma: Diagnosis of renal angiomyolipoma and TSC. Breast Cancer: Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole). Neuroendocrine tumors of gastrointestinal (GI) or lung origin: Diagnosis of progressive, well-differentiated, non-functional NET of GI or lung origin AND patient has unresectable, locally advanced or metastatic disease. |
| **Age Restrictions** | SEGA associated with TSC: Patient is 1 year of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All Indications: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# AFINITOR DISPERZ (S)

## 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** | Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. TSC-associated partial-onset seizures: Diagnosis of TSC-associated partial-onset seizures. |
| **Age Restrictions** | SEGA associated with TSC: Patient is 1 year of age or older. TSC-associated partial-onset seizures: Patient is 2 years of age or older. |
| **Prescriber Restrictions** | TSC-associated partial-onset seizures: Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# AIMOVIG (S)

**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. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. 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** | EM, CM (initial): 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | EM, CM (initial): 6 months. EM, CM (reauth): 12 months. |
| **Other Criteria** | EM, CM (reauth): Patient has experienced a positive response to therapy. Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (reauth): Patient continues to be monitored for medication overuse headache. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# AKEEGA (S)

**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. One of the following: a) Used in combination with a gonadotropin-releasing hormone (GnRH) analog, or b) Patient has had a bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ALECENSA (S)

**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. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ALPHA-1 PROTEINASE INHIBITOR, PROLASTIN (S)

**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. Continued conventional treatment for emphysema (e.g., bronchodilators). One of the following: 1) PiZZ, PiZ(null), or Pi(null)(null) protein phenotypes (homozygous) OR 2) other rare AAT disease genotypes associated with pre-treatment serum AAT level less than 11 µM/L [e.g., Pi(Malton, Malton), Pi(SZ)]. Circulating pre-treatment serum AAT level less than 11 µM/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry), unless the patient has a concomitant diagnosis of necrotizing panniculitis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | AAT deficiency (initial, reauth): 12 months |
| **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 (S)

**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 NSCLC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# AMPYRA (S)

**Products Affected**

- Dalfampridine Er

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple Sclerosis (MS) (initial): Diagnosis of MS. Physician confirmation that patient has difficulty walking (eg, timed 25 foot walk test). One of the following: expanded disability status scale (EDSS) score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial): Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | MS (Initial): 6 months. (Reauth): 12 months. |
| **Other Criteria** | MS (Reauth): Physician confirmation that the patient's walking improved with therapy. One of the following: EDSS score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ARFORMOTEROL (S)

## Products Affected

- Arformoterol Tartrate

| 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): Diagnosis of COPD. Used for maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | COPD: 12 months. |
| **Other Criteria** | Subject to Part B vs. Part D review. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ARIKAYCE (S)

**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** | 12 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# AUGTYRO (S)

**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) locally advanced, or b) metastatic. Patient has ROS1 rearrangement positive tumor(s). Solid Tumors: Diagnosis of solid tumors. Disease has neurotrophic 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 previous treatment (e.g., radiation therapy, systemic therapy, tyrosine kinase inhibitor [TKI]), or b) Disease has no satisfactory alternative treatments. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All indications: 12 months. |
| **Other Criteria** | All indications: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# AUSTEDO (S)

## Products Affected

- Austedo
- Austedo Xr
- Austedo Xr Patient Titration Kit

| 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 (initial): Diagnosis of Chorea associated with Huntington's disease. Tardive dyskinesia (initial): 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 (initial): Prescribed by or in consultation with a neurologist. Tardive dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist. |
| **Coverage Duration** | Initial, Reauth: 12 months. |
| **Other Criteria** | All indications (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# AVMAPKI FAKZYNJA (S)

**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).<br>Presence of a KRAS-mutation as detected by a Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).<br>Patient has received prior systemic therapy (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# AVTOZMA IV (S)

**Products Affected**

- Avtozma INJ 200MG/10ML, 400MG/20ML, 80MG/4ML

| 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: a) Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinib), or b) attestation demonstrating a trial may be inappropriate, OR c) For continuation of prior therapy. Systemic Juvenile Idiopathic arthritis (SJIA) (Initial): Diagnosis of active SJIA. TF/C/I to one of the following conventional therapies at maximally tolerated doses: minimum duration of a one month trial of a nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen), or minimum duration of a 2-week trial of a systemic glucocorticoid (eg, prednisone). Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: a) TF/C/I to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq/LQ, or Xeljanz (tofacitinib), OR b) for continuation of prior therapy. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. Cytokine Release Syndrome (CRS): Patient will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy [e.g., Kymriah (tisagenlecleuce), Yescarta (axicabtagene ciloleucel)]. Coronavirus disease 2019 (COVID-19): Diagnosis of COVID-19. Patient is hospitalized. Currently receiving systemic corticosteroids. Patient requires one of the following: supplemental oxygen, non-invasive mechanical ventilation, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA, SJIA, PJIA, GCA (initial): Prescribed by or in consultation with a rheumatologist. CRS: Prescribed by or in consultation with an oncologist or hematologist. |

| | |
|---|---|
| **Coverage Duration** | RA, SJIA, PJIA, GCA (Init): 6 mo, (reauth): 12 mo. CRS: 2 mo. COVID-19: 14 days. |
| **Other Criteria** | RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. SJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in clinical features or symptoms (eg, pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline. GCA (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# AVTOZMA SC (S)

**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: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. Minimum duration of a one month trial of a nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated dose. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: a) TF/C/I to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq/LQ, or Xeljanz (tofacitinib), OR b) for continuation of prior therapy. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (Initial): Diagnosis of SSc-ILD as documented by the following: a) Exclusion of other known causes of ILD AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD, OR ii) In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA, GC, SJIA, PJIA (initial): Prescribed by or in consultation with a rheumatologist. SSc-ILD (initial): Prescribed by or in consultation with a pulmonologist or rheumatologist. |

| | |
|---|---|
| **Coverage Duration** | RA, GC, SJIA, PJIA, SSc-ILD (initial): 6 months, (reauth): 12 months |
| **Other Criteria** | RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. SJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in clinical features or symptoms (eg, pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline. GC, SSc-ILD (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# AYVAKIT (S)

**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. Disease is one of the following: unresectable or metastatic. Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Advanced Systemic Mastocytosis (AdvSM): Diagnosis of AdvSM. Patient has one of the following: a) aggressive systemic mastocytosis (ASM), b) systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or c) mast cell leukemia (MCL). Platelet count is greater than or equal to 50 x 10^9/L. 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** | 12 months. |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# BALVERSA (S)

**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). Disease is one of the following: Locally advanced or Metastatic. Presence of susceptible fibroblast growth factor receptor (FGFR) 3 genetic alterations as detected by an U.S. Food and Drug Administration (FDA)-approved test (therascreen FGFR RGQ RT-PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has progressed on or after at least one line of prior systemic therapy (e.g., chemotherapy). One of the following: 1) Patient had been treated with prior PD-1 inhibitor (e.g., Opdivo [nivolumab], Keytruda [pembrolizumab]) or PD-L1 inhibitor therapy (e.g., Bavencio [avelumab]) or 2) Patient is not a candidate for PD-1 or PD-L1 inhibitor therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# BENLYSTA (S)

**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) (init): Diagnosis of active SLE. Autoantibody positive (ie, anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL). 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 (init): 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). |
| **Age Restrictions** | SLE, Lupus Nephritis (init): Benlysta IV (vial), SC (prefilled syringe): Patient is 5 years of age or older. |
| **Prescriber Restrictions** | SLE (init): Prescribed by or in consultation with a rheumatologist. Lupus Nephritis (init): Prescribed by or in consultation with a nephrologist or rheumatologist. |
| **Coverage Duration** | SLE, Lupus Nephritis (init, reauth): 6 months |
| **Other Criteria** | SLE, Lupus Nephritis (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# BESREMI (S)

## Products Affected

- Besremi
- Besremi Pen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Polycythemia vera: Diagnosis of polycythemia vera. For high-risk polycythemia vera only (patient greater than or equal to 60 years old or prior thrombosis history), trial and inadequate response, contraindication or intolerance to hydroxyurea. Essential thrombocythemia: Diagnosis of essential thrombocythemia. Trial and inadequate response, contraindication, or intolerance to hydroxyurea. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Essential thrombocythemia: Prescribed by or in consultation with a hematologist/oncologist. |
| **Coverage Duration** | All indications: 12 months |
| **Other Criteria** | All indications: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# BOSULIF (S)

## Products Affected

- Bosulif
- Bosutinib

| 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 Philadelphia chromosome-positive (Ph+) CML. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# BRAFTOVI (S)

**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. Cancer is BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 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. Cancer is BRAF V600E mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Both of the following a) Used in combination with Erbitux (cetuximab) AND b) One of the following: i) Patient has received prior therapy OR ii) Used in combination with fluorouracil-based chemotherapy (e.g., mFOLFOX6, FOLFIRI). Non-Small Cell Lung Cancer (NSCLC): Diagnosis of metastatic NSCLC. Cancer is BRAF V600E mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Mektovi (binimetinib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |

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

# BRIVIACT (S)

## Products Affected

- Brivaracetam SOLN
- Brivaracetam TABS
- Briviact SOLN
- Briviact 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** | Patient is 1 month of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# BRONCHITOL (S)

**Products Affected**

- Bronchitol

| 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 (CF). Patient has passed the Bronchitol Tolerance Test (BTT). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center. |
| **Coverage Duration** | Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# BRUKINSA (S)

**Products Affected**

- Brukinsa

| 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. Patient has received at least one prior therapy for MCL [e.g., Calquence (acalabrutinib)]. Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. Disease is relapsed or refractory. Patient has received at least one prior anti-CD20-based regimen for MZL (e.g., rituximab, obinutuzumab). Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of ONE of the following: 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 (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months. |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# CABLIVI (S)

**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** | Prescribed by or in consultation with a hematologist or oncologist. |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CABOMETYX (S)

**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 RCC. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Trial and failure, contraindication, or intolerance to Nexavar (sorafenib tosylate). Differentiated Thyroid Cancer (DTC): Diagnosis of DTC. Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib]). Disease or patient is refractory to radioactive iodine treatment or ineligible. Neuroendocrine Tumors: Diagnosis of one of the following: 1) Pancreatic neuroendocrine tumors (pNET) or 2) Extra-pancreatic neuroendocrine tumors (epNET). Disease is one of the following: 1) Unresectable, 2) Locally advanced, or 3) Metastatic. Tumors are well-differentiated. Patient has been previously treated (e.g., octreotide, lanreotide, chemotherapy). |
| **Age Restrictions** | DTC: Patient is 12 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# CALQUENCE (S)

**Products Affected**

- Calquence

| 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: A) All of the following: 1) Patient has received no prior therapy for MCL (e.g., bortezomib, rituximab), 2) Patient is ineligible for autologous hematopoietic stem cell transplantation (HSCT), and 3) Used in combination with bendamustine and rituximab, OR B) 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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# CAPLYTA (S)

**Products Affected**

- Caplyta

| 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 to two of the following oral generic formulary atypical antipsychotic agents: asenapine, aripiprazole, olanzapine, paliperidone, quetiapine (IR or ER), risperidone, ziprasidone. Bipolar disorder: Diagnosis of bipolar I or II disorder (bipolar depression). Patient has depressive episodes associated with bipolar disorder. Used as monotherapy or as adjunctive therapy with lithium or valproate. Trial and failure, contraindication, or intolerance to quetiapine (IR or ER) or olanzapine. Major depressive disorder (MDD): Diagnosis of MDD. Used as adjunctive therapy with an antidepressant (e.g., escitalopram, sertraline, venlafaxine/desvenlafaxine, etc.). Trial and failure, contraindication, or intolerance to both of the following oral generic formulary atypical antipsychotic agents: aripiprazole and quetiapine IR/ER. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# CAPRELSA (S)

**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 one of the following: a) metastatic medullary thyroid cancer (MTC) or b) unresectable locally advanced MTC. Patient has symptomatic disease or progressive disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CAYSTON (S)

## 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) (Initial, Reauth): Diagnosis of CF AND Patient has evidence of Pseudomonas aeruginosa in the lungs. |
| **Age Restrictions** | CF (Initial): 7 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CF (Initial, reauth): 12 months |
| **Other Criteria** | CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CERDELGA (S)

**Products Affected**

- Cerdelga

| 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 Gaucher disease type 1. Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test. |
| **Age Restrictions** | Gaucher disease: Patient is 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Gaucher disease: 12 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CHOLBAM (S)

**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 based on one of the following: a) an abnormal urinary bile acid analysis by mass spectrometry OR b) molecular genetic testing consistent with the diagnosis. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of a peroxisomal disorder based on one of the following: a) an abnormal urinary bile acid analysis by mass spectrometry OR b) molecular genetic testing consistent with the diagnosis, 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** | All uses (initial): Prescribed by a hepatologist, medical geneticist, gastroenterologist, OR other specialist that treats inborn errors of metabolism. |
| **Coverage Duration** | All uses: 4 months (initial), 12 months (reauth). |
| **Other Criteria** | All uses (reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement in liver function. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CIALIS (S)

**Products Affected**

- Tadalafil TABS 2.5MG, 5MG

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

# CICLOPIROX (S)

## Products Affected

- Ciclodan SOLN
- Ciclopirox Nail Lacquer

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | All of the following: 1) Patient does not have lunula (matrix) involvement, 2) one of the following: a) Diagnosis of onychomycosis of the toenails, OR b) Diagnosis of onychomycosis of the fingernails, 3) Diagnosis of onychomycosis has been confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, 4) If toenail onychomycosis, patient has mild to moderate disease involving at least 1 target toenail, AND 5) One of the following: a) For onychomycosis of fingernails, Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine, or b) For onychomycosis of toenails, trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 48 weeks. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# CINRYZE (S)

**Products Affected**

- Cinryze

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prophylaxis of hereditary angioedema (HAE) attacks (initial): Diagnosis of 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 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) 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** | HAE (prophylaxis) (initial): Patient is 6 years of age or older |
| **Prescriber Restrictions** | HAE (prophylaxis) (initial): Prescribed by or in consultation with an immunologist or an allergist |
| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. Not used in combination with other approved treatments for prophylaxis against HAE attacks. |

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

# COBENFY (S)

## 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 two of the following oral generic formulary atypical antipsychotic agents: 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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# COMETRIQ (S)

**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 Metastatic MTC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# COPIKTRA (S)

**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], Rituxan [rituximab], etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# COSENTYX (S)

## 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. Minimum duration of a 4-week trial and failure, 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. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) Enthesitis-Related Arthritis (ERA) (Initial): Diagnosis of active ERA. nr-axSpA, ERA (Initial): 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 |

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| **Prescriber Restrictions** | Plaque psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS, nr-axSpA, ERA (initial): Prescribed by or in consultation with a rheumatologist. |
| **Coverage Duration** | All uses (initial): 6 months. All uses (reauth): 12 months |
| **Other Criteria** | PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS, nr-axSpA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. ERA (Reauth): Patient demonstrates a positive clinical response to therapy as evidenced by at least one of the following: Reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. HS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the abscess and inflammatory nodule count from baseline, reduced formation of new sinus tracts and scarring, improvement in symptoms (eg, pain, suppuration) from baseline. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# COSENTYX IV (S)

**Products Affected**

- Cosentyx INJ 125MG/5ML

| 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. One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Cosentyx SC (secukinumab), Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Sotyktu (deucravacitinib), Tremfya (guselkumab), one formulary ustekinumab product, Rinvoq/LQ (upadacitinib), or Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: a) TF/C/I to two of the following: Cosentyx SC, Enbrel, one formulary adalimumab product, Rinvoq, Xeljanz/XR, OR b) for continuation of prior therapy. Non-radiographic axial spondyloarthritis (nr-axSpA) (Initial): Dx of active nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints). One of the following: a) TF/C/I to both of the following: Cosentyx SC and Rinvoq, OR b) for continuation of prior therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS, nr-axSpA (Initial): Prescribed by or in consultation with a rheumatologist. |
| **Coverage Duration** | All uses (Initial): 6 months. All uses (Reauth): 12 months. |

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|---|---|
| **Other Criteria** | PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the body surface area (BSA) involvement from baseline. AS, nr-axSpA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# COTELLIC (S)

**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. Patient has a BRAF V600E or V600K mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Zelboraf (vemurafenib). Histiocytic Neoplasm: Diagnosis of histiocytic neoplasm. Used as monotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CRESEMBA ORAL (S)

**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** | Fungal infection: Diagnosis of invasive aspergillosis or invasive mucormycosis. |
| **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. |

# CTEXLI (S)

**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 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **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: 12 months. Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# CYCLOBENZAPRINE (S)

## Products Affected

- Cyclobenzaprine Hydrochloride TABS 10MG, 5MG

| 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. Muscle spasm: Diagnosis of muscle spasm associated with acute, painful musculoskeletal conditions. Fibromyalgia (off-label): Used to treat fibromyalgia related symptoms (e.g., difficulty sleeping). Acute temporomandibular disorder (off-label): All of the following: a) Diagnosis of acute temporomandibular disorder, b) Patient has pain on palpitation of the lower jaw muscle, and c) Used in combination with a nonsteroidal anti-inflammatory drug (NSAID) (e.g., naproxen). |
| **Age Restrictions** | PA applies to patients 65 years or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Muscle spasm, temporomandibular disorder: 4 weeks. Fibromyalgia: 12 months. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# DALIRESP (S)

## 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** | COPD (init, reauth): 12 months |
| **Other Criteria** | COPD (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# DANZITEN (S)

**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 Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# DARAPRIM (S)

**Products Affected**

- Pyrimethamine TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Toxoplasmosis: 1) Patient is using pyrimethamine for the active treatment of toxoplasmosis (e.g., toxoplasmic encephalitis, ocular toxoplasmosis), secondary prophylaxis of toxoplasmosis, or treatment of congenital toxoplasmosis OR 2) Patient is using pyrimethamine for the primary prophylaxis of toxoplasmosis, patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX), and one of the following: patient has been re-challenged with TMP-SMX using a desensitization protocol and is still unable to tolerate, or evidence of life-threatening reaction to TMP-SMX in the past (eg, toxic epidermal necrolysis, Stevens-Johnson syndrome). Malaria: Requests for coverage of any pyrimethamine products for the treatment and/or prophylaxis of malaria are not authorized and will not be approved. The use of pyrimethamine for the treatment and/or prophylaxis of malaria is not recommended by the Centers for Disease Control and Prevention (CDC). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Toxoplasmosis: Prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | Toxoplasmosis: 12 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# DAURISMO (S)

**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 Used 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 comorbidities that preclude the use of intensive induction chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# DEFERASIROX (S)

**Products Affected**

- Deferasirox

| 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 due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Myelodysplastic Syndrome (MDS) (Initial): Diagnosis of MDS. Patient has Low or Intermediate-1 disease or is a potential transplant patient. Patient has received more than 20 red blood cell transfusions. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) (Initial): Diagnosis of chronic iron overload due to NTDT. Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher. Serum ferritin level greater than 300 mcg/L. |
| **Age Restrictions** | Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Iron Overload Due to Blood Transfusions, MDS (initial, reauth):12 mo. NTDT (initial, reauth): 6mo. |
| **Other Criteria** | Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin level or LIC. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# DEMSER (S)

## Products Affected

- Metyrosine

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Preoperative preparation: Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: a) plasma free metanephrines OR b) urinary fractioned metanephrines. Medication is being used for preoperative preparation. Trial and failure, contraindication, or intolerance to both of the following: a) alpha-adrenergic blocker (e.g., phenoxybenzamine, doxazosin, terazosin) AND b) beta-adrenergic blocker (e.g., propranolol, metoprolol). Treatment of pheochromocytoma (initial): Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: a) plasma free metanephrines OR b) urinary fractioned metanephrines. Patient with hormonally active (catecholamine excess) pheochromocytoma. One of the following: a) patient is not a candidate for surgery OR b) chronic treatment due to malignant pheochromocytoma. Patient has not reached normotension after treatment with a selective alpha-1-adrenergic blocker (e.g., doxazosin, terazosin) and beta-adrenergic blocker (e.g., propranolol, metoprolol). Medication will not be used to control essential hypertension. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Preop prep: Prescribed by or in consultation with an endocrinologist OR Endocrine surgeon. Pheochromocytoma (initial): Prescribed by or in consultation with endocrinologist OR provider who specializes in the management of pheochromocytoma. |
| **Coverage Duration** | Preop prep: 4 wks. Treatment of pheo (initial): 6 months, (reauth): 12 months. |
| **Other Criteria** | Treatment of pheochromocytoma (reauth): Patient demonstrates positive clinical response to therapy (e.g., decreased frequency and severity of hypertensive attacks). |

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

# DIACOMIT (S)

**Products Affected**

- Diacomit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with clobazam. Patient weighs 7kg or more. |
| **Age Restrictions** | Patient is 6 months of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# DOPTELET (S)

**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. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | ITP (initial): Prescribed by or in consultation with a hematologist/oncologist. |
| **Coverage Duration** | TPPP: 1 month. ITP (initial, reauth): 12 months |
| **Other Criteria** | ITP (reauth): Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# DULERA (S)

**Products Affected**

- Dulera

| 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 asthma. Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age), or intolerance to Breo Ellipta (fluticasone furoate and vilanterol trifenatate). |
| **Age Restrictions** | Initial: Patient is 5 years or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, reauth: 12 months |
| **Other Criteria** | Asthma (reauthorization): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# DUPIXENT (S)

**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 mod to severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-tx) peripheral blood eosinophil level greater than or equal to 150 cells/ml. One of the following: 1) Pt has had 2 or more asthma exacerbations requiring systemic corticosteroids (CS) (eg, prednisone) w/in the past 12 mo, 2) Prior asthma-related hospitalization w/in the past 12 mo. Corticosteroid Dependent Asthma (CDA) (init): Dx of mod to severe asthma. Pt is currently dependent on oral CS for the treatment of asthma. EA, CDA (init): One of the following: 1) Both of the following: a) Pt is at least 6 yo but less than 12 yo b) Pt is currently being treated w/ 1 of the following unless there is a contraindication or intolerance (C/I) to these meds: i) Medium-dose inhaled corticosteroid (ICS) (eg, greater than 100–200mcg fluticasone propionate equivalent/day) and Additional asthma controller med (eg, leukotriene receptor antagonist [LTRA] [eg, montelukast], long-acting beta-2 agonist [LABA] [eg, salmeterol], long-acting muscarinic antagonist [LAMA] [eg, tiotropium]) or ii) 1 medium dosed combo ICS/LABA product (eg, fluticasone propionate 100mcg/salmeterol50mcg, budesonide80mcg/formoterol4.5mcg, fluticasone furoate 50mcg/vilanterol 25mcg) OR 2) Pt is at least 12 yo and Pt is currently being treated w/ 1 of the following unless there is a C/I to these meds: a) Both of the following: i) High-dose ICS [eg, greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller med, OR b) 1 maximally-dosed combo ICS/LABA product [eg, fluticasone propionate 500mcg/salmeterol50mcg, budesonide160mcg/formoterol4.5mcg, fluticasone200mcg/vilanterol25mcg]. Chronic rhinosinusitis with nasal polyposis (CRSwNP) (init): Dx of CRSwNP. Unless contraindicated, the pt has had an inadequate response to 2 mo of tx with an intranasal CS (eg, fluticasone, mometasone). Used in combination with another agent for CRSwNP. |

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| **Age Restrictions** | AD (initial): Patient is 6 months or age or older. CRSwNP, PN: no age restriction. EoE (initial): Patient is at least 1 year of age. |
| **Prescriber Restrictions** | AD, PN, CSU, BP (Init): Prescribed/consult with a dermatologist or allergist/immunologist. Asthma (init): Prescribed/consult with a pulmonologist or allergist/immunologist. CRSwNP (init, reauth): Prescribed/consult with an otolaryngologist, allergist/immunologist, or pulmonologist. EoE (init): Prescribed/consult with a gastroenterologist or allergist/immunologist. AFRS (init): Prescribed/consult with an otolaryngologist, allergist/immunologist, or pulmonologist. |
| **Coverage Duration** | AFRS, CRSwNP, EoE (Init/Reauth): 12 mo. Asthma, AD, PN, COPD, CSU, BP (Init): 6 mo, (reauth): 12 mo. |

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| **Other Criteria** | Eosinophilic esophagitis (EoE) (init): Dx of EoE. Pt has symptoms of esophageal dysfunction (eg, dysphagia, food impaction, GERD/heartburn symptoms, chest pain, abdominal pain). Pt has at least 15 intraepithelial eosinophils per high power field. Other causes of esophageal eosinophilia have been excluded. Pt weighs at least 15 kg. Trial and failure, contraindication, or intolerance (TF/C/I) to at least an 8-wk trial of 1 of the following: proton pump inhibitors (eg, pantoprazole, omeprazole) or topical (esophageal) CS (eg, budesonide, fluticasone). PN (init): Dx of PN. Atopic dermatitis (AD) (init): Dx of mod to severe AD. 1 of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing AD (SCORAD) index value of at least 25. TF of a min 30-day supply (14-day supply for TCS), CI (eg, safety concerns, not indicated for pt's age/wt), or intol to 1 of the following: a) Medium or higher potency TCS, b) Pimecrolimus, c) Tacrolimus ointment, or d) crisaborole. Chronic Obstructive Pulmonary Disease (COPD) (init): Dx of COPD. Presence of type 2 inflammation evidenced by baseline blood eosinophils greater than or equal to 300 cells/mcL. Pt is receiving 1 of the following at maximally tolerated doses: triple therapy [ie, an ICS, a LAMA, and a LABA] OR if CI to ICS, a LAMA and a LABA. Pt has had at least 2 exacerbations where systemic CS [IM/IV/oral] were required at least once OR COPD-related hospitalization w/in the past 12 mo. Bullous Pemphigoid (BP) (init): Dx of BP as confirmed by skin biopsy or serology. Will be used in combo w/ a tapering course of oral CS until disease control has occurred. AD (reauth): Pt demonstrates positive clinical response to therapy as evidenced by a reduction in BSA involvement or SCORAD index value from baseline. AFRS, EA, CDA, PN, CRSwNP, COPD, BP (reauth): Pt demonstrates positive clinical response to therapy. CRSwNP (reauth): Used in combination with another agent for CRSwNP. EoE (reauth): Pt demonstrates positive clinical response to therapy as evidenced by improvement of 1 of the following from baseline: symptoms (eg, dysphagia, food impaction, chest pain, heartburn), histologic measures (eg, esophageal intraepithelial eosinophil count), or endoscopic measures (eg, edema, furrows, exudates, rings, strictures). COPD (reauth): Pt cont on triple therapy (ie, an ICS, a LAMA, and a LABA) OR if CI to ICS, a LAMA and a LABA. Chronic Spontaneous Urticaria (CSU) (init): Dx of CSU. Persistent symptoms (itching and hives) with a 2nd generation H1 antihistamine (H1A) (eg, cetirizine, fexofenadine), unless C/I to H1A. Used concurrently with an H1A unless C/I to H1A. CSU (reauth): Pt demonstrates positive clinical response to therapy as evidenced by a reduction from baseline in itching severity or number of hives. Allergic Fungal Rhinosinusitis (AFRS) (init): Dx of AFRS. Pt has history of sino-nasal surgery. |

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

# EBGLYSS 2 (S)

**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 of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) crisaborole 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: 6 months. Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# EMGALITY (S)

**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. Chronic Migraines (CM) (120 mg strength/mL only) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 8 migraine days per month. Episodic Cluster Headache (ECH) (100 mg/mL strength only) (initial): Diagnosis of episodic cluster headache. 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. EM, CM (120 mg/mL strength only) (initial): Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. |
| **Age Restrictions** | EM, CM, ECH (initial): 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | EM, CM (initial): 6 months. ECH (initial): 3 months. EM, CM, ECH (reauth): 12 months. |

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| **Other Criteria** | EM, CM (120 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy. Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (120 mg/mL strength only) (reauth): Patient continues to be monitored for medication overuse headache. ECH (100 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy. Medication will not be used in combination with another injectable CGRP inhibitor. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# EMPAVELI (S)

**Products Affected**

- Empaveli

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Paroxysmal Nocturnal Hemoglobinuria (PNH) (initial): Diagnosis of PNH. Complement 3 Glomerulopathy (C3G) or Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN) (initial): Diagnosis of C3G or primary IC-MPGN. For primary IC-MPGN, patient has not had a kidney transplant. Used to reduce proteinuria. Patient is currently being treated with a maximally tolerated dose of one of the following for at least 12 weeks prior to initiating treatment: 1) Angiotensin-converting enzyme inhibitors (e.g., benazepril, lisinopril), 2) Angiotensin receptor blockers (e.g., losartan, valsartan), or 3) Sodium-glucose cotransporter-2 (SGLT2) inhibitors (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]). |
| **Age Restrictions** | C3G, Primary IC-MPGN (initial): Patient is 12 years of age or older. |
| **Prescriber Restrictions** | PNH (initial): Prescribed by or in consultation with a hematologist or oncologist. C3G, Primary IC-MPGN (initial): Prescribed by or in consultation with a nephrologist. |
| **Coverage Duration** | PNH, C3G, Primary IC-MPGN (initial, reauth): 12 months. |
| **Other Criteria** | PNH (reauth): Patient demonstrates positive clinical response to therapy. C3G, Primary IC-MPGN (reauth): Patient demonstrates positive clinical response to therapy. For primary IC-MPGN, patient has not had a kidney transplant. Patient continues to be treated with a maximally tolerated dose of one of the following: 1) Angiotensin-converting enzyme inhibitors (e.g., benazepril, lisinopril), 2) Angiotensin receptor blockers (e.g., losartan, valsartan), or 3) Sodium-glucose cotransporter-2 (SGLT2) inhibitors (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]). |

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

# ENBREL (S)

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion 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 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), 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). Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA (initial), PJIA (initial), AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist. |

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| **Coverage Duration** | All uses (initial): 6 months. All uses (reauth): 12 months |
| **Other Criteria** | RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ENDARI (S)

**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): 12 months |
| **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 (S)

**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). Disease is one of the following: a) Locally advanced or b) Metastatic. Disease is anaplastic lymphoma kinase (ALK) rearrangement-positive as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has not previously received an ALK-inhibitor [e.g., Alecensa (alectinib), Alunbrig (brigatinib), Lorbrena (lorlatinib), Xalkori (crizotinib), Zykadia (ceritinib)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# EPCLUSA PREFERRED (S)

**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. Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine, Liver transplant specialist. Prescriber requirement does not apply for patient who is Hepatitis C treatment naive without decompensation. |
| **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. |

# EPIDIOLEX (S)

**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** | LGS, DS, TSC: Patient is 1 year of age or older. |
| **Prescriber Restrictions** | LGS, DS, TSC: Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# EPOETIN ALFA (S)

**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 with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with chemo (Initial):Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is receiving chemo. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon/peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 36% or Hgb less than 12 g/dL) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa. Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

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|---|---|
| **Coverage Duration** | CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo. MDS:(init) 3mo,(reauth)12mo. Preop:1mo. |
| **Other Criteria** | Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Patient demonstrates positive clinical response to therapy from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Patient demonstrates positive clinical response to therapy from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Patient demonstrates positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Patient demonstrates positive clinical response to therapy from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Patient demonstrates a positive clinical response to therapy from pre-treatment level. Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): 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 (S)

**Products Affected**

- Erivedge

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Basal cell carcinoma: One of the following: A) Diagnosis of metastatic basal cell carcinoma OR B) Both of the following: 1) Diagnosis of locally advanced basal cell carcinoma AND 2) One of the following: a) Disease recurred following surgery or b) Patient is not a candidate for surgery and radiation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ERLEADA (S)

## Products Affected

- Erleada

| 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. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ESBRIET (S)

**Products Affected**

- Pirfenidone

| 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 as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity), AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | IPF (initial): Prescribed by or in consultation with a pulmonologist |
| **Coverage Duration** | initial, reauth: 12 months |
| **Other Criteria** | IPF (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# EUCRISA (S)

**Products Affected**

- Eucrisa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Atopic dermatitis (initial): Diagnosis of mild to moderate atopic dermatitis. Trial and failure, contraindication, or intolerance to one prescription strength topical corticosteroid (e.g., triamcinolone acetonide, fluocinolone acetonide), unless the affected area is sensitive (i.e., face, axillae, groin). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Reauth: Patient demonstrates a positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity). |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# EVRYSDI (S)

**Products Affected**

- Evrysdi SOLR

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

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| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | SMA (Reauth): Patient demonstrates positive clinical response to therapy. Pt is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) pt has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) pt has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# FABRAZYME (S)

**Products Affected**

- Fabrazyme

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Fabry Disease (init): Diagnosis of Fabry disease. One of the following: a) detection of pathogenic mutations in the GLA gene by molecular genetic testing, b) deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS), or c) significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata). Will not be used in combination with other drugs used for Fabry disease. |
| **Age Restrictions** | Fabry Disease (init): Patient is 2 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Fabry Disease (init, reauth): 12 months |
| **Other Criteria** | Fabry Disease (reauth): Patient demonstrates positive clinical response to therapy. Will not be used in combination with other drugs used for Fabry disease. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# FASENRA (S)

## 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** | Asthma (initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: 1) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months, OR 2) Prior asthma-related hospitalization within the past 12 months. 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 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 (e.g., greater than 100-200 mcg fluticasone propionate equivalent/day) and Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) or ii) One medium dosed combination ICS/LABA product (e.g., 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: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and ii) additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]), OR b) One maximally-dosed combination ICS/LABA product [e.g., Wixela Inhub (fluticasone propionate 500mcg/salmeterol 50mcg), budesonide 160mcg/formoterol 4.5mcg, Breo Ellipta (fluticasone 200mcg/vilanterol 25mcg)]. |

| | |
|---|---|
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Asthma (initial): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. EGPA (initial): Prescribed by or in consultation with a pulmonologist, rheumatologist, or allergist/immunologist. HES (initial): Prescribed by or in consultation with an allergist/immunologist or hematologist. |
| **Coverage Duration** | Asthma (init): 6 months. Asthma (reauth): 12 months. EGPA, HES (init/reauth): 12 months. |
| **Other Criteria** | Eosinophilic granulomatosis with polyangiitis (EGPA) (initial): Diagnosis of EGPA. 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). Asthma, EGPA, HES (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# FENTANYL (S)

**Products Affected**

- Fentanyl Citrate Oral Transmucosal

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, Oral hydrocodone at a dose of greater than or equal to 60 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# FINTEPLA (S)

**Products Affected**

- Fintepla

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Dravet Syndrome: Diagnosis of seizures associated with Dravet syndrome. Lennox-Gastaut Syndrome: Diagnosis of seizures associated with Lennox-Gastaut syndrome. |
| **Age Restrictions** | All Indications: Patient is 2 years of age or older. |
| **Prescriber Restrictions** | All Indications: Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | All Indications: 12 months |
| **Other Criteria** | All Indications: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# FIRAZYR (S)

## 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** | Treatment of hereditary angioedema (HAE) attacks (initial): Diagnosis of 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 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) 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** | Initial: Patient is 18 years of age or older |
| **Prescriber Restrictions** | HAE (initial): Prescribed by or in consultation with an immunologist or an allergist |
| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. Not used in combination with other approved treatments for acute HAE attacks. |

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

# FIRMAGON (S)

**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** | Diagnosis of advanced or metastatic prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# FOTIVDA (S)

**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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# FRUZAQLA (S)

**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 metastatic colorectal cancer. Patient has been previously treated with both of the following: A) Fluoropyrimidine-, oxaliplatin-, irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI), and B) Anti-VEGF biological therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-afibercept]). 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 both of the following: 1) An anti-EGFR biological therapy (e.g., Vectibix [panitumumab], Erbitux [cetuximab]), and 2) One of the following: i) Lonsurf [trifluridine/tipiracil] or ii) Stivarga [regorafenib]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# GAMASTAN (S)

## Products Affected

- Gamastan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Immune globulin is being used intramuscularly. The immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Patient requires immunization for hepatitis A, measles, rubella, or varicella. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 14 days |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# GAVRETO (S)

## 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. Presence of metastatic rearranged during transfection (RET) gene fusion-positive tumor(s) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Thyroid Cancer: Diagnosis of thyroid cancer. Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. One of the following: patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate. |
| **Age Restrictions** | Thyroid Cancer: Patient is 12 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# GILENYA (S)

## Products Affected

- Fingolimod Hydrochloride

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

# GILOTRIF (S)

**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): A) Diagnosis of advanced or metastatic (stage IIIB or IV) NSCLC AND B) One of the following: 1) Both of the following: a) Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND b) GILOTRIF will be used as first-line treatment, OR 2) All of the following: a) disease progressed after platinum-based chemotherapy (e.g., cisplatin, carboplatin) and b) squamous NSCLC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# GLATIRAMER ACETATE (S)

## Products Affected

- Glatiramer Acetate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS. |
| **Required Medical Information** | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial, reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (initial, reauth): 12 months |
| **Other Criteria** | MS (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# GLEEVEC (S)

**Products Affected**

- Imatinib Mesylate TABS

| 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 Philadelphia chromosome positive (Ph+)/BCR ABL-positive chronic myelogenous leukemia (CML) OR B) Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL) OR C) Gastrointestinal stromal tumor (GIST) OR D) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic OR E) Hypereosinophilic syndrome or chronic eosinophilic leukemia OR F) Myelodysplastic syndrome (MDS) or myeloproliferative disease OR G) Aggressive systemic mastocytosis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All uses: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# GLYCOPYRROLATE TABLET (S)

**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 (S)

**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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# GROWTH HORMONE, PREFERRED (S)

## 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 |

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|---|---|
| **Coverage Duration** | All uses (initial, reauth): 12 months |
| **Other Criteria** | AGHD(initial):dx of AGHD with clin records supporting 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/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. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. 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. |

# HERNEXEOS (S)

**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-squamous non-small cell lung cancer (NSCLC). Disease is one of the following: a) unresectable, b) metastatic. Presence of HER2 (ERBB2) tyrosine kinase domain activating mutations as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months. |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# HUMIRA (S)

## Products Affected

- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pediatric Crohns Disease Starter Pack INJ 0, 80MG/0.8ML
- Humira Pen
- Humira Pen-cd/uc/hs Starter
- Humira Pen-pediatric Uc Starter Pack
- Humira Pen-ps/uv Starter INJ 0

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |

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|---|---|
| **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 TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque Psoriasis (PsO) (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. 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). Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA, AS, PJIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. PsO, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist. |
| **Coverage Duration** | UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo. |

| | |
|---|---|
| **Other Criteria** | Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. Hidradenitis Suppurativa (HS) (Initial): Diagnosis of moderate to severe HS (ie, Hurley Stage II or III). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. HS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the abscess and inflammatory nodule count from baseline, reduced formation of new sinus tracts and scarring, improvement in symptoms (eg, pain, suppuration) from baseline. Uveitis (Reauth): Patient demonstrates positive clinical response to therapy. PsO (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# HYRNUO (S)

**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-squamous non-small cell lung cancer (NSCLC). Disease is locally advanced or metastatic. Presence of HER2 (ERBB2) tyrosine kinase domain activating mutations as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received prior systemic therapy (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# IBRANCE (S)

**Products Affected**

- Ibrance

| 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. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# IBTROZI (S)

**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) Locally advanced or 2) Metastatic. Presence of ROS1 rearrangement-positive tumor as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ICLUSIG (S)

**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 leukemia: Diagnosis of chronic myelogenous leukemia. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL). One of the following: a) Used in combination with chemotherapy up to 20 cycles OR b) Used as monotherapy in patients where one of the following applies: i) No other kinase inhibitors are indicated OR ii) Disease is T315I-positive Ph+ ALL. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All uses: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# IDHIFA (S)

**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. Disease is relapsed or refractory. Patient has an isocitrate dehydrogenase-2 (IDH2) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH2 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# IGALMI (S)

**Products Affected**

- Igalmi

| 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: Schizophrenia or Bipolar I or II disorder. For the treatment of acute agitation. Trial and failure, contraindication or intolerance to at least two products used in acute agitation (e.g., olanzapine, ziprasidone). Patient is currently being managed with maintenance medication for their underlying disorder (e.g., aripiprazole, olanzapine, quetiapine, lithium, valproic acid). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 14 days |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# IMBRUVICA (S)

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Waldenstrom's macroglobulinemia: Diagnosis of Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma. Small lymphocytic lymphoma (SLL): Diagnosis of SLL. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD AND trial and failure of one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate). |
| **Age Restrictions** | (cGVHD): Patient is 1 year of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All Uses: 12 months |
| **Other Criteria** | All Uses: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# IMKELDI (S)

**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 Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) CML. Acute Lymphoblastic Leukemia/Acute Lymphoblastic Lymphoma (ALL): Diagnosis of Ph+/BCR ABL+ ALL. Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD): Diagnosis of MDS/MPD. Aggressive Systemic Mastocytosis (ASM): Diagnosis of ASM. Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL): Diagnosis of at least one of the following: a) HES or b) CEL. Dermatofibrosarcoma Protuberans (DFSP): Diagnosis of unresectable, recurrent, or metastatic DFSP. Gastrointestinal Stromal Tumors (GIST): Diagnosis of GIST. All indications: Patient is unable to swallow generic imatinib tablet due to one of the following: a) Age, b) Physical impairment (e.g., difficulties with motor or oral coordination), c) Dysphagia, or d) Patient is using a feeding tube or nasal gastric tube. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# INBRIJA (S)

**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. Patient is currently being treated with carbidopa/levodopa. Trial and failure, contraindication or intolerance to two of the following: MAO-B inhibitor (e.g., rasagiline, selegiline), dopamine agonist (e.g., pramipexole, ropinirole), or COMT Inhibitor (e.g., entacapone). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PD (initial): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | PD (initial, reauth): 12 months |
| **Other Criteria** | PD (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# INCRELEX (S)

**Products Affected**

- Increlex

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Insulin-like Growth Factor-1 (IGF-1) deficiency (initial): Diagnosis of severe primary IGF-1 deficiency. Height standard deviation score of -3.0 or less. Basal IGF-1 standard deviation score of -3.0 or less. Normal or elevated growth hormone (GH). GH gene deletion (initial): Diagnosis of GH gene deletion in patients who have developed neutralizing antibodies to GH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Initial, reauth: 12 months |
| **Other Criteria** | (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# INFLECTRA (S)

**Products Affected**

- Inflectra

| 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) and Fistulizing Crohn's Disease (FCD) (initial): Diagnosis (Dx) of moderately to severely active CD or FCD. 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. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroids (eg, prednisone), methotrexate. 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. TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, 6-mercaptopurine. Rheumatoid arthritis (RA) (initial): Dx of moderately to severely active RA. Used in combination with 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 (initial): Dx of chronic severe (ie, extensive and/or disabling) 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. Minimum duration of a 4-week trial and failure, 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). |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | RA, AS: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed by or in consultation with a rheumatologist or dermatologist. CD, FCD, UC: Prescribed by or in consultation with a gastroenterologist. Plaque Psoriasis: Prescribed by or in consultation with a dermatologist. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist. |
| **Coverage Duration** | All uses (initial): 6 months, (reauth): 12 months. |
| **Other Criteria** | 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. Sarcoidosis (initial): Dx of sarcoidosis. TF/C/I to one of the following: corticosteroid (eg, prednisone) OR immunosuppressant (eg, methotrexate, cyclophosphamide, azathioprine). Plaque psoriasis (reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. RA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Sarcoidosis (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# INGREZZA (S)

**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 (initial): Diagnosis of moderate to severe 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 (initial): Diagnosis of chorea in patients with Huntington's disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Tardive Dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist. Chorea associated with Huntington's disease (initial): Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | initial, reauth: 12 months |
| **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. |

# INLURIYO (S)

**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. Disease is advanced or metastatic. Disease is estrogen receptor (ER)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Presence of estrogen receptor-1 (ESR1) mutation(s) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# INLYTA (S)

**Products Affected**

- Inlyta

| 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. One of the following: (1) used as first-line treatment in combination with avelumab or pembrolizumab or (2) used after failure of one prior systemic therapy (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# INQOVI (S)

**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) or chronic myelomonocytic leukemia (CMML): Diagnosis of one of the following: i) MDS or ii) CMML. Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS). Acute Myeloid Leukemia (AML): Diagnosis of newly-diagnosed 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** | All indications: 12 months |
| **Other Criteria** | All indications: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# INREBIC (S)

**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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# IRESSA (S)

**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 metastatic NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ISTURISA (S)

**Products Affected**

- Isturisa TABS 1MG, 5MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cushing's Syndrome (initial): Diagnosis of Cushing's syndrome. Used for treatment of endogenous hypercortisolemia. One of the following: a) Patient is not a candidate for surgery (e.g., adrenalectomy, transsphenoidal surgery), OR b) Surgery has not been curative for the patient. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Cushing's Syndrome (initial): Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Cushing's Syndrome (initial, reauth): 12 months |
| **Other Criteria** | Cushing's Syndrome (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ITOVEBI (S)

**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 (as detected by a U.S. Food and Drug Administration [FDA]-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments [CLIA]): a) PIK3CA-mutated, b) Hormone receptor (HR)-positive, 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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ITRACONAZOLE CAPSULE (S)

**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 Infection (SFI): Diagnosis of a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis). Fingernail Onychomycosis: Diagnosis of fingernail onychomycosis as confirmed by one of the following: i) positive potassium hydroxide (KOH) preparation, ii) fungal culture, OR iii) nail biopsy. Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine. Toenail Onychomycosis: Diagnosis of toenail onychomycosis as confirmed by one of the following: i) positive potassium hydroxide (KOH) preparation, ii) fungal culture, OR iii) nail biopsy. Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | SFI:6mo.Fingernail Onychomycosis:5wks.Toenail Onychomycosis:3mo. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# IVERMECTIN (S)

**Products Affected**

- Ivermectin TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Strongyloidiasis: Diagnosis of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis. Onchocerciasis: Diagnosis of onchocerciasis due to the nematode parasite Onchocerca volvulus. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Strongyloidiasis: 3 weeks. Onchocerciasis: 6 months. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# IVIG (S)

## Products Affected

- Bivigam INJ 10%, 5GM/50ML
- Privigen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG – Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. Continued in Other Criteria Section. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist). |
| **Coverage Duration** | 4 months: Solid organ transplant. 12 months: all other diagnoses. |
| **Other Criteria** | [D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-Barré syndrome. 3) Inflammatory myopathies (dermatomyositis or polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid. 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises. 7) Stiff person syndrome AND Patient had a TF/C/I to at least one standard therapy (i.e., baclofen, corticosteroid). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. Patient does not meet criteria for Part B or patient is in a long-term care facility. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# IWILFIN (S)

**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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# JAKAFI (S)

## 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: Diagnosis of primary myelofibrosis, OR post-polycythemia vera myelofibrosis, OR post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera, AND trial and failure, contraindication, or intolerance to hydroxyurea. Acute graft versus host disease (aGVHD): Diagnosis of aGVHD. Disease is steroid-refractory. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD. Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months. |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# JAYPIRCA (S)

**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 therapies 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. Disease is one of the following: a) Relapsed, or b) Refractory. 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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# JIDEYTRO (S)

## Products Affected

- Jideytro

| 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. Disease is i) locally advanced or ii) metastatic. Presence of ROS1 rearrangement positive tumor(s) as detected by a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received prior treatment with a ROS1 kinase inhibitor (e.g., Augtyro, Xalkori, Rozlytrek). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# JYLAMVO (S)

**Products Affected**

- Jylamvo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Neoplastic diseases: Diagnosis of one of the following: A) acute lymphoblastic leukemia (ALL), B) mycosis fungoides (cutaneous T-cell lymphoma), or C) relapsed or refractory non-hodgkin lymphomas. Rheumatoid arthritis (RA): Diagnosis of RA. Psoriasis: Diagnosis of severe psoriasis. Polyarticular juvenile idiopathic arthritis (pJIA): Diagnosis of polyarticular juvenile idiopathic arthritis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA: Prescribed by or in consultation with a rheumatologist. Psoriasis: Prescribed by or in consultation with a dermatologist. pJIA: Prescribed by or in consultation with a rheumatologist. |
| **Coverage Duration** | Neoplastic diseases, RA, Psoriasis, pJIA: 12 months. |
| **Other Criteria** | Subject to Part B vs D review. Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# JYNARQUE (S)

## Products Affected

- Jynarque TABS
- 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: Patient has received Jynarque for less than or equal to 18 months AND 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: Patient has received Jynarque for longer than 18 months AND 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** | 12 months |
| **Other Criteria** | ADPKD (reauth): Patient demonstrates positive clinical response to therapy. One of the following: 1) Patient does not have signs or symptoms consistent with hepatic injury or 2) Patient has uncomplicated polycystic liver disease. One of the following: 1) Both of the following: Patient has received Jynarque for less than or equal to 18 months AND 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: Patient has received Jynarque for longer than 18 months AND 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 (S)

## 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 cystic fibrosis. Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | CF (initial): Patient is 1 month of age or older. |
| **Prescriber Restrictions** | CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist |
| **Coverage Duration** | CF (initial, reauth): 12 months |
| **Other Criteria** | CF (Reauth): Patient demonstrates positive clinical response (i.e. improvement in lung function [percent predicted forced expiratory volume in one second (PPFEV1)], decreased number of pulmonary exacerbations) while on therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KERENDIA (S)

**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. Both of the following: 1) 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, AND 2) Patient is not receiving drug in combination with spironolactone or eplerenone. One of the following: 1) Patient is receiving drug in combination with a sodium-glucose cotransporter-2 (SGLT2) inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]), OR 2) Patient has a contraindication or intolerance to an SGLT2 inhibitor. |
| **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: 12 months |
| **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, OR 2) Patient has a contraindication or intolerance to an SGLT2 inhibitor. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# KESIMPTA (S)

**Products Affected**

- Kesimpta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple Sclerosis (MS) (Initial): Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS [e.g., Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Gilenya fingolimod)], OR 2) For continuation of prior therapy. Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ocrelizumab [Ocrevus]). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (Initial, Reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (Initial, Reauth): 12 months |
| **Other Criteria** | MS (Reauth): Patient demonstrates positive clinical response to therapy. Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ocrelizumab [Ocrevus]). |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# KINERET (S)

## 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: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID AND dx of NOMID has been 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 allergist/immunologist or rheumatologist or pediatrician. |
| **Coverage Duration** | RA, NOMID (initial): 6 months, (reauth): 12 months. DIRA: 12 months. |

| | |
|---|---|
| **Other Criteria** | RA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. NOMID (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# KISQALI (S)

**Products Affected**

- Kisqali

| 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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KISQALI-FEMARA PACK (S)

## Products Affected

- Kisqali Femara 200 Dose
- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast cancer: Diagnosis of breast cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KOMZIFTI (S)

**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. Presence of a susceptible nucleophosmin 1 (NPM1) mutation as detected by a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KORLYM (S)

**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** | Cushing's syndrome (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. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Initial, reauth: 6 months |
| **Other Criteria** | Reauth: Patient demonstrates one of the following: patient has improved glucose tolerance while on therapy or patient has stable glucose tolerance while on therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KOSELUGO (S)

**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). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KRAZATI (S)

**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. Disease is one of the following: locally advanced or metastatic. Disease is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy). Colorectal Cancer (CRC): Diagnosis of CRC. Disease is one of the following: locally advanced or metastatic. Tumor is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Erbitux (cetuximab). Patient has received prior treatment with ALL of the following: a) fluoropyrimidine-based chemotherapy, b) oxaliplatin-based chemotherapy, and c) irinotecan-based chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# KUVAN (S)

## Products Affected

- Sapropterin Dihydrochloride
- Zelvysia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient will have blood Phe levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | PKU (Init): 2 months (Reauth): 12 months |
| **Other Criteria** | PKU (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# KYGEVVI (S)

**Products Affected**

- Kygevvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of thymidine kinase 2 deficiency (TK2d). Diagnosis confirmed by the presence of a mutation in the TK2 gene. Patient experienced symptom onset on or before 12 years of age. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial, Reauth: Prescribed by or in consultation with a clinical specialist knowledgeable in the treatment of TK2d (e.g., geneticist, neurologist). |
| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | Reauth: Provider attests the patient would benefit from continued therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LAZCLUZE (S)

**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 locally advanced or metastatic. Used as first line treatment of NSCLC. Used in combination with Rybrevant (amivantamab). Presence of epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LENVIMA (S)

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Differentiated thyroid cancer (DTC): Diagnosis of DTC. Renal Cell Carcinoma (RCC): Diagnosis of RCC. One of the following: 1) Both of the following: a) Used as first-line treatment and b) Used in combination with Keytruda (pembrolizumab), or 2) Both of the following: a) Treatment follows one prior anti-angiogenic therapy and b) Used in combination with everolimus. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Endometrial Carcinoma (EC): Diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR) [i.e. disease is mismatch repair proficient (pMMR)], as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has disease progression following systemic therapy. Used in combination with Keytruda (pembrolizumab) therapy. Patient is not a candidate for curative surgery or radiation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

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

# LETAIRIS (S)

## 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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH (Initial): 6 months. PAH (Reauth): 12 months |
| **Other Criteria** | PAH (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LIDOCAINE TOPICAL (S)

## Products Affected

- Lidocaine OINT 5%
- Lidocaine/prilocaine CREA
- Premium Lidocaine

| 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** | 3 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LIDODERM (S)

## 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** | 12 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LIFYORLI (S)

**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 one of the following: 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 (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LIVMARLI (S)

**Products Affected**

- Livmarli

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Alagille syndrome (ALGS) (initial): Both of the following: a) Diagnosis of ALGS, and b) Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene. Progressive Familial Intrahepatic Cholestasis (PFIC) (initial): Both of the following: a) Diagnosis of PFIC, and b) Molecular genetic testing confirms mutations in the ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, or MYO5B gene. |
| **Age Restrictions** | ALGS (initial): Patient is 3 months of age or older. PFIC (initial): Patient is 12 months of age or older. |
| **Prescriber Restrictions** | All indications (initial): Prescribed by or in consultation with a hepatologist or gastroenterologist. |
| **Coverage Duration** | ALGS (initial, reauth): 12 months. PFIC (initial): 6 months, (reauth): 12 months. |
| **Other Criteria** | All indications (reauth): Patient demonstrates positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LONSURF (S)

**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 metastatic colorectal cancer AND One of the following: Used as a single agent or Used in combination with bevacizumab AND Patient has been previously treated with both of the following: A) fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI) AND B) anti-VEGF therapy (e.g., Avastin [bevacizumab]) AND One of the following: A) patient has RAS wild-type tumors and patient has been previously treated with one anti-EGFR therapy (e.g., Vectibix [panitumumab], Erbitux [cetuximab]) OR Patient has RAS mutant tumors. Gastric/Gastroesophageal Junction Adenocarcinoma: Diagnosis of metastatic gastric cancer or diagnosis of metastatic gastroesophageal junction adenocarcinoma. Patient has been previously treated with two of the following: fluropyrimidine-based chemotherapy (e.g. fluorouracil), Platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin), Taxane (e.g., docetaxel, paclitaxel) or irinotecan-based chemotherapy, HER2/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LORBRENA (S)

**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 metastatic NSCLC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LOTRONEX (S)

## Products Affected

- Alosetron Hydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women (initial): All of the following: 1) diagnosis of severe diarrhea-predominant IBS, 2) symptoms for at least 6 months, 3) female patient, AND 4) trial and failure, contraindication, or intolerance to an antidiarrheal agent [eg, loperamide]. |
| **Age Restrictions** | Initial: 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | IBS (initial): 12 weeks. IBS (reauth): 6 mo. |
| **Other Criteria** | IBS (reauth): Symptoms of IBS continue to persist. Patient demonstrates positive clinical response to therapy (e.g., relief of IBS abdominal pain and discomfort, improvement in stool consistency and frequency, improvement as measured by the Global Improvement Scale). |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LUMAKRAS (S)

**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) locally advanced or b) metastatic. Presence of KRAS G12C-mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy). Metastatic Colorectal Cancer (mCRC): Diagnosis of mCRC. Presence of KRAS G12C-mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received prior therapy with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy. Used in combination with Vectibix (panitumumab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LUPRON (S)

**Products Affected**

- Leuprolide Acetate INJ 1MG/0.2ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Prostate CA: 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LUPRON DEPOT (S)

## 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): Diagnosis of advanced or metastatic prostate cancer. Endometriosis (3.75 mg, 11.25 mg): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or 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). Uterine Leiomyomata (UL) (3.75 mg, 11.25 mg): a) For use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) OR b) all of the following: treatment of anemia, anemia is caused by uterine leiomyomata (fibroids), and for use prior to surgery. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Prostate CA: 12 mo. Endomet:6mo. UL (anemia):3 mo (fibroids):4 mo |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# LUPRON DEPOT PED (S)

## Products Affected

- Lupron Depot-ped (1-month)
- Lupron Depot-ped (3-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 CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | CPP (initial, reauth): Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | CPP (initial, reauth): 12 months |
| **Other Criteria** | CPP (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LYNPARZA TABLET (S)

**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** | Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Breast cancer: Diagnosis of breast cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Pancreatic adenocarcinoma: Diagnosis of pancreatic adenocarcinoma. Prostate cancer: Diagnosis of castration-resistant prostate cancer. All indications: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# LYTGOBI (S)

**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 intrahepatic cholangiocarcinoma. Disease is one of the following: a) unresectable, b) locally advanced, or c) metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangements. Patient has been previously treated (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# MARINOL (S)

**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 to one 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). Trial and failure, contraindication, or intolerance to one of the following: Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Zyprexa (olanzapine). AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS. Patient is on antiretroviral therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CINV: 6 months. AIDS anorexia: 12 months. |
| **Other Criteria** | Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving cancer chemotherapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# MAVYRET (S)

**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** | One of the following: 1) Non-transplant patient who is treatment-naïve without decompensation, or 2) Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine, Liver transplant specialist. |
| **Coverage Duration** | 8 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. |

# MAYZENT (S)

## Products Affected

- Mayzent
- Mayzent Starter Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS. |
| **Required Medical Information** | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial, reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (initial, reauth): 12 months |
| **Other Criteria** | MS (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# MEKINIST (S)

**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 V600E or V600K mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Tafinlar (dabrafenib).Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Tafinlar (dabrafenib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic ATC. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Tafinlar (dabrafenib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |

| | |
|---|---|
| **Other Criteria** | Approve for continuation of prior therapy. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Tafinlar (dabrafenib). Low-grade glioma: Diagnosis of low-grade glioma. Patient requires systemic therapy. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Tafinlar (dabrafenib). |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# MEKTOVI (S)

**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. Cancer is BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Braftovi (encorafenib). Non-Small Cell Lung Cancer (NSCLC): Diagnosis of metastatic NSCLC. Cancer is BRAF V600E mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Braftovi (encorafenib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# MIGRANAL (S)

**Products Affected**

- Dihydroergotamine Mesylate SOLN

| 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 headaches with or without aura. Will be used for the acute treatment of migraine. One of the following: Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or contraindication to all triptans. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# MODEYSO (S)

**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 diffuse midline glioma. Disease is confirmed by the presence of H3 K27M mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has progressed following prior therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# MOUNJARO (S)

**Products Affected**

- Mounjaro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: One of the following: a) For patients requiring ongoing treatment for type 2 diabetes mellitus (T2DM), submission of medical records (e.g., chart notes) confirming diagnosis of T2DM, OR b) Submission of medical records (e.g., chart notes) confirming diagnosis of T2DM as evidenced by one of the following laboratory values: i) A1c greater than or equal to 6.5%, ii) fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, or iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# MS INTERFERONS (NON-PREFERRED) (S)

## Products Affected

- Rebif
- Rebif Rebidose
- Rebif Rebidose Titration Pack
- Rebif Titration Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS. |
| **Required Medical Information** | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one of the following: Avonex (interferon beta-1a) or Betaseron (interferon beta-1b), or 2) for continuation of prior therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial, reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (initial, reauth): 12 months |
| **Other Criteria** | MS (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# MS INTERFERONS (PREFERRED) (S)

## Products Affected

- Avonex INJ 30MCG/0.5ML
- Avonex Pen
- Betaseron

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS. |
| **Required Medical Information** | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial, reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (initial, reauth): 12 months |
| **Other Criteria** | MS (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NERLYNX (S)

**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 Breast cancer: Diagnosis (dx) of early stage breast cancer. Advanced or Metastatic Breast Cancer: Dx of advanced or metastatic breast cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NEULASTA (S)

## Products Affected

- Neulasta
- Neulasta Onpro Kit

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

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

# NEXAVAR (S)

## Products Affected

- Sorafenib
- 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 advanced RCC. Hepatocellular carcinoma (HCC): Diagnosis of HCC. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC. One of the following: locally recurrent disease, or metastatic disease. Patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NEXLETOL (S)

**Products Affected**

- Nexletol

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Heterozygous familial hypercholesterolemia (HeFH), Hypercholesterolemia, or Prevention of Cardiovascular (CV) Events in patients at increased risk for major adverse cardiovascular events (Initial): One of the following diagnoses: A) HeFH, B) Hypercholesterolemia, C) At increased risk for a major adverse CV event. One of the following LDL-C values within the last 120 days: (1) LDL-C greater than or equal to 55 mg/dL with ASCVD or (2) LDL-C greater than or equal to 70 mg/dL without ASCVD. One of the following: 1) Used as adjunct to statin therapy, 2) Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase), OR 3) Patient has a contraindication to all statins. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy (eg reduction in LDL-C levels). Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) or pt has a documented inability to take other lipid-lowering therapy (eg statins, ezetimibe). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NEXLIZET (S)

**Products Affected**

- Nexlizet

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Heterozygous familial hypercholesterolemia (HeFH), Hypercholesterolemia, or Prevention of Cardiovascular (CV) Events in patients at increased risk for major adverse cardiovascular events (Initial): One of the following diagnoses: A) HeFH, B) Hypercholesterolemia, C) At increased risk for a major adverse CV event (e.g., cardiovascular death, myocardial infarction, stroke, or coronary revascularization). One of the following LDL-C values within the last 120 days: (1) LDL-C greater than or equal to 55 mg/dL with ASCVD or (2) LDL-C greater than or equal to 70 mg/dL without ASCVD. One of the following: 1) Used as adjunct to statin therapy, 2) Pt is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase), OR 3) Patient has a contraindication to all statins. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy (eg reduction in LDL-C levels). Patient continues to receive other lipid-lowering tx (eg statins, ezetimibe) or patient has a documented inability to take other lipid-lowering therapy (eg statins, ezetimibe). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NILOTINIB (S)

## Products Affected

- Nilotinib D-tartrate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NINLARO (S)

**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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NORTHERA (S)

## 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) (init): 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. Trial and failure, contraindication, or intolerance to one of the following agents: fludrocortisone acetate, midodrine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | NOH (init): Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist |
| **Coverage Duration** | NOH (init): 1 month (reauth): 12 months |
| **Other Criteria** | NOH (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# NOXAFIL SUSPENSION (S)

**Products Affected**

- Posaconazole SUSP

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prophylaxis of systemic fungal infections (SFI): 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 OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Oropharyngeal Candidiasis (OPC): Diagnosis of OPC. One of the following: 1) Trial and failure, contraindication, or intolerance to fluconazole OR 2) Susceptibility results demonstrate resistance to fluconazole. |
| **Age Restrictions** | Prophylaxis of SFI, OPC: Patient is 13 years or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Prophylaxis of SFI: 6 months. OPC: 1 month. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# NUBEQA (S)

**Products Affected**

- Nubeqa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Castration-resistant prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) prostate cancer. Metastatic Castration-sensitive prostate cancer (mCSPC): Diagnosis of metastatic castration-sensitive prostate cancer (mCSPC) [also known as metastatic hormone-sensitive prostate cancer (mHSPC)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CRPC, mCSPC: 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NUCALA (S)

## Products Affected

- Nucala

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Asthma (init): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by one of the following: baseline(pre-tx) peripheral blood eosinophil level is greater than or equal to 150cells/ml or peripheral blood eosinophil levels were greater than or equal to 300cells/ml within the past 12 mo. Patient has had two or more asthma exacerbations requiring systemic corticosteroids(eg, prednisone) within the past 12 mo or Patient has had a prior asthma-related hospitalization within the past 12 mo. 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 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 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: a)Both of the following: i)High-dose ICS(eg, greater than 500 mcg fluticasone propionate equivalent/day) and ii)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 b)One maximally-dosed combination ICS/LABA product(eg, Wixela Inhub[fluticasone propionate 500mcg/salmeterol 50mcg], budesonide 160mcg/formoterol 4.5mcg, Breo Ellipta[fluticasone 200mcg/vilanterol 25mcg]) |

| | |
|---|---|
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Asthma (init): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (init, reauth): 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. |
| **Coverage Duration** | Asthma, COPD (init): 6 mo, (reauth): 12 months. CRSwNP, EGPA, HES (init, reauth): 12 months |
| **Other Criteria** | Hypereosinophilic Syndrome (HES) (init): Diagnosis (dx) of HES. Patient (Pt) has been diagnosed for at least 6 months. Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy). Pt is FIP1L1-PDGFRA-negative. Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter. Trial and failure, contraindication (CI), or intolerance to corticosteroid (CS) therapy (tx) (e.g., prednisone) or cytotoxic/immunosuppressive tx (e.g., hydroxyurea, cyclosporine, imatinib). Asthma (reauth): Pt demonstrates positive clinical response to tx. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (init): Dx of CRSwNP. Unless CI, the pt has had an inadequate response to 2 months of treatment with an intranasal CS (e.g., fluticasone, mometasone). Used in combination with another agent for CRSwNP. Eosinophilic Granulomatosis with Polyangiitis (EGPA) (init): Dx of EGPA. Pt's disease has relapsed or is refractory to standard of care tx (i.e., CS treatment with or without immunosuppressive tx). Pt is currently receiving CS tx (e.g., prednisolone, prednisone) unless there is a CI or intolerance to CS tx. CRSwNP (reauth): Pt demonstrates positive clinical response to tx. Used in combination with another agent for CRSwNP. EGPA, HES (reauth): Pt demonstrates positive clinical response to tx. Chronic Obstructive Pulmonary Disease (COPD) (init): Dx of COPD. Presence of Type 2 inflammation evidenced by 1 of the following: a) Blood eosinophils greater than or equal to 150 cells/microliter at baseline, or b) Blood eosinophils greater than or equal to 300 cells/microliter in the last 12 months. Pt is receiving 1 of the following: a) Triple tx (i.e., ICS, LAMA, and a LABA), or b) If CI to ICS, a LAMA and a LABA. Pt has had 1 of the following within the past 12 months: a) At least 2 exacerbations where systemic CS [intramuscular, intravenous, or oral (e.g., prednisone)] were required at least once, or b) COPD-related hospitalization. COPD (reauth): Pt demonstrates positive clinical response to tx. Pt continues to receive 1 of the following tx: a) Triple tx (i.e., ICS, LAMA, and LABA, or b) If CI to ICS, a LAMA and a LABA. |

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

# NUEDEXTA (S)

## Products Affected

- Dextromethorphan Hydrobromide/quinidine Sulfate
- 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. Patient does not have any of the following contraindications: a) Concomitant use with other drugs containing quinidine, quinine, or mefloquine, b) History of dextromethorphan/quinidine, 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): Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist. |
| **Coverage Duration** | PBA (initial/reauth): 12 months |
| **Other Criteria** | PBA (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NUPLAZID (S)

## 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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# NURTEC (S)

**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. |
| **Age Restrictions** | All Indications (initial): 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Acute Treatment (init): 12mo. Preventive Treatment (init): 6mo. All Indications (reauth): 12mo. |
| **Other Criteria** | Preventive Treatment of Episodic Migraine (EM) (initial): Both of the following: 1) Diagnosis of EM and 2) Patient has greater than or equal to 4 migraine days per month. Acute Treatment of Migraine (reauth): Patient has experienced a positive response to therapy. Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines. Preventive Treatment of EM (reauth): Patient has experienced a positive response to therapy. Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# NUVIGIL (S)

## 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 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: 12 mo |
| **Other Criteria** | OSA, Narcolepsy (Reauth): Patient demonstrates positive clinical response to armodafinil therapy. SWD (Reauth): Patient demonstrates positive clinical response to armodafinil therapy. |

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

# ODACTRA (S)

**Products Affected**

- Odactra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Allergic rhinitis (AR) (Initial): Diagnosis of house dust mite (HDM)-induced allergic rhinitis. One of the following: 1) positive in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, OR 2) skin testing to licensed house dust mite allergen extracts. Trial and failure, contraindication, or intolerance to an intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, flunisolide nasal spray) AND an antihistamine (e.g., cetirizine, loratadine, azelastine nasal spray, olapatadine nasal spray). |
| **Age Restrictions** | AR (Initial): Patient is 5 to 65 years of age |
| **Prescriber Restrictions** | AR (Initial): Prescribed by or in consultation with an allergist or immunologist |
| **Coverage Duration** | AR (initial, reauth): 12 months |
| **Other Criteria** | AR (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ODOMZO (S)

**Products Affected**

- Odomzo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma AND One of the following: 1) Cancer has recurred following surgery or radiation therapy or 2) Patient is not a candidate for surgery or radiation therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# OFEV (S)

## Products Affected

- Nintedanib Esylate
- Ofev

| 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 as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (initial): Diagnosis of SSc-ILD as documented by all of the following: a) exclusion of other known causes of ILD (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on HRCT revealing SSc-ILD or probable SSc-ILD, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD. Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype (initial), Progressive Pulmonary Fibrosis (PPF): 1) diagnosis of chronic fibrosing interstitial lung disease or progressive pulmonary fibrosis (PPF), AND 2) patient has a high-resolution computed tomography (HRCT) showing fibrotic features, AND 3) 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** | All Indications (initial): Prescribed by or in consultation with a pulmonologist or a rheumatologist. |
| **Coverage Duration** | Initial, reauth: 12 months |
| **Other Criteria** | All Indications (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# OGSIVEO (S)

**Products Affected**

- Ogsiveo

| 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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# OJEMDA (S)

**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 as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# OJJAARA (S)

**Products Affected**

- Ojjaara

| 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) Primary myelofibrosis, b) Post-polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Patient has anemia. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ONPATTRO (S)

**Products Affected**

- Onpattro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) (initial): Diagnosis of hATTR amyloidosis with polyneuropathy. Presence of a transthyretin (TTR) mutation (e.g., V30M) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy). Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Vyndaqel). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | hATTR amyloidosis (initial): Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | hATTR amyloidosis (initial, reauth): 12 months. |
| **Other Criteria** | Subject to Part B vs D review. hATTR amyloidosis (reauth): Patient demonstrates postive clinical response to therapy. Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Vyndaqel). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ONUREG (S)

**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, etc.). 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 able to complete intensive curative therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# OPIPZA (S)

**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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# OPSUMIT (S)

## Products Affected

- Macitentan
- Opsumit

| 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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | PAH (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ORENCIA IV (S)

**Products Affected**

- Orencia INJ 250MG

| 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 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. Acute graft versus host disease (aGVHD): Used for prophylaxis of aGVHD. Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor. Recommended antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia and continued for six months after HSCT. Used in combination with both of the following: calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate. |
| **Age Restrictions** | aGVHD: Patient is 2 years of age or older |
| **Prescriber Restrictions** | RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. |
| **Coverage Duration** | RA, JIA, PsA (initial): 6 months, (reauth): 12 months. aGVHD: 2 months |

| | |
|---|---|
| **Other Criteria** | RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ORENCIA SC (S)

## Products Affected

- Orencia INJ 125MG/ML, 50MG/0.4ML, 87.5MG/0.7ML
- Orencia Clickject

| 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 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. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. |
| **Coverage Duration** | All uses (initial): 6 months, (reauth): 12 months |
| **Other Criteria** | RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. |

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

# ORENITRAM (S)

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | PAH (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ORGOVYX (S)

**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 advanced or metastatic prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ORKAMBI (S)

**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 (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | CF (Initial): Patient is 6 years of age or older |
| **Prescriber Restrictions** | CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist |
| **Coverage Duration** | CF (initial, reauth): 12 months |
| **Other Criteria** | CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ORSERDU (S)

**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. Disease is estrogen receptor (ER)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Presence of estrogen receptor (ESR1) mutation(s) as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# OSENVELT (S)

**Products Affected**

- Osenvelt

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Skeletal prevention in Multiple Myeloma (MM)/Bone Metastasis from Solid Tumors (BMST): One of the following: 1) Both of the following: a) Diagnosis of multiple myeloma and b) Trial and failure, contraindication (e.g., renal insufficiency), or intolerance to one bisphosphonate therapy, OR 2) Both of the following: a) Diagnosis of solid tumors (e.g., breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) and b) Documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Diagnosis of giant cell tumor of bone. One of the following: 1) One of the following: a) tumor is unresectable or b) surgical resection is likely to result in severe morbidity, OR 2) Approve for continuation of prior therapy. Hypercalcemia of malignancy (HCM): Diagnosis of hypercalcemia of malignancy. Trial and failure, contraindication, or intolerance to one bisphosphonate therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | MM/BMST, GCTB, HCM: 12 months. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# OSPHENA (S)

## 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 (initial): Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause. Vaginal dryness (initial): 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** | All uses (Initial, reauth): 12 months |
| **Other Criteria** | Dyspareunia, Vaginal dryness (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# OTEZLA (S)

## 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. Minimum duration of a 4-week trial and failure, 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). Patient weighs at least 20 kg. Oral ulcers associated with Behcet's Disease (Initial): Diagnosis of Behcet's Disease. Patient has active oral ulcers. |
| **Age Restrictions** | Plaque psoriasis (initial): Patient is 6 years of age or older. |
| **Prescriber Restrictions** | PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist. |
| **Coverage Duration** | All uses (initial): 6 months. All uses (reauth): 12 months. |
| **Other Criteria** | PsA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (reauth): Patient demonstrates positive clinical response to therapy. Oral ulcers associated with Behcet's Disease (reauth): Patient demonstrates positive clinical response to therapy (eg, reduction in pain from oral ulcers or reduction in number of oral ulcers). |

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

# OZEMPIC (S)

**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** | N/A |
| **Required Medical Information** | Diabetes Mellitus (DM) Initial: One of the following: a) For patients requiring ongoing treatment for type 2 diabetes mellitus (T2DM), submission of medical records (e.g., chart notes) confirming diagnosis of T2DM, OR b) Submission of medical records (e.g., chart notes) confirming diagnosis of T2DM as evidenced by one of the following laboratory values: i) A1c greater than or equal to 6.5%, ii) fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, or iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test). 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 diagnosis has been confirmed by one of the following: FibroScan-aspartate aminotransferase (FAST), MRI-aspartate aminotransferase (MAST), or liver biopsy. Submission of medical records (e.g., chart notes) confirming disease is fibrosis stage F2 or F3 as confirmed by one of the following: FibroScan, Fibrosis-4 index (FIB-4), or Magnetic Resonance Elastography (MRE). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MASH (Initial): Prescribed by or in consultation with one of the following: gastroenterologist, endocrinologist, or hepatologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | DM (Reauth): Patient demonstrates positive clinical response to therapy. MASH (Reauth): Patient demonstrates positive response to therapy. |

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

# OZEMPIC TABLET (S)

**Products Affected**

- Ozempic TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: One of the following: a) For patients requiring ongoing treatment for type 2 diabetes mellitus (T2DM), submission of medical records (e.g., chart notes) confirming diagnosis of T2DM, OR b) Submission of medical records (e.g., chart notes) confirming diagnosis of T2DM as evidenced by one of the following laboratory values: i) A1c greater than or equal to 6.5%, ii) fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, or iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# PEGASYS (S)

## 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** | Chronic Hepatitis C: Prescribed by or in consultation with one of the following: hepatologist, gastroenterologist, infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine |
| **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 (S)

## 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 or metastatic. Disease is confirmed by the presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior line of therapy (e.g., chemotherapy). Myeloid/lymphoid neoplasms: Diagnosis of myeloid/lymphoid neoplasms (MLNs). Disease is relapsed or refractory. Disease is confirmed by the presence of a fibroblast growth factor receptor 1 (FGFR1) rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# PENNSAID (S)

## 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** | Osteoarthritis of the knees (initial): Diagnosis of osteoarthritis of the knees. Patient meets one of the following: 1) Trial and failure, contraindication or intolerance to at least two prescription strength topical or oral non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) OR 2) History of peptic ulcer disease/gastrointestinal bleed OR 3) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, reauth: 12 months |
| **Other Criteria** | Osteoarthritis of the knees (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# PHESGO (S)

**Products Affected**

- Phesgo

| 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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# PIQRAY (S)

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion 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. Cancer is PIK3CA-mutated as detected by an FDA-approved test (therascreen PIK3CA RGQ PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# POMALYST (S)

## Products Affected

- Pomalidomide
- Pomalyst

| 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. Kaposi sarcoma (KS): One of the following: 1) Diagnosis of AIDS-related KS, OR 2) Both of the following: a) Diagnosis of KS and b) Patient is HIV-negative. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# POSACONAZOLE TABLET (S)

**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 systemic fungal infections (SFI): 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 OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Treatment (Tx) of SFI: Used as treatment of systemic fungal infections caused by Aspergillus. |
| **Age Restrictions** | All indications: Patient is 2 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All indications: 6 months. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# PRALUENT (S)

## Products Affected

- Praluent

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | HeFH/ASCVD/Primary HLD/Hypercholesterolemia/Prevention of Cardiovascular (CV) Events in patients at increased risk for a major adverse cardiovascular event (init): One of the following diagnoses: A) HeFH, B) ASCVD, OR C) Primary hyperlipidemia (HLD) or hypercholesterolemia, OR D) At increased risk for a major adverse CV event. One of the following: 1) Patient has been receiving highest tolerable dose of statin therapy, 2) Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (eg, creatine kinase), OR 3) Patient has an FDA labeled contraindication to all statins. HoFH (init): Diagnosis of HoFH as confirmed by one of the following: 1) Genetic confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2) untreated LDL greater than 400, AND either xanthoma before 20 yo or evidence of HeFH in both parents. One of the following: 1) Patient is receiving other lipid-lowering therapy (eg, statin, ezetimibe) or 2) Patient has a documented inability to take other lipid-lowering therapy (eg, statin, ezetimibe). |
| **Age Restrictions** | HeFH (Initial): Patient is 8 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, Reauth: 12 months |

| | |
|---|---|
| **Other Criteria** | HeFH/ASCVD/Primary HLD/Hypercholesterolemia/Prevention of Cardiovascular (CV) Events in patients at increased risk for a major adverse cardiovascular event (reauth): Patient continues to receive other lipid-lowering therapy (eg, statins, ezetimibe) at max tolerated dose (unless patient has documented inability to take these medications). HoFH (reauth): One of the following: 1) Patient continues to receive other lipid-lowering therapy (eg, statin, ezetimibe) or 2) Patient has a documented inability to take other lipid-lowering therapy (eg, statin, ezetimibe). HeFH/ASCVD/Primary HLD/Hypercholesterolemia/Prevention of Cardiovascular (CV) Events in patients at increased risk for a major adverse cardiovascular event/HoFH (reauth): Patient demonstrates positive clinical response to therapy as evidenced by a reduction in LDL-C levels from baseline. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# PROMACTA (S)

## 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** | Immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: relapsed/refractory ITP, persistent ITP, or chronic ITP. Baseline platelet count is less than 30,000/mcL. Trial and failure, intolerance, contraindication to corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C-associated thrombocytopenia. One of the following: 1) Planning to initiate and maintain interferon-based treatment, or 2) 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). Used in combination with standard immunosuppressive therapy (e.g., horse antithymocyte globulin, 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 one of the following: a) neutrophils less than 0.5 x 10^9/L, b) platelet count less than 30,000/mcL, or c) reticulocytes less than 60 x 10^9/L. Insufficient response to immunosuppressive therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | ITP and SAA: Prescribed by or in consultation with a hematologist/oncologist. Chronic hepatitis C associated thrombocytopenia: Prescribed by or in consultation with a hematologist/oncologist, gastroenterologist, hepatologist, infectious disease specialist, or HIV specialist certified through the American Academy of HIV Medicine. |
| **Coverage Duration** | ITP(init,reauth):12mo.HepC:3mo(init),12mo(reauth).1stline SAA:6mo.RefractSAA:16wk-init,12mo-reauth |

| | |
|---|---|
| **Other Criteria** | ITP (reauth): Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding. Hepatitis C (reauth): Patient currently on antiviral interferon therapy for treatment of chronic hepatitis C. Refractory SAA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# PROVIGIL (S)

**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. 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. Idiopathic Hypersomnia (Initial): Diagnosis of idiopathic hypersomnia 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** | Narcolepsy, MS Fatigue: Init, Reauth: 12 mo. All other indications: Init, Reauth: 6 mo. |
| **Other Criteria** | OSA, SWD, MS Fatigue, Narcolepsy, Idiopathic Hypersomnia (Reauth): Patient demonstrates positive clinical response to therapy. Depression (reauth): Patient demonstrates positive clinical response to modafinil therapy. Used as adjunctive therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# PULMOZYME (S)

**Products Affected**

- Pulmozyme SOLN 2.5MG/2.5ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cystic Fibrosis (CF) (Initial, Reauth): Diagnosis of CF. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CF (initial, reauth): 12 months |
| **Other Criteria** | Part B vs D determination applies. CF (reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# PYRUKYND (S)

## 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: 12 months. |
| **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 (S)

**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). Disease is advanced. Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# QUALAQUIN (S)

**Products Affected**

- Quinine Sulfate CAPS 324MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Excluded if used solely for the treatment or prevention of nocturnal leg cramps. |
| **Required Medical Information** | Malaria: Diagnosis of uncomplicated malaria. One of the following: 1) Treatment in areas of chloroquine-sensitive malaria, and trial and failure, contraindication, or intolerance to chloroquine or hydroxychloroquine, OR 2) Treatment in areas of chloroquine-resistant malaria. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 7 days |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# QULIPTA (S)

**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. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. 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** | EM, CM (initial): 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | EM, CM (init): 6mo. EM, CM (reauth): 12mo. |
| **Other Criteria** | EM, CM (reauth): Patient has experienced a positive response to therapy. Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (reauth): Patient continues to be monitored for medication overuse headache. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# RELGAABI (S)

**Products Affected**

- Gabapentin CAPS 200MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of postherpetic neuralgia or partial onset seizures. Trial or intolerance to generic gabapentin (generic Neurontin). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# REMICADE (S)

## Products Affected

- Infliximab

| 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) and Fistulizing Crohn's Disease (FCD) (Initial): Diagnosis (Dx) of moderately to severely active CD or FCD. 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. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. 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. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine). Rheumatoid arthritis (RA) (Initial): Dx of moderately to severely active RA. Used in combination with 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 (Initial): Dx of chronic severe (ie, extensive and/or disabling) 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. Minimum duration of a 4-week trial and failure, 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). |
| **Age Restrictions** | N/A |

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|---|---|
| **Prescriber Restrictions** | CD, FCD, UC (initial): Prescribed by or in consultation with a gastroenterologist. RA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with rheumatologist or dermatologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist. |
| **Coverage Duration** | All uses (initial): 6 months, (reauth): 12 months |
| **Other Criteria** | 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. Sarcoidosis (Initial): Dx of sarcoidosis. TF/C/I to both of the following: one immunosuppressant (eg, methotrexate, cyclophosphamide, azathioprine) AND one corticosteroid (eg, prednisone). Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. RA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Sarcoidosis (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# RENFLEXIS (S)

## Products Affected

- Renflexis

| 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) and Fistulizing Crohn's Disease (FCD) (initial): Diagnosis (Dx) of moderately to severely active CD or FCD. 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. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroids (eg, prednisone), methotrexate. 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. TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, 6-mercaptopurine. Rheumatoid arthritis (RA) (initial): Dx of moderately to severely active RA. Used in combination with 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 (initial): Dx of chronic severe (ie, extensive and/or disabling) 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. Minimum duration of a 4-week trial and failure, 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). |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | Initial: RA, AS: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed or in consultation with a rheumatologist or dermatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed by or in consultation with a gastroenterologist. Plaque Psoriasis: Prescribed by or in consultation with a dermatologist. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist. |
| **Coverage Duration** | All indications (initial): 6 months, (reauth): 12 months. |
| **Other Criteria** | 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. Sarcoidosis (initial): Dx of sarcoidosis. TF/C/I to one of the following: corticosteroid (eg, prednisone) OR immunosuppressant (eg, methotrexate, cyclophosphamide, azathioprine). Plaque psoriasis (reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. RA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Sarcoidosis (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# REPATHA (S)

## Products Affected

- Repatha
- Repatha Pushtronex System
- Repatha Sureclick

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | HeFH/ASCVD/Primary HLD/Hypercholesterolemia/Prevention of Cardiovascular (CV) Events in patients at increased risk for a major adverse CV event (init): One of the following diagnoses: A) HeFH, B) ASCVD, C) Primary hyperlipidemia (HLD) or hypercholesterolemia, OR D) At increased risk for a major adverse CV event. One of the following: a) Patient has been receiving the highest tolerable dose of statin therapy, OR b) Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (eg, creatine kinase), OR c) Patient has an FDA labeled contraindication to all statins. HoFH (init): Diagnosis of HoFH as confirmed by one of the following: 1) Genetic confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2) untreated LDL greater than 400, AND either xanthoma before 20 yo or evidence of HeFH in both parents. One of the following: 1) Patient is receiving other lipid-lowering therapy (eg, statin, ezetimibe) or 2) Patient has a documented inability to take other lipid-lowering therapy (eg, statin, ezetimibe). |
| **Age Restrictions** | (Initial) HeFH/HoFH: 10 years or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, Reauth: 12 months |

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|---|---|
| **Other Criteria** | HeFH/ASCVD/Primary HLD/Hypercholesterolemia/Prevention of Cardiovascular (CV) Events in patients at increased risk for a major adverse CV event (reauth): Patient continues to receive other lipid-lowering therapy (eg, statins, ezetimibe) at max tolerated dose (unless patient has documented inability to take these medications). HoFH (reauth): One of the following: 1) Patient continues to receive other lipid-lowering therapy (eg, statin, ezetimibe) or 2) Patient has a documented inability to take other lipid-lowering therapy (eg, statin, ezetimibe). HeFH/ASCVD/Primary HLD/Hypercholesterolemia/Prevention of Cardiovascular (CV) Events in patients at increased risk for a major adverse CV event/HoFH (reauth): Patient demonstrates positive clinical response to therapy as evidenced by a reduction in LDL-C levels from baseline. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# RETACRIT (S)

**Products Affected**

- Retacrit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with chemo (Initial):Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is receiving chemo. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon/peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 36% or Hgb less than 12 g/dL) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa. Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo. MDS:(init) 3mo,(reauth)12mo. Preop:1mo. |
| **Other Criteria** | Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Patient demonstrates positive clinical response to therapy from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Patient demonstrates positive clinical response to therapy from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Patient demonstrates positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Patient demonstrates positive clinical response to therapy from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Patient demonstrates positive clinical response to therapy from pre-treatment level. Other Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): 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. |

# RETEVMO (S)

## Products Affected

- Retevmo

| 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 locally advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is advanced or metastatic. Disease has presence of RET gene mutation tumor(s) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease requires treatment with systemic therapy. Patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate. Solid Tumors: Diagnosis of solid tumors. Disease is locally advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). ONE of the following: a) Disease has progressed on or following prior systemic treatment (e.g., chemotherapy), OR b) There are no satisfactory alternative treatment options. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

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|---|---|
| **Coverage Duration** | Non-Small Cell Lung Cancer, MTC, Thyroid Cancer, Solid Tumors: 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# REVATIO (S)

**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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | PAH (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# REVCOVI (S)

**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** | 12 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# REVLIMID (S)

## 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 syndromes (MDS): Diagnosis of transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q. Mantle cell lymphoma (MCL): Diagnosis of MCL. Follicular Lymphoma (FL): Diagnosis of FL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# REVUFORJ (S)

**Products Affected**

- Revuforj

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute leukemia: Diagnosis of acute leukemia. Disease is relapsed or refractory. Presence of lysine methyltransferase 2A gene (KMT2A) translocation. Acute myeloid leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. One of the following: 1) Presence of a lysine methyltransferase 2A gene (KMT2A) translocation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR 2) Presence of a susceptible nucleophosmin 1 (NPM1) mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# REZDIFFRA (S)

**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). 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. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with one of the following: gastroenterologist, endocrinologist, or hepatologist. |
| **Coverage Duration** | Initial, Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient demonstrates positive response to therapy. Patient has not progressed to cirrhosis. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# REZLIDHIA (S)

**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. Presence of a susceptible isocitrate dehydrogenase-1(IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# REZUROCK (S)

## Products Affected

- Rezurock

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic graft versus host disease (cGVHD) (initial): Diagnosis of cGVHD. Trial and failure of two or more lines of systemic therapy [e.g., corticosteroids (e.g., prednisone, methylprednisolone), mycophenolate, chemotherapy]. |
| **Age Restrictions** | Initial: Patient is 12 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | cGVHD (initial, reauth): 12 months |
| **Other Criteria** | cGVHD (reauth): Patient does not show evidence of progressive disease while on therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# RINVOQ (S)

## 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. RA,PJIA(init): Minimum (min) duration of a 3-mo(RA)/6-wk(PJIA) trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, (RA only) 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. Pt has signs of inflammation. Pt has had an inadequate response or intolerance to one TNF inhibitors (TNF-I) (eg, certolizumab pegol). AS, NRAS(init): Min duration of a 1-mo TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. RA, PJIA, PsA, AS(init): Pt has had an inadequate response or intolerance to one or more TNF-I (eg, adalimumab, etanercept). RA, PJIA, PsA, AS, NRAS(init, reauth): Not used in combo with other JAK inhibitors (JAK-I), biologic DMARDs, or potent immunosuppressants (eg, azathioprine [AZA], cyclosporine [CYC]). Atopic dermatitis(AD)(init): Dx of moderate to severe AD. One of the following: Involvement of at least 10% body surface area (BSA), or SCORing Atopic Dermatitis (SCORAD) index value of at least 25. TF of a min 30-day supply (14-day supply for topical corticosteroids), C/I to one of the following: Medium or higher potency topical corticosteroid, Pimecrolimus, Tacrolimus oint, or Eucrisa. One of the following: 1) TF of a min 12-wk supply of at least one systemic drug product for the treatment of AD (examples include, but are not limited to, Adbry, Dupixent), OR 2) Pt has a C/I, or treatment is inadvisable with both of the following FDA-approved AD therapies: Adbry and Dupixent. Not used in combo with other JAK-I, biologic immunomodulators, or other immunosuppressants (eg, AZA, CYC). |
| **Age Restrictions** | AD (initial): Patient is 12 years of age or older |

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| **Prescriber Restrictions** | RA, PJIA, AS, NRAS, GCA (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. AD (init): Prescribed by or in consultation with a dermatologist or allergist/immunologist. CD, UC (init): Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | RA, PJIA, PsA, AS, NRAS, CD, UC, AD, GCA (init): 6 months, (reauth): 12 months. |

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|---|---|
| **Other Criteria** | Polyarticular juvenile idiopathic arthritis (PJIA) (init): Dx of active PJIA. 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/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): Pt has had an inadequate response or intolerance to one or more TNF-I (eg, adalimumab), OR if treatment is inadvisable (ie, CI) with a TNF-I, pt has had a trial of a systemic therapy approved for CD/UC (eg, risankizumab, ustekinumab). Not used in combination with other JAK-I, biological therapies for CD/UC, or potent immunosuppressants (eg, AZA, CYC). Giant cell arteritis (GCA) (init): Dx of GCA. GCA (reauth): Pt demonstrates positive clinical response to therapy. GCA (init, reauth): Not used in combo with other JAK-I, biologic DMARDs, or potent immunosuppressants (eg, AZA, CYC). RA, PJIA (reauth): Pt demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Pt demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS, NRAS (Reauth): Pt demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (ESR, CRP), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. AD (reauth): Pt demonstrates positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. Not used in combination with other JAK-I, biologic immunomodulators, or other immunosuppressants (eg, AZA, CYC). CD/UC (Reauth): Pt demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, ESR, CRP]) from baseline OR reversal of high fecal output state. Not used in combination with other JAK-I, biological therapies for CD/UC, or potent immunosuppressants (eg, AZA, CYC). |

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

# RINVOQ LQ (S)

**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): 6 months, (reauth): 12 months. |
| **Other Criteria** | PJIA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. |

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

# RIVFLOZA (S)

**Products Affected**

- Rivfloza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of primary hyperoxaluria type 1 (PH1). Disease has been confirmed by both of the following: a) One of the following: i) Elevated urinary oxalate excretion, ii) Elevated plasma oxalate concentration, or iii) Spot urinary oxalate to creatinine molar ratio greater than normal for age, and b) One of the following: i) Genetic testing demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene, or ii) Liver biopsy demonstrating absence or reduced alanine:glyoxylate aminotransferase (AGT) activity. Patient has preserved kidney function (e.g., eGFR greater than or equal to 30mL/min/1.73m^2). |
| **Age Restrictions** | Initial: Patient is 2 years of age or older. |
| **Prescriber Restrictions** | Initial, Reauth: Prescribed by or in consultation with one of the following: hepatologist, nephrologist, urologist, geneticist, or specialist with expertise in the treatment of PH1. |
| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ROMVIMZA (S)

**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). Patient is symptomatic. Surgical resection will potentially cause worsening functional limitation or severe morbidity. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ROZLYTREK (S)

## 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). Presence of ROS1 rearrangement positive tumor(s). Solid Tumors: Diagnosis of solid tumors. Presence of neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). No 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). One of the following: disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) or disease has no satisfactory alternative treatments. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# RUBRACA (S)

**Products Affected**

- Rubraca

| 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 epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Prostate cancer: Diagnosis of castration-resistant prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# RYBELSUS (S)

**Products Affected**

- Rybelsus TABS 14MG, 3MG, 7MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: One of the following: a) For patients requiring ongoing treatment for type 2 diabetes mellitus (T2DM), submission of medical records (e.g., chart notes) confirming diagnosis of T2DM, OR b) Submission of medical records (e.g., chart notes) confirming diagnosis of T2DM as evidenced by one of the following laboratory values: i) A1c greater than or equal to 6.5%, ii) fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, or iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# RYDAPT (S)

**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): Newly diagnosed acute myeloid leukemia (AML), FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. 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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SABRIL (S)

## Products Affected

- Vigabatrin
- Vigadrone
- Vigpoder

| 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. Failure, contraindication, or intolerance to two formulary anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)]. Infantile Spasms (IS): Diagnosis of infantile spasms. |
| **Age Restrictions** | IS: 1 month to 2 years of age. CPS: 2 years or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# SANDOSTATIN (S)

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acromegaly (initial): Diagnosis of acromegaly. One of the following: A) Inadequate response to surgical resection and/or pituitary irradiation OR B) Patient is not a candidate for surgical resection or pituitary irradiation. Trial and failure, contraindication or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses (initial, reauth): 12 months |
| **Other Criteria** | Acromegaly (reauth): Patient demonstrates positive clinical response to therapy. Carcinoid tumor (reauth): Patient has improvement in number of diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (reauth): Patient has improvement in number of diarrhea episodes. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# SCEMBLIX (S)

## 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+). Disease is in chronic phase. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SCIG (S)

**Products Affected**

- Hizentra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Medication is being used subcutaneously. Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) OR one of the following FDA-approved or literature supported diagnoses: 1) Common variable immunodeficiency (CVID), OR 2) Congenital agammaglobulinemia (X-linked or autosomal recessive), OR 3) Severe combined immunodeficiencies (SCID), OR 4) Wiskott-Aldrich syndrome, OR 5) Other primary immunodeficiency with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). |
| **Age Restrictions** | Primary immunodeficiency (Hyqvia only) (initial): Patient is 2 years of age or older. |
| **Prescriber Restrictions** | All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on SCIG therapy (e.g., immunologist, hematologist, neurologist). |
| **Coverage Duration** | Initial, reauth: 12 months |
| **Other Criteria** | Subject to Part B vs. Part D review. Patient does not meet criteria for Part B or patient is in a long-term care facility. All uses (reauth): Patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy. |

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

# SIGNIFOR (S)

**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 (initial): Diagnosis of Cushing’s disease. One of the following: a) Pituitary surgery has not been curative for the patient or b) Patient is not a candidate for pituitary surgery. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Cushing's disease (initial, reauth): 12 months |
| **Other Criteria** | Cushing's disease (reauth): Patient demonstrates positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SKYCLARYS (S)

**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** | Initial: Patient is 16 years of age or older. |
| **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: 12 months. |
| **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 (S)

## 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 moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, OR palmoplantar (ie, palms, soles), facial, scalp, 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): 6 months, (reauth): 12 months |

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| **Other Criteria** | Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# SKYRIZI IV (S)

**Products Affected**

- Skyrizi INJ 600MG/10ML

| 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): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Will be administered as an intravenous induction dose. Ulcerative Colitis (UC): 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. Will be administered as an intravenous induction dose. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | UC, CD: Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | UC, CD: 3 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SOMAVERT (S)

## 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. One of the following: 1) failure to one of the following: surgery, radiation therapy, or other medical therapies (such as dopamine agonists [e.g., bromocriptine, cabergoline]) or 2) not a candidate for one of the following: surgery, radiation therapy, or dopamine agonist (e.g., 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). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Acromegaly (initial): Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Initial and reauth: 12 months |
| **Other Criteria** | Acromegaly (reauth): Patient has experienced a positive clinical response to therapy (biochemical control, decrease or normalization of IGF-1 levels). |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# SPEVIGO (S)

## Products Affected

- Spevigo INJ 150MG/ML, 300MG/2ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of generalized pustular psoriasis (GPP) as defined by primary, sterile, macroscopically visible pustules (excluding cases where pustulation is restricted to psoriatic plaques). Subcutaneous formulation will not be used to treat GPP flare. Patient weighs at least 40kg. |
| **Age Restrictions** | Initial: Patient is 12 years of age or older. |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with a dermatologist. |
| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SPRAVATO (S)

## Products Affected

- Spravato 56mg Dose
- Spravato 84mg Dose

| 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) Both of the following: 1) Diagnosis of major depressive disorder and 2) Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode OR B) All of the following: 1) Diagnosis of major depressive disorder, 2) Patient has both of the following: a) depressive symptoms and b) acute suicidal ideation or behavior, and 3) Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a psychiatrist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SPRYCEL (S)

## Products Affected

- Dasatinib

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Philadelphia chromosome positive (Ph+)/BCR ABL chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML. Ph+/BCR ABL acute lymphoblastic leukemia (ALL): Diagnosis of Ph+/BCR ABL ALL. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All Uses: 12 months |
| **Other Criteria** | All Uses: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# STELARA (IV) (S)

**Products Affected**

- Stelara INJ 130MG/26ML

| 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): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Ulcerative Colitis (UC): 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. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | One time |
| **Other Criteria** | Stelara is to be administered as an intravenous induction dose. Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# STELARA (S)

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion 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): 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 - 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): 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. All indications (initial): Trial of either Steqeyma or Wezlana. |
| **Age Restrictions** | Plaque psoriasis, PsA (Initial): Patient is 6 years of age or older. |
| **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 uses (Initial): 6 months. All uses (reauth): 12 months |

| | |
|---|---|
| **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. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD (Reauth), UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# STEQEYMA (S)

## 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): 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 - 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): 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. Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction dose. |
| **Age Restrictions** | Plaque psoriasis, PsA (Initial): Patient is 6 years of age or older. |
| **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): 6 months. All uses (Reauth): 12 months. |

| | |
|---|---|
| **Other Criteria** | PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# STEQEYMA IV (S)

**Products Affected**

- Steqeyma INJ 130MG/26ML

| 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): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Ulcerative Colitis (UC): 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. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | One time |
| **Other Criteria** | Will be administered as an intravenous induction dose. Induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# STIVARGA (S)

**Products Affected**

- Stivarga

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Metastatic colorectal cancer (mCRC): Diagnosis of mCRC. Gastrointestinal stromal tumor (GIST): Diagnosis of locally advanced, unresectable or metastatic GIST. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# STRENSIQ (S)

**Products Affected**

- Strensiq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Hypophosphatasia (initial): Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia. One of the following: 1) Both of the following: a) Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age and gender-adjusted normal range AND b) Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level]) OR 2) Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing. For patients requesting the 80 mg/0.8 mL vial only: Patient's weight is greater than or equal to 40 kg. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Hypophosphatasia (initial, reauth): Prescribed by a specialist experienced in the treatment of inborn errors of metabolism or an endocrinologist |
| **Coverage Duration** | Hypophosphatasia (initial): 6 months, (reauth): 12 months |
| **Other Criteria** | Hypophosphatasia (reauth): Patient demonstrates positive clinical response to therapy. For patients requesting the 80 mg/0.8 mL vial only: Patient's weight is greater than or equal to 40 kg. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SUCRAID (S)

## Products Affected

- Sucraid

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Congenital Sucrase-Isomaltase Deficiency (CSID) (initial): Diagnosis of sucrase deficiency (which is part of congenital sucrose-isomaltase deficiency [CSID]). |
| **Age Restrictions** | CSID (initial): Patient is 5 months of age or older. |
| **Prescriber Restrictions** | CSID (initial): Prescribed by or in consultation with a gastroenterologist or geneticist. |
| **Coverage Duration** | CSID (initial, reauth): 12 months. |
| **Other Criteria** | CSID (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# SUTENT (S)

**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** | Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma. Gastrointestinal stromal tumor (GIST): Diagnosis of GIST after disease progression on, or contraindication or intolerance to Gleevec (imatinib). Pancreatic neuroendocrine tumors: Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumor that is unresectable locally advanced or metastatic disease. Adjuvant treatment of renal cell carcinoma: Diagnosis of renal cell carcinoma (RCC). Used as adjuvant therapy. Patient is at high risk of recurrent RCC following nephrectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All Indications: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# SYPRINE (S)

## Products Affected

- Trientine Hydrochloride CAPS 250MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration). Trial and failure, contraindication, or intolerance to a penicillamine product (e.g., Depen, Cuprimine) |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TABRECTA (S)

**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). Disease is metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TAFAMIDIS (S)

**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) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), 2) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits, OR 3) Both of the following: i) echocardiogram or cardiac magnetic resonance imaging or scintigraphy scan suggestive of amyloidosis, and ii) absence of light-chain amyloidosis. Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure. Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Diflunisal). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist |
| **Coverage Duration** | ATTR-CM (initial, reauth): 12 months |
| **Other Criteria** | ATTR-CM (reauth): Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure. Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Diflunisal). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TAFINLAR (S)

**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 or metastatic melanoma AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR both of the following: cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and medication is used in combination with Mekinist (trametinib). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 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): Diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Mekinist (trametinib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic anaplastic thyroid cancer. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Mekinist (trametinib) . |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Mekinist (trametinib). Low-grade Glioma: Diagnosis of low-grade glioma. Patient requires systemic therapy. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Mekinist (trametinib). |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TAGRISSO (S)

**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): One of the following: A) All of the following: Diagnosis of metastatic NSCLC. One of the following: 1) Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), OR 2) Both of the following: a) Patient has known active EGFR T790M mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and b) Patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib), or Vizimpro (dacomitinib). OR B) All of the following: Diagnosis of NSCLC. Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Both of the following: 1) Patient is receiving as adjuvant therapy, and 2) Patient has had a complete surgical resection of the primary NSCLC tumor. OR C) All of the following: Diagnosis of NSCLC. Disease is locally advanced. Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. FDA-approved test or a test performed at a facility approved by CLIA. Used in combination with both of the following: a) Pemetrexed, and b) Platinum-based chemotherapy (e.g., cisplatin, carboplatin). Or D) Refer to Other Criteria element for additional indication and criteria. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | NSCLC cont: OR D) All of the following: Diagnosis of NSCLC. Disease is Locally advanced, Unresectable (Stage III). Presence of known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy. All indications: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TALZENNA (S)

**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. Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer (mCRPC). Disease is homologous recombination repair (HRR) gene-mutated. Taken in combination with Xtandi (enzalutamide). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TARCEVA (S)

**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): Diagnosis of locally advanced or metastatic (Stage III or IV) NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Pancreatic Cancer: Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer AND erlotinib will be used in combination with gemcitabine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All Indications: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TARGRETIN (S)

## 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 CTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [eg, corticosteroids {ie, clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}] or systemic therapies [eg, brentuximab vedotin, methotrexate]). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TASIGNA (S)

**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** | Chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TAVNEOS (S)

**Products Affected**

- Tavneos

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: a) Granulomatosis with polyangiitis (GPA) OR b) Microscopic polyangiitis (MPA). Diagnosis is confirmed by one of the following: a) ANCA test positive for proteinase 3 (PR3) antigen, b) ANCA test positive for myeloperoxidase (MPO) antigen, OR c) Tissue biopsy. Patient is receiving concurrent immunosuppressant therapy with one of the following: a) cyclophosphamide OR b) rituximab. One of the following: a) Patient is concurrently on glucocorticoids (e.g., prednisone) OR b) History of contraindication or intolerance to glucocorticoids (e.g., prednisone). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial, Reauth: Prescribed by or in consultation with one of the following, with shared decision-making regarding treatment risks: 1) nephrologist, 2) pulmonologist, or 3) rheumatologist. |
| **Coverage Duration** | Initial, Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient does not show evidence of progressive disease while on therapy. Patient is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab). |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TAZVERIK (S)

**Products Affected**

- Tazverik

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Epithelioid sarcoma: Diagnosis of epithelioid sarcoma. Disease is one of the following: metastatic or locally advanced. Patient is not eligible for complete resection. Follicular lymphoma: Diagnosis of follicular lymphoma. Disease is one of the following: relapsed or refractory. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TECFIDERA (S)

## Products Affected

- Dimethyl Fumarate CPDR
- Dimethyl Fumarate Starterpack CDPK 0

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS. |
| **Required Medical Information** | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial, reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (initial, reauth): 12 months |
| **Other Criteria** | MS (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TEPMETKO (S)

**Products Affected**

- Tepmetko

| 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 metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TERIPARATIDE (S)

## Products Affected

- Bonsity
- Forteo INJ 560MCG/2.24ML
- 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 uses (initial): 24 months. All uses (reauth): 12 months. |

| | |
|---|---|
| **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. |

# TESTOSTERONE (S)

## Products Affected

- Testosterone GEL 20.25MG/1.25GM, 25MG/2.5GM, 40.5MG/2.5GM, 50MG/5GM
- Testosterone Cypionate INJ 100MG/ML, 200MG/ML
- Testosterone Pump GEL 12.5MG/ACT, 20.25MG/ACT

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Gender Dysphoria (GD)/Gender Incongruence (off-label): Dx of GD/Gender Incongruence. Using hormones to change characteristics to align with gender expression. |
| **Age Restrictions** | Testosterone cypionate only: HG (init): 12 years of age or older. All other testosterone: HG (init): Patient is 18 years of age or older. |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reauth): 12 mo. GD: 12 mo. |
| **Other Criteria** | HG (Reauth): 1) Follow-up total serum T level within or below the normal limits of the reporting lab, or 2) Follow-up total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Follow-up calculated free or bioavailable T level within or below the normal limits of the reporting lab, or follow-up calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TESTOSTERONE ENANTHATE (S)

**Products Affected**

- Testosterone Enanthate INJ

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

| | |
|---|---|
| **Other Criteria** | HG (Reauth): 1) Follow-up total serum T level within or below the normal limits of the reporting lab, or 2) Follow-up total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Follow-up calculated free or bioavailable T level within or below the normal limits of the reporting lab, or follow-up calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TEVIMBRA (S)

**Products Affected**

- Tevimbra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Esophageal Squamous Cell Carcinoma: Diagnosis of esophageal squamous cell carcinoma. Disease is unresectable or metastatic. One of the following: 1) Both of the following: a) Patient has received prior systemic chemotherapy and b) Patient has not previously been treated with a PD-(L)1 inhibitor (e.g., Keytruda, Opdivo) OR 2) Used in combination with platinum-containing chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin). Gastric or Gastroesophageal Junction Adenocarcinoma: Diagnosis of gastric or gastroesophageal junction adenocarcinoma. Disease is unresectable or metastatic. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Tumor(s) express PD-L1 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with platinum (e.g., carboplatin, cisplatin, oxaliplatin) and fluoropyrimidine (e.g., fluorouracil)-based chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# THALOMID (S)

**Products Affected**

- Thalomid

| 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. Used in combination with dexamethasone, unless the patient has an intolerance to steroids. Erythema nodosum leprosum (ENL): Diagnosis of moderate to severe ENL with cutaneous manifestations. Thalomid is not used as monotherapy if moderate to severe neuritis is present. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TIBSOVO (S)

**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. Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. One of the following: 1) patient is greater than or equal to 75 years old OR 2) patient has comorbidities that preclude use of intensive induction chemotherapy. Locally Advanced or Metastatic Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is locally advanced or metastatic. Patient has been previously treated. Relapsed or Refractory Myelodysplastic Syndromes: Diagnosis of myelodysplastic syndromes (MDS). Disease is relapsed or refractory. All indications: Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TOPICAL RETINOID (S)

**Products Affected**

- Tretinoin CREA 0.025%, 0.05%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne). |
| **Age Restrictions** | PA applies to members 26 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TORPENZ (S)

**Products Affected**

- Torpenz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. Renal cell carcinoma: Diagnosis of advanced renal cell carcinoma AND trial and failure, contraindication, or intolerance to SUTENT (sunitinib) or NEXAVAR (sorafenib). Neuroendocrine tumors of pancreatic origin (pNET): Diagnosis of progressive pNET that are unresectable, locally advanced, or metastatic. Renal angiomyolipoma: Diagnosis of renal angiomyolipoma and TSC. Breast Cancer: Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole). Neuroendocrine tumors of gastrointestinal (GI) or lung origin: Diagnosis of progressive, well-differentiated, non-functional NET of GI or lung origin AND patient has unresectable, locally advanced or metastatic disease. |
| **Age Restrictions** | SEGA associated with TSC: Patient is 1 year of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All Indications: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TRELSTAR (S)

## Products Affected

- Trelstar Mixject INJ 11.25MG, 22.5MG

| 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 advanced or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to any brand Lupron formulation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TREMFYA INTRAVENOUS (S)

**Products Affected**

- Tremfya INJ 200MG/20ML

| 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): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, C-reactive protein [CRP]), OR CD Activity Index (CDAI) greater than 220. Will be administered as an intravenous induction dose. Ulcerative Colitis (UC): 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, erythrocyte sedimentation rate [ESR], CRP), OR dependent on, or refractory to, corticosteroids. Will be administered as an intravenous induction dose. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | CD, UC: Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | CD, UC: 3 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TREMFYA SC (S)

## Products Affected

- Tremfya INJ 100MG/ML, 200MG/2ML
- Tremfya Induction Pack For Crohns Disease/ulcerative Colitis
- Tremfya 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 moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, OR palmoplantar (ie, palms, soles), facial, scalp, 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. One of the following: a) Will be used as a maintenance dose following the intravenous induction doses, OR b) Both of the following: 1) Will be used as induction dosing, and 2) One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, C-reactive protein [CRP]), OR CD Activity Index (CDAI) greater than 220. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: a) Will be used as a maintenance dose following the intravenous induction doses, OR b) Both of the following: 1) Will be used as induction dosing, and 2) 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. |
| **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): 6 months, (reauth): 12 months |
| **Other Criteria** | Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TRIKAFTA (S)

**Products Affected**

- Trikafta TBPK 100MG; 0; 50MG

| 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. Presence of at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). CFTR mutation is responsive based on clinical and/or in vitro data OR CFTR mutation results in the production of CFTR protein. |
| **Age Restrictions** | CF (initial): For granule packets: patient is at least 2 to less than 6 years of age. For tablets: patient is 6 years of age or older. |
| **Prescriber Restrictions** | CF (initial): Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center. |
| **Coverage Duration** | CF (initial, reauth): 12 months |
| **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. |

# TRULICITY (S)

**Products Affected**

- Trulicity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: One of the following: a) For patients requiring ongoing treatment for type 2 diabetes mellitus (T2DM), submission of medical records (e.g., chart notes) confirming diagnosis of T2DM, OR b) Submission of medical records (e.g., chart notes) confirming diagnosis of T2DM as evidenced by one of the following laboratory values: i) A1c greater than or equal to 6.5%, ii) fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, or iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TRUQAP (S)

**Products Affected**

- Truqap

| 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: locally advanced or metastatic. Will be taken in combination with fulvestrant. Disease is hormone receptor (HR)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Patient has one or more PIK3CA/AKT1/PTEN-alterations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). One of the following: A) Following progression on at least one endocrine-based regimen in the metastatic setting (e.g., anastrozole, letrozole, exemestane, tamoxifen, etc.) OR B) Recurrence on or within 12 months of completing adjuvant therapy (e.g., chemotherapy). Prostate Cancer: Diagnosis of prostate cancer. Disease is metastatic. Used in combination with abiraterone and prednisone. Disease is androgen pathway modulation-naïve or -sensitive (mAPMN/S). Tumor is PTEN deficient as detected by a FDA approved test or a test performed at a facility approved by Clinical Laboratory Amendments. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All indications: 12 months |
| **Other Criteria** | All indications: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TRYNGOLZA (S)

**Products Affected**

- Tryngolza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Familial Chylomicronemia syndrome (FCS) (Initial): Diagnosis of FCS (type 1 hyperlipoproteinemia). One of the following: a) Genetic confirmation of biallelic pathogenic variants in FCS-causing genes (i.e., LPL, GPIHBP1, APOA5, APOC2, or LMF1), b) A North American FCS (NAFCS) Score of greater than or equal to 45, or c) A Moulin score greater than 10. Baseline fasting triglyceride levels are greater than or equal to 880 mg/dL prior to treatment with requested drug. Severe hypertriglyceridemia (Initial): Diagnosis of severe hypertriglyceridemia. Baseline fasting triglyceride levels prior to treatment with requested drug are greater than or equal to 500 mg/dL. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | All uses (Initial): Prescribed by or in consultation with a cardiologist, endocrinologist, gastroenterologist, or lipid specialist (lipidologist). |
| **Coverage Duration** | All uses (Initial, Reauth): 12 months. |
| **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. |

# TUKYSA (S)

**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 received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TURALIO (S)

**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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TYENNE SC (S)

**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: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. TF/C/I to one of the following conventional therapies at maximally tolerated doses: minimum duration of a one month trial of a nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen), minimum duration of a 3-month trial of methotrexate, or minimum duration of a 2-week trial of a systemic glucocorticoid (eg, prednisone). Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: a) TF/C/I to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq/LQ, or Xeljanz (tofacitinib), OR b) for continuation of prior therapy. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (Initial): Diagnosis of SSc-ILD as documented by the following: a) Exclusion of other known causes of ILD AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD, OR ii) In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | RA, GC, SJIA, PJIA (initial): Prescribed by or in consultation with a rheumatologist. SSc-ILD (initial): Prescribed by or in consultation with a pulmonologist or rheumatologist. |
| **Coverage Duration** | RA, GC, SJIA, PJIA, SSc-ILD (initial): 6 months, (reauth): 12 months |
| **Other Criteria** | RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. SJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in clinical features or symptoms (eg, pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline. GC, SSc-ILD (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# TYKERB (S)

## 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: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer. Disease is one of the following: advanced, metastatic, or recurrent. Used in combination with one of the following: Trastuzumab, Xeloda (capecitabine), or aromatase inhibitors [eg, Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# TYMLOS (S)

**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** | 24 months (max 24 months of therapy per lifetime) |

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

# UBRELVY (S)

**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** | Initial: 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient has experienced a positive response to therapy. Will not be used for preventive treatment of migraine. Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# UDENYCA (S)

**Products Affected**

- Udenyca

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

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

# UDENYCA ONBODY (S)

**Products Affected**

- Udenyca Onbody

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of FN (off-label): Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | All uses: Prescribed by or in consultation with a hematologist/oncologist |
| **Coverage Duration** | FN (prophylaxis, treatment): 3 mo or duration of tx. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# USTEKINUMAB (S)

## Products Affected

- Ustekinumab 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): 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 - 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): 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. 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 (initial): Trial of either Steqeyma or Wezlana. |
| **Age Restrictions** | Plaque psoriasis, PsA (Initial): Patient is 6 years of age or older. |
| **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): 6 months. All uses (Reauth): 12 months. |
| **Other Criteria** | PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# VALCHLOR (S)

**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) (initial): All 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 [e.g., clobetasol, fluocinonide], bexarotene topical gel [Targretin topical gel], etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# VANFLYTA (S)

**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. Patient has a FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (FLT3-ITD) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Both of the following: a) Used in combination with standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin) induction and cytarabine consolidation, and b) Used as maintenance monotherapy following consolidation chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VENCLEXTA (S)

## 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): Diagnosis of newly diagnosed AML. Used in combination with azacitidine, or decitabine, or low-dose cytarabine. One of the following: 1) age 75 years or older OR 2) comorbidities that preclude use of intensive induction chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VENTAVIS (S)

## Products Affected

- Ventavis

| 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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH (Initial): 6 months. (Reauth): 12 months |
| **Other Criteria** | Subject to Part B vs D review. PAH (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VEOPOZ (S)

**Products Affected**

- Veopoz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of active CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease. Patient has a confirmed genotype of biallelic CD55 loss-of-function mutation. Patient has hypoalbuminemia (serum albumin concentration of less than or equal to 3.2 g/dL). Patient has at least one of the following signs or symptoms within the last six months: abdominal pain, diarrhea, peripheral edema, or facial edema. |
| **Age Restrictions** | Initial: Patient is 1 year of age or older. |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with an immunologist, geneticist, hematologist, or gastroenterologist. |
| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VEOZAH (S)

**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: 1) If patient has been on therapy for less than 9 months, provider attests to 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, or 2) If patient has been on therapy for greater than or equal to 9 months, provider attests to both of the following: a) No hepatic issues arose during the first 9 months of therapy, and b) Patient does not currently have any hepatic related issues (e.g., signs or symptoms of hepatic strain). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VERQUVO (S)

**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): 12 months |
| **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 (S)

**Products Affected**

- Verzenio

| 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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VIGAFYDE (S)

**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** | Patient is 1 month to 2 years of age. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# VITRAKVI (S)

**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. One of the following: 1) Diagnosis of secretory breast cancer, mammary analogue secretory cancer (MASC), congenital mesoblastic nephroma (CMN), or infantile fibrosarcoma, or 2) Both of the following: i) Disease is confirmed by the presence of neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and ii) Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]. Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy) OR Disease has no satisfactory alternative treatments. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# VIZIMPRO (S)

**Products Affected**

- Vizimpro

| 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 metastatic. Disease is positive for one of the following epidermal growth factor receptor (EGFR) mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA): exon 19 deletion or exon 21 L858R substitution. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VONJO (S)

**Products Affected**

- Vonjo

| 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) Primary myelofibrosis, b) Post-polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Pre-treatment platelet count below 50 x 10^9/L. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VOQUEZNA (S)

## 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 inadequate response, contraindication, or intolerance to TWO of the following generic PPIs: a) omeprazole, b) esomeprazole, c) pantoprazole, d) lansoprazole, e) rabeprazole, or f) dexlansoprazole. 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 inadequate response, contraindication, or intolerance to TWO of the following generic PPIs: a) omeprazole, b) esomeprazole, c) pantoprazole, d) lansoprazole, e) rabeprazole, or f) dexlansoprazole. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | H. pylori, NERD: 1 mo. HRH: 2 months. MHRH: 6 mos. |

| | |
|---|---|
| **Other Criteria** | Relief of Heartburn associated with Non-Erosive Gastroesophageal Reflux Disease (NERD): 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 inadequate response, contraindication, or intolerance to TWO of the following generic PPIs: a) omeprazole, b) esomeprazole, c) pantoprazole, d) lansoprazole, e) rabeprazole, or f) dexlansoprazole. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# VORANIGO (S)

**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 a susceptible 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** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VORICONAZOLE INJECTION (S)

**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 (S)

**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 not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine, Liver transplant specialist. |
| **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 (S)

## Products Affected

- Pazopanib Hydrochloride

| 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 advanced/metastatic RCC. Soft tissue sarcoma: Diagnosis of advanced soft tissue sarcoma. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VOWST (S)

**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 two 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** | Patient is 18 years of age or older. |
| **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. |

# VUMERITY (S)

**Products Affected**

- Vumerity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS. |
| **Required Medical Information** | MS (initial): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Teriflunomide, 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial, reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (initial, reauth): 12 months |
| **Other Criteria** | MS (reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# VYJUVEK (S)

**Products Affected**

- Vyjuvek

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of dystrophic epidermolysis bullosa (DEB). Patient has mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene. Medication is being used for the treatment of wounds that require healing. One of the following: a) Medication will be applied by a healthcare professional or b) Patient or caregiver has received training for the application of Vyjuvek. Wound(s) being treated has no signs of infection. Medication is not being used concurrently with other FDA approved therapies (e.g., Filsuvez) for the treatment of epidermolysis bullosa. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial, Reauth: Prescribed by or in consultation with a dermatologist or specialist with expertise in wound care. |
| **Coverage Duration** | Initial, Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. Wound(s) being treated has no signs of infection. Medication is not being used concurrently with other FDA approved therapies (e.g., Filsuvez) for the treatment of epidermolysis bullosa. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# VYVGART (S)

**Products Affected**

- Vyvgart Hytrulo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Generalized myasthenia gravis (gMG) (Initial): Diagnosis of gMG. One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus), or 2) TF/C/I to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus), and TF/C/I to chronic plasmapheresis/plasma exchange (PE) or intravenous immunoglobulin (IVIG). Chronic inflammatory demyelinating polyneuropathy (CIDP) (Only applies for Vyvgart Hytrulo) (Initial): Diagnosis of CIDP as confirmed by all of the following: 1) Progressive symptoms present for at least 2 months, 2) Symptomatic polyradiculoneuropathy as indicated by one of the following: a) Progressive or relapsing motor impairment of more than one limb OR b) Progressive or relapsing sensory impairment of more than one limb. Trial and failure, contraindication, or intolerance to one of the following standard of care treatments: corticosteroids (minimum 3 month trial duration), immunoglobulin, or plasma exchange. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | gMG (Initial): Prescribed by or in consultation with a neurologist. CIDP (Initial, Reauth): Prescribed by or in consultation with an immunologist, neurologist, or hematologist. |
| **Coverage Duration** | gMG (Initial, Reauth): 12 months. CIDP (Initial): 6 months, (Reauth): 12 months. |
| **Other Criteria** | gMG, CIDP (Reauth): Patient demonstrates positive clinical response to therapy. |

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

# WELIREG (S)

**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 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 Monotherapy: Diagnosis of advanced renal cell carcinoma. Disease has progressed after treatment with both of the following: a) One of the following: i) Programmed death receptor-1 (PD-1) inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab)], or ii) Programmed death-ligand 1 (PD-L1) inhibitor [e.g., Bavencio (avelumab), Imfinzi (durvalumab)], and b) Vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) [e.g., Votrient (pazopanib), Inlyta (axitinib)]. Pheochromocytoma or Paraganglioma (PPGL): Diagnosis of Pheochromocytoma or Paraganglioma (PPGL). Disease is one of the following: a) locally advanced, b) unresectable, or c) metastatic. Renal Cell Carcinoma with a Clear Cell Component (ccRCC): Diagnosis of ccRCC. Used in combination with one of the following: a) pembrolizumab, or b) pembrolizumab and berahyaluronidase alfa-pmph. One of the following: a) Patient is at intermediate-high or high risk of recurrence following nephrectomy, or b) Used following nephrectomy and resection of metastatic lesions. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

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

# WEZLANA (S)

## Products Affected

- Wezlana 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): 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 - 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): 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** | Plaque psoriasis, PsA (Initial): Patient is 6 years of age or older. |
| **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): 6 months. All uses (Reauth): 12 months. |

| | |
|---|---|
| **Other Criteria** | PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# WEZLANA IV (S)

**Products Affected**

- Wezlana INJ 130MG/26ML

| 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): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Ulcerative Colitis (UC): 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. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | One time |
| **Other Criteria** | Will be administered as an intravenous induction dose. Induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# WINREVAIR (S)

## 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) (Initial): 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) Endopthelin receptor antagonists (ie, Bosentan, ambrisentan or macitentan) and b) Phosphodiesterase 5 inhibitors (ie, Tadalafil or sildenafil). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | PAH (Reauth): Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# WYOST (S)

**Products Affected**

- Wyost

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Skeletal prevention in Multiple Myeloma (MM)/Bone Metastasis from Solid Tumors (BMST): One of the following: 1) Both of the following: a) Diagnosis of multiple myeloma and b) Trial and failure, contraindication (e.g., renal insufficiency), or intolerance to one bisphosphonate therapy, OR 2) Both of the following: a) Diagnosis of solid tumors (e.g., breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) and b) Documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Diagnosis of giant cell tumor of bone. One of the following: 1) One of the following: a) tumor is unresectable or b) surgical resection is likely to result in severe morbidity, OR 2) Approve for continuation of prior therapy. Hypercalcemia of malignancy (HCM): Diagnosis of hypercalcemia of malignancy. Trial and failure, contraindication, or intolerance to one bisphosphonate therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | MM/BMST, GCTB, HCM: 12 months. |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# XALKORI (S)

**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 metastatic NSCLC AND One of the following: A) Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) or B) Patient has ROS1 rearrangement-positive tumor as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Anaplastic Large Cell Lymphoma (ALCL): Diagnosis of systemic ALCL. Disease is relapsed or refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Inflammatory Myofibroblastic Tumor (IMT): Diagnosis of IMT. Disease is one of the following: a) unresectable, b) recurrent, or c) refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | IMT, ALCL: Patient is 1 year of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

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

# XATMEP (S)

**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): Diagnosis of polyarticular juvenile idiopathic arthritis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | pJIA: Prescribed by or in consultation with a rheumatologist. |
| **Coverage Duration** | ALL, pJIA: 12 months. |
| **Other Criteria** | Subject to Part B vs D review. Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# XCOPRI (S)

**Products Affected**

- Xcopri

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of partial onset seizures. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# XELJANZ (S)

## Products Affected

- Tofacitinib Citrate SOLN
- Tofacitinib Citrate TABS
- Tofacitinib Citrate Er
- Xeljanz
- Xeljanz Xr

| 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 and solution/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 (e.g., 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 (initial): 6 mo, (reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo. |
| **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): Not used in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (eg, azathioprine, cyclosporine). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. RA, PsA, AS, PJIA (reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. 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. |

# XENAZINE (S)

**Products Affected**

- Tetrabenazine

| 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 (HD) (Initial): Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia (Initial): 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 (Initial): Patient has tics associated with Tourette's syndrome. Trial and failure, contraindication, or intolerance to Haldol (haloperidol). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | HD (Initial): Prescribed by or in consultation with a neurologist. Tardive dyskinesia, Tourette's syndrome (Initial): Prescribed by or in consultation with neurologist or psychiatrist. |
| **Coverage Duration** | Initial, Reauth: 12 months. |
| **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. |

# XERMELO (S)

**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 [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) 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: 12 months |
| **Other Criteria** | Carcinoid syndrome diarrhea (Reauthorization): Patient demonstrates positive clinical response to therapy AND drug will continue to be used in combination with SSA therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# XIFAXAN (S)

**Products Affected**

- Xifaxan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Travelers' diarrhea (TD): Diagnosis of travelers' diarrhea. One of the following: a) Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR b) resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin). Prophylaxis (ppx) of hepatic encephalopathy (HE) recurrence (initial): Used for the prophylaxis of hepatic encephalopathy recurrence, AND One of the following: 1) Trial and failure, contraindication or intolerance to lactulose or 2) Add-on treatment to lactulose. Treatment (tx) of HE: Used for the treatment of HE. One of the following: 1) Trial and failure, contraindication, or intolerance to lactulose or 2) Add-on treatment to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (initial): Diagnosis of IBS-D, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | TD: 14 days. HE (tx): 12 months. HE (ppx) (init, reauth): 12 months. IBS-D (init, reauth): 2 weeks. |
| **Other Criteria** | Prophylaxis of HE recurrence (reauth): Patient demonstrates positive clinical response to therapy. IBS-D (reauth): Symptoms of IBS continue to persist. Patient demonstrates positive clinical response to therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# XOLAIR (S)

**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 (init): Diagnosis of moderate to severe persistent allergic asthma. Positive skin test or in vitro reactivity to a perennial aeroallergen. 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) Pretreatment serum immunoglobulin (Ig)E 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: i) Both of the following: 1) Medium-dose inhaled corticosteroid [ICS] (eg, greater than 100-200 mcg fluticasone propionate equivalent/day), and 2) 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 B) All of the following: a) Patient is 12 years of age or older, b) 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: i) Both of the following: 1) High-dose ICS [eg, greater than 500 mcg fluticasone propionate equivalent/day], and 2) Additional asthma controller medication (eg, LTRA [eg, montelukast], LABA [eg, salmeterol], LAMA [eg, tiotropium]), OR ii) One maximally-dosed combination ICS/LABA product [eg, Wixela Inhub (fluticasone propionate 500mcg/salmeterol 50mcg), budesonide 160mcg/ formoterol 4.5mcg, Breo Ellipta (fluticasone 200mcg/vilanterol 25mcg)]. |
| **Age Restrictions** | IgE-Mediated Food Allergy (init): Patient is 1 year of age or older. |

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| **Prescriber Restrictions** | Asthma (init): Prescribed by or in consultation with an allergist/immunologist, or pulmonologist. CSU (init): Prescribed by or in consultation with an allergist/immunologist, or dermatologist. CRSwNP (init/reauth): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist. IgE-Mediated Food Allergy (Init/Reauth): Prescribed by or in consultation with an allergist/immunologist. |
| **Coverage Duration** | Asthma, CSU, Allergy (init, reauth): 12 months. CRSwNP: 12 months. |
| **Other Criteria** | Asthma (reauth): Patient demonstrates positive clinical response to therapy. Chronic Spontaneous Urticaria (CSU) (init): Diagnosis 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. Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines. CSU (reauth): Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment. Patient has experienced one or both of the following: Reduction in itching severity from baseline or Reduction in the number of hives from baseline. Chronic Rhinosinusitis with Nasal polyps (CRSwNP) (init): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to an intranasal corticosteroid (eg, fluticasone, mometasone). Used in combination with another agent for chronic rhinosinusitis with nasal polyps. CRSwNP (reauth): Patient demonstrates positive clinical response to therapy. Used in combination with another agent for chronic rhinosinusitis with nasal polyps. 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 (greater than or equal to 6 kUA/L), 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 tx) 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. Used in conjunction with food allergen avoidance. Dosing will continue to be based on body weight and pretreatment total IgE serum levels. |

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

# XOLREMDI (S)

**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 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has an absolute neutrophil count (ANC) less than 500 cells/µL. |
| **Age Restrictions** | Initial: Patient is 12 years of age or older. |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with one of the following: immunologist, hematologist, geneticist, dermatologist, or allergist. |
| **Coverage Duration** | Initial: 6 months, Reauth: 12 months |
| **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 (S)

**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). Disease is relapsed or refractory. Patient has a FMS-like tyrosine kinase (FLT3) mutation as determined by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# XPOVIO (S)

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of Multiple Myeloma. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# XTANDI (S)

**Products Affected**

- Xtandi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Castration-resistant prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) prostate cancer. Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of metastatic castration-sensitive prostate cancer. Non-metastatic castrion-sensitive prostate cancer (nm-CSPC): Diagnosis of non-metastatic castration-sensitive prostate cancer (nmCSPC). Patient has high-risk biochemical recurrence (BCR) defined by a PSA doubling time less than or equal to 9 months and one of the following: A) PSA values greater than or equal to 1 ng/mL if the patient had prior prostatectomy (with or without radiotherapy) OR B) PSA values at least 2 ng/mL above the nadir if the patient had prior radiotherapy only. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# XYREM (S)

**Products Affected**

- Sodium Oxybate

| 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 one of the following: 1) amphetamine-based stimulant (eg, amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant. |
| **Age Restrictions** | All Indications (initial): Patient is 7 years of age or older. |
| **Prescriber Restrictions** | All uses (initial): Prescribed by or in consultation with one of the following: neurologist, psychiatrist, or sleep medicine specialist. |
| **Coverage Duration** | All uses (initial): 6 months. All uses (reauth): 12 months |
| **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. |

# YONSA (S)

**Products Affected**

- Yonsa

| 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 castration-resistant (chemical or surgical) prostate cancer. Trial and failure or intolerance to Xtandi (enzalutamide). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# YULITHIRA (S)

**Products Affected**

- Yulithira

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. Renal cell carcinoma: Diagnosis of advanced renal cell carcinoma. Trial and failure, contraindication, or intolerance to Sutent (sunitinib) or Nexavar (sorafenib). Neuroendocrine tumors of pancreatic origin (pNET): Diagnosis of progressive pNET. Disease is unresectable, locally advanced, or metastatic. Renal angiomyolipoma: Diagnosis of renal angiomyolipoma and TSC. Breast cancer: Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer. Trial and failure, contraindication, or intolerance to Femara (letrozole) or Arimidex (anastrozole). Neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin: Diagnosis of progressive, well-differentiated, non-functional NET of GI or lung origin. Disease is unresectable, locally advanced, or metastatic. |
| **Age Restrictions** | SEGA associated with TSC: Patient is 1 year of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months. |
| **Other Criteria** | All uses: Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ZAVESCA (S)

## 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. Niemann-Pick disease type C (NPC) (off-label) (initial): Diagnosis of NPC. Requested drug will be used in combination with Miplyffa (arimoclomol). |
| **Age Restrictions** | Gaucher disease: Patient is 18 years of age or older. |
| **Prescriber Restrictions** | NPC (initial): Prescribed by or in consultation with a specialist knowledgeable in the treatment of Niemann-Pick disease type C. |
| **Coverage Duration** | Gaucher disease: 12 months. NPC (initial): 6 months, (reauth): 12 months. |
| **Other Criteria** | NPC (reauth): Patient demonstrates positive clinical response to therapy. Requested drug will be used in combination with Miplyffa (arimoclomol). |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ZEJULA (S)

**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** | Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ZELBORAF (S)

**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 melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (eg, cobas 4600 BRAFV600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 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** | 12 months |
| **Other Criteria** | All indications: Approve for continuation of therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ZENBEXUS (S)

**Products Affected**

- Zenbexus

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of multiple myeloma. Patient has received at least one prior line of therapy including both of the following: a) One proteasome inhibitor (e.g., bortezomib), and b) One immunomodulatory agent (e.g., pomalidomide, lenalidomide). Used in combination with both of the following: a) Darzalex (daratumumab) or Darzalex Faspro (daratumumab and hyaluronidase-fihj), and b) Dexamethasone. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ZOKINVY (S)

**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** | 12 months |
| **Other Criteria** | N/A |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ZOLINZA (S)

**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. Progressive, persistent or recurrent disease on or contraindication or intolerance to two systemic therapies (e.g., bexarotene, romidepsin, etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ZTALMY (S)

**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** | Patient is 2 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ZURZUVAE (S)

**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** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 14 days |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ZYDELIG (S)

**Products Affected**

- Zydelig

| 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): Diagnosis of CLL. Used in combination with Rituxan (rituximab). The patient has relapsed on at least one prior therapy (eg, purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab]). Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (eg, coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD]). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES require use of a prerequisite Part D drug. |

# ZYKADIA (S)

**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** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC that is metastatic or recurrent. Tumor is anaplastic lymphoma kinase (ALK)-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# ZYTIGA (PREFERRED) (S)

## Products Affected

- Abiraterone Acetate TABS 250MG, 500MG
- Abirtega

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Castration-Resistant Prostate Cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or recurrent prostate cancer. Castration-Sensitive Prostate Cancer (CSPC): Diagnosis of castration-sensitive prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CRPC, CSPC: 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |
| **Prerequisite Therapy Required** | Criteria DOES NOT require use of a prerequisite Part D drug. |

# PART B VERSUS PART D

## Products Affected

- Abelcet
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Aminosyn II INJ 107.6MEQ/L; 1490MG/100ML; 1527MG/100ML; 1050MG/100ML; 1107MG/100ML; 750MG/100ML; 450MG/100ML; 990MG/100ML; 1500MG/100ML; 1575MG/100ML; 258MG/100ML; 405MG/100ML; 447MG/100ML; 1083MG/100ML; 795MG/100ML; 50MEQ/L; 600MG/100ML; 300MG/100ML; 750MG/100ML, 993MG/100ML; 1018MG/100ML; 700MG/100ML; 738MG/100ML; 500MG/100ML; 300MG/100ML; 660MG/100ML; 1000MG/100ML; 1050MG/100ML; 172MG/100ML; 270MG/100ML; 298MG/100ML; 722MG/100ML; 530MG/100ML; 400MG/100ML; 200MG/100ML; 500MG/100ML
- Aminosyn-pf INJ 46MEQ/L; 698MG/100ML; 1227MG/100ML; 527MG/100ML; 820MG/100ML; 385MG/100ML; 312MG/100ML; 760MG/100ML; 1200MG/100ML; 677MG/100ML; 180MG/100ML; 427MG/100ML; 812MG/100ML; 495MG/100ML; 70MG/100ML; 512MG/100ML; 180MG/100ML; 44MG/100ML; 673MG/100ML
- Amphotericin B INJ
- Amphotericin B Liposome
- Aprepitant
- Astagraf XL
- Azathioprine TABS 50MG
- Budesonide SUSP
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclosporine CAPS
- Cyclosporine Modified
- Engerix-b
- Envarsus Xr
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Formoterol Fumarate NEBU
- Ganciclovir INJ 500MG, 500MG/10ML
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Heplisav-b
- Hyperhep B INJ 110UNIT/0.5ML
- Imovax Rabies (h.d.c.v.)
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU
- 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
- Pentamidine Isethionate INHALATION SOLR
- Plenamine INJ 147.4MEQ/L; 2.17GM/100ML; 1.47GM/100ML; 434MG/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 749MG/100ML; 1.04GM/100ML; 1.18GM/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 592MG/100ML; 749MG/100ML; 250MG/100ML; 39MG/100ML; 960MG/100ML

- Prehevbrio
- Prograf PACK
- Rabavert
- Recombivax Hb
- Sandimmune SOLN
- Sirolimus SOLN
- Sirolimus TABS
- Tacrolimus CAPS
- Tacrolimus Er
- Tobramycin NEBU 300MG/5ML
- Yupelri

## Details

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

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