people powered health plans

# 2021 PRIOR AUTHORIZATION CRITERIA

**UCare Individual & Family Plans**
**UCare Individual & Family Plans with M Health Fairview**

UCare requires your physician to get prior authorization for certain drugs. This means that you will need to get approval from UCare before you fill your prescriptions. If you don't get approval, UCare may not cover the drug.

Effective: 12/1/2021

U6497 (10/2021)

# Actemra

**Products Affected**

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Polymyalgia Rheumatica. |
| **Exclusion Criteria** | Concurrent Use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or Targeted Synthetic DMARD. Crohn's disease. COVID-19. |
| **Required Medical Information** | Diagnosis and other medications tried for the diagnosis provided |
| **Age Restrictions** | PJIA/SJIA - 2 years of age and older. All other conditions - 18 years of age and older. |
| **Prescriber Restrictions** | RA/PJIA/SJIA/PMR/GCA - Prescribed by or in consultation with a rheumatologist. ILD - Prescribed by or in consultation with a rheumatologist or a pulmonologist. |
| **Coverage Duration** | ILD - 1 yr. GCA/PMR - 6 mo. RA/SJIA - 3 mo. PJIA - 4 mo. Continuation - 1 yr. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Giant Cell Arteritis (GCA) - approve if pt has tried one systemic corticosteroid (e.g. prednisone). Interstitial Lung Disease Associated with Systemic Sclerosis (ILD) - approve if pt has elevated acute phase reactants (C-reactive protein (CRP) greater than 6 mg/mL, erythrocyte sedimentation rate (ESR) greater than 28 mm/h, or platelet count greater than 330 x 109/L), forced vital capacity (FVC) is greater than 55% of the predicted value, and diagnosis is confirmed by high-resolution computed tomography. Polyarticular Juvenile Idiopathic Arthritis (PJIA) - approve if the patient has tried a specific biologic DMARD (Humira, Enbrel, an infliximab product, or Simponi Aria) OR the pt has heart failure or a previously treated lymphoproliferative disorder. Rheumatoid Arthritis (RA) - approve if the patient has tried a specific biologic DMARD (Humira, Cimzia, Enbrel, an infliximab product, or Simponi) OR the pt has heart failure or a previously treated lymphoproliferative disorder. Systemic Juvenile Idiopathic Arthritis (SJIA) - approve if the patient has tried ONE other systemic agent for this condition (e.g., a corticosteroid, a conventional synthetic DMARD, or a 1-month trial of an NSAID). Polymyalgia Rheumatica (PMR) - approve if the patient has tried one systemic corticosteroid (e.g., prednisone). Continuation RA/PJIA - approve if patient has had a response to therapy, as determined by the prescriber AND pt has been taking Actemra for at least 90 days. Continuation ILD - approve if pt has experienced a beneficial response to therapy over the last year while receiving Actemra. Continuation for other conditions - approve if patient has had a response to therapy, as determined by the prescriber. |

# Aimovig

**Products Affected**

- AIMOVIG AUTOINJECTOR SUBCUTANEOUS AUTO-INJECTOR 140 MG/ML, 70 MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Combination use with other prophylactic CGRP agents. Acute treatment of migraines. Cluster headache. Hemiplegic migraine. |
| **Required Medical Information** | Diagnosis, number of migraine headaches per month, prior therapies tried |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Migraine Headache Prevention - Pt has 4 or more migraine headache days per month (prior to initiating a migraine-preventative medication), and has tried at least two prophylactic pharmacologic therapies from different classes (e.g., tricyclic antidepressant, beta-blocker) and had an inadequate response or adverse events, according to the prescriber. Pt must also have also tried triptan therapy, unless contraindicated according to the prescriber, unless pt is currently taking a CGRP inhibitor for migraine headache prevention and has had a significant clinical benefit from the medication as determined by the prescriber or the pt is switching from a different CGRP inhibitor for migraine headache prevention to Aimovig. |

# Ajovy

**Products Affected**

- AJOVY AUTOINJECTOR
- AJOVY SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Combination use with other prophylactic CGRP agents. Acute treatment of migraines. Cluster headache. |
| **Required Medical Information** | Diagnosis, number of migraine headaches per month, prior therapies tried |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Migraine Headache Prevention - Pt has 4 or more migraine headache days per month (prior to initiating a migraine-preventative medication), and has tried at least two prophylactic pharmacologic therapies from different classes (e.g., tricyclic antidepressant, beta-blocker) and had an inadequate response or adverse events, according to the prescriber. Pt must also have also tried triptan therapy, unless contraindicated according to the prescriber, unless pt is currently taking Ajovy for migraine headache prevention and has had a significant clinical benefit from the medication as determined by the prescriber or the pt is switching from a different CGRP inhibitor for migraine headache prevention to Ajovy. |

# Alecensa

**Products Affected**

- ALECENSA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indication not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | mutation results |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC) - approve if the pt has metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC. |

# Alunbrig

**Products Affected**

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLETS,DOSE PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Soft Tissue Sarcoma - Inflammatory Myofibroblastic Tumor (IMT) |
| **Exclusion Criteria** | |
| **Required Medical Information** | mutation results |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Metastatic NSCLC - Approve if pt has metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC as detected by an approved test. Soft Tissue Sarcoma - Inflammatory Myofibroblastic Tumor (IMT) - Approve if pt has IMT with ALK translocation. |

# Amifampridine

**Products Affected**

- FIRDAPSE
- RUZURGI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indication not otherwise excluded |
| **Exclusion Criteria** | History of seizures (initial therapy) |
| **Required Medical Information** | Diagnosis, seizure history, lab and test results |
| **Age Restrictions** | Firdapse - 18 years of age or older. Ruzurgi - 6 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a neuromuscular specialist (initial therapy) |
| **Coverage Duration** | Initial-3 months, Cont-1 year |
| **Other Criteria** | Initial therapy-Diagnosis confirmed by at least one electrodiagnostic study (e.g., repetitive nerve stimulation) OR anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing according to the prescribing physician. Continuation-patient continues to derive benefit (e.g., improved muscle strength, improvements in mobility) from Firdapse/Ruzurgi, according to the prescribing physician. |

# Ampyra

**Products Affected**

- *dalfampridine*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS. |
| **Coverage Duration** | Authorization will be for 3 years |
| **Other Criteria** | Used to improve mobility in a patient with MS. |

# Anabolic Steroids

**Products Affected**

- *oxandrolone*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Girls w/ Turner's Syndrome or Ullrich-Turner Syndrome (oxandrolone only), management of protein catabolism w/ burns or burn injury (oxandrolone only), AIDS wasting and cachexia. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months, unless otherwise specified. |
| **Other Criteria** | |

# Aranesp

**Products Affected**

- ARANESP (IN POLYSORBATE)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Anemia due to myelodysplastic syndrome (MDS). Anemia Associated with Myelofibrosis. |
| **Exclusion Criteria** | Anemia associated with cancer in pts not receiving myelosuppressive cancer chemotherapy. Anemia associated with AML, CML or other myeloid cancers. Anemia associated with radiotherapy for cancer. Athletic performance enhancement. Anemia due to acute blood loss. |
| **Required Medical Information** | |
| **Age Restrictions** | Anemia due to MDS - 18 years or older |
| **Prescriber Restrictions** | Anemia due to MDS/Anemia due to Myelofibrosis - prescribed by or in consultation with a hematologist or oncologist. |
| **Coverage Duration** | CKD on dialysis - 3 yrs. CKD/MDS - 1 yr. Chemo - 6 months. Myelofibrosis: 3 mo, cont - 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Anemia due to CKD on dialysis - approve. Anemia due to CKD not on dialysis - For pts 18 years of age or older, must have a hemoglobin less than 10 g/dL (less than 11.5 g/dL if already receiving an erythropoiesis-stimulating agent[ESA]). If less than 18 years of age, must have a hemoglobin equal to or less than 11 g/dL (equal to or less than 12 g/dL if already receiving an ESA). Pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to Chemotherapy - Approve if pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) OR has a serum erythropoietin level equal to or less than 500 mU/mL, is currently recieving myelosuppressive chemotherapy AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to MDS - Pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) OR has a serum erythropoietin level equal to or less than 500 mU/mL AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to Myelofibrosis - Pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) OR has a serum erythropoietin level equal to or less than 500 mU/mL AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. For pts already receiving an ESA, the pt has responded according to the prescriber as defined by a hemoglobin greater than 10 g/dL or an increase of greater than 2 g/dL. |

# Arcalyst

**Products Affected**

- ARCALYST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use with other biologic therapies for an inflammatory condition. COVID-19 |
| **Required Medical Information** | Diagnosis, genetic testing |
| **Age Restrictions** | CAPS/Pericarditis - 12 years and older |
| **Prescriber Restrictions** | CAPS - Prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist. IL-1 RA- Prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders. |
| **Coverage Duration** | CAPS/Pericard init- 3 mo. IL-1 RA init- 6 mo. Cont for CAPS/IL-1 RA- 3 yrs. Cont for Pericard- 1 yr. |
| **Other Criteria** | Cryopyrin-Associated Periodic Syndromes (CAPS) [Familial Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disease or chronic infantile neurological cutaneous and articular syndrome]- Initial - Approve. Deficiency of Interleukin-1 Receptor Antagonist (IL-1 RA)- Initial - approve if pt is greater than 10 kg (22 lbs) AND genetic testing has confirmed a mutation in the IL1RN gene and according to the prescriber, patient has demonstrated a clinical benefit with Kineret. Pericarditis - Approve if pt has recurrent pericarditis with a history of at least three episodes of pericarditits in the past AND pt is currently receiving standard treatment or standard treatment is contraindicated. Continuation for all - Approve it pt has responded to therapy, as determined by prescriber. |

# Arikayce

**Products Affected**

- ARIKAYCE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Cystic Fibrosis. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous medication history, sensitivity results |
| **Age Restrictions** | MAC - 18 years or older |
| **Prescriber Restrictions** | MAC - Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections. CF - prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | MAC Lung disease - Approve if pt has completed greater than or equal to 6 consecutive months of a background multidrug regimen AND has a positive sputum culture for Mycobacterium avium complex (within the past 3 months, taken after completion of 6 months of therapy) which is susceptible to amikacin with a minimum inhibitor concentration (MIC) of less than 64 µg/mL AND Arikayce will be used in conjunction to a background multidrug regimen. MAC Continuation - Approve if Arikayce will be used in conjunction with a background multidrug regimen AND pt has not achieved negative sputom cultures for at least 12 months (will be approved up to 12 months as needed to result in 12 months of negative sputum cultures). Cystic Fibrosis - Approve if pt has Pseudomonas aeruginosa in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture). |

# Aubagio

**Products Affected**

- AUBAGIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded |
| **Exclusion Criteria** | Non-relapsing forms of MS. Concurrent use of other disease-modifying agents used for MS (examples include interferon beta 1a, interferon beta 1b, glatiramer, peginterferon beta-1a, fingolimod, cladribine, siponomid, dimethyl fumarate DR, ocrelizumab, natalizumab, and alemtuzumab) |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |

# Austedo

**Products Affected**

- AUSTEDO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis and previous medications tried |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | Chorea - Prescribed by or in consultation with a neurologist. Dyskinesia - Prescribed by or in consultation with a neurologist or psychiatrist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Chorea associated with Huntington's Disease - approve if pt has been diagnosed with chorea associated with Huntington's disease AND diagnosis of Huntington's disease is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36.)  Tardive Dyskinesia - approve. |

# Avonex

**Products Affected**

- AVONEX INTRAMUSCULAR PEN INJECTOR KIT KIT
- AVONEX INTRAMUSCULAR SYRINGE
- AVONEX INTRAMUSCULAR SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Non-relapsing forms of multiple sclerosis. Concurrent use of other disease-modifying agents used for multiple sclerosis. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. |

# Ayvakit

**Products Affected**

- AYVAKIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded from coverage. Myeloid/Lymphoid Neoplasms with Eosinophilia. |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, mutation results |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Gastrointestinal Stromal Tumor (GIST) - Approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation (PDGFRA exon 18 mutation includes PDGFRA D842V mutations) or pt has previously tried imatinib, sunitinib, regorafinib, and ripretinib. Systemic Mastocytosis - approve if pt has a platlet count of greater than 50,000/mcL and has aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, or mast cell leukemia. Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) D842V mutation. |

# Balversa

**Products Affected**

- BALVERSA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies, test results |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Urothelial Carcinoma - Approve if the patient has locally advanced or metastatic disease AND susceptible fibroblast growth factor receptor 3 or fibroblast growth factor receptor 2 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy (i.e., cisplatin, oxaliplatin). |

# Benlysta

**Products Affected**

- BENLYSTA INTRAVENOUS
- BENLYSTA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use with other biologics. Rheumatoid Arthritis. |
| **Required Medical Information** | Diagnosis, lab results, other therapies tried |
| **Age Restrictions** | Subcutaneous - 18 years or older, IV - 5 years or older |
| **Prescriber Restrictions** | LN - Prescribed by or in consultation with a nephrologist or rheumatologist. SLE - Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist. |
| **Coverage Duration** | LN initial - 6 mo. SLE initial - 4 mo. Continuation - 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Lupus Nephritis (LN) - Approve if pt has autoantibody-positive SLE, defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody and the medication is being used concurrently with at least one other standard therapy, unless intolerant as determined by the prescriber. Continuation - Approve if pt has responded to Benlysta and the medication is being used concurrently with at least one other standard therapy, unless intolerant, as determined by the prescriber. Systemic Lupus Erythematosus (SLE) - Approve if pt has autoantibody-positive SLE, defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody and the medication is being used concurrently with at least one other standard therapy, unless intolerant as determined by the prescriber. Continuation - Approve if pt has responded to Benlysta and the medication is being used concurrently with at least one other standard therapy, unless intolerant, as determined by the prescriber. |

# Betaseron

**Products Affected**

- BETASERON SUBCUTANEOUS KIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded from coverage. |
| **Exclusion Criteria** | Concurrent use of other disease-modifying agent used for multiple sclerosis. Non-relapsing forms of MS. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or after consultation with a neurologist or an MS specialist. |
| **Coverage Duration** | 3 Years |
| **Other Criteria** | Multiple Sclerosis - pt has a relapsing form of MS. |

# Bosulif

**Products Affected**

- BOSULIF

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Acute Lymphoblastic Leukemia. Myeloid/Lymphoid Neoplasms with Eosinophilia. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies |
| **Age Restrictions** | Chronic Myeloid Leukemia, Acute Lymphoblastic Leukemia - 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Chronic Myeloid Leukemia - approve if pt has Philadelphia chromosome positive chronic myeloid leukemia. Acute Lymphoblastic Leukemia - approve if pt has Philadelphia chromosome-positive acute lymphoblastic leukemia and has tried at least one other tyrosine kinase inhibitor for Philadelphia chromosome-positive acute lymphoblastic leukemia. (e.g., imatinib and dasatinib). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if tumor has an ABL1 rearrangement. |

# Braftovi

**Products Affected**

- BRAFTOVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Plus Colon or Rectal Cancer. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, mutation results |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Colon or Rectal Cancer - approve if pt has BRAF V600 mutation positive disease and has previously received a chemotherapy regimen for colon or rectal cancer and Braftovi will be prescribed as part of a combination regimen for colon or rectal cancer. Melanoma - approve if pt has unresectable, advanced, or metastatic melanoma which is BRAF V600 mutation positive. |

# Brukinsa

**Products Affected**

- BRUKINSA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Chronic Lymphocytic Leukemia. Marginal Zone Lymphoma. Small Lymphocytic Lymphoma. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prior treatments |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Mantle Cell Lymphoma/Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia - approve if pt has tried at least one prior systemic therapy. Marginal Zone Lymphoma - approve if pt has tried at least one prior systemic therapy and according to the prescriber, the patient has intolerance or contraindication to Imbruvica (ibrutinib capsule or tablet). Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma - Approve. |

# Cablivi

**Products Affected**

- CABLIVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, concurrent medications |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist |
| **Coverage Duration** | 3 months |
| **Other Criteria** | Acquired Thrombotic Thrombocytopenic Purpura (aTTP) - Approve if Cablivi was initiated in the inpatient setting in combination with plasma exchange therapy AND the patient is currently receiving at least one immunosuppressive therapy (e.g. corticosteroids, rituximab, cyclosporine, cyclophosphamide, mycophenolate, hydroxychloroquine, Velcade) AND if the patient has previously received Cablivi, he/she has not had more than two recurrences of aTTP while on Cablivi. |

# Cabometyx

**Products Affected**

- CABOMETYX ORAL TABLET 20 MG, 40 MG, 60 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Bone Cancer. Gastrointestinal Stromal Tumors. Non-Small Cell Lung Cancer. |
| **Exclusion Criteria** | Metastatic Castration-Resistant Prostate Cancer |
| **Required Medical Information** | Diagnosis, medication history, mutation status |
| **Age Restrictions** | Thyroid carcinoma - 12 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Hepatocellular Carcinoma - Approve if pt has been previously treated with at least one kinase inhibitor therapy (e.g., sorafenib, lenvatinib). Renal Cell Carcinoma - Approve if pt has relapsed or stage IV disease. Thyroid Carcinoma - Approve if pt has differentiated thyroid carcinoma, is refractory to radioactive iodine therapy, and has tried a vascular endothelial growth factor receptor (VEGFR)-targeted therapy. Bone Cancer - approve if pt has tried at least one previous systemic regimen AND has Ewing sarcoma or osteosarcoma. Gastrointestinal Stromal Tumors (GIST) - Approve if pt has tried Sutent (sunitinib capsules), Stivarga (regorafinib tablets), and Gavreto (ripretinib tablets) AND either imatinib or Ayvakit (avapritinib tablets). Non-Small Cell Lung Cancer - Approve if tumor is positive for RET rearrangements. |

# Calquence

**Products Affected**

- CALQUENCE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Marginal Zone Lymphoma. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, prior treatments |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Approve. Mantle Cell Lymphoma - Approve if pt has tried at last one prior therapy. Marginal Zone Lymphoma - approve if pt has tried at least one prior systemic therapy and according to the prescriber, the patient has intolerance or contraindication to Imbruvica (ibrutinib capsule or tablet). Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma - approve if pt has tried at least one prior therapy. |

# Caprelsa

**Products Affected**

- CAPRELSA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Differentiated Thyroid Carcinoma. Non-Small Cell Lung Cancer. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, mutation results |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Medullary Thyroid Cancer - approve. Differentiated Thyroid Carcinoma (i.e., papillary, follicular, and Hürthle)- approve if refractory to radioactive iodine therapy. Non-Small Cell Lung Cancer - approve if tumor has RET gene rearrangements. |

# Chenodal

**Products Affected**

- CHENODAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Cerebrotendinous Xanthomatosis. |
| **Exclusion Criteria** | Combination Therapy with Cholbam (cholic acid). |
| **Required Medical Information** | Diagnosis, previously tried therapies |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Gallstones - Approve if pt has previously tried or is currently using an ursodiol product. |

# Cimzia

**Products Affected**

- CIMZIA
- CIMZIA POWDER FOR RECONST
- CIMZIA STARTER KIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications. Spondyloarthritis (SpA), Other subtypes. |
| **Exclusion Criteria** | Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD). |
| **Required Medical Information** | diagnosis, medication history |
| **Age Restrictions** | CD/PP - 18 years and older |
| **Prescriber Restrictions** | AS/nr-axSpA/RA/SpA - prescribed by or in consultation with a rheumatologist. CD - prescribed by or in consultation with a gastroenterologist. PP - prescribed by or in consultation with a dermatologist. PsA - prescribed by or in consultation with a rheumatologist or a dermatologist. |
| **Coverage Duration** | Initial - 3 months. Continuation - 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Ankylosing Spondylitis (AS) - approve if pt has tried TWO of Enbrel, Humira, and Taltz. Crohn's disease (CD) - approve if pt has tried Humira. Non-Radiographic Axial Spondyloarthritis (nr-axSpA) - approve if pt has C-reactive protein (CRP) elevated beyond the upper limit of normal OR sacroiliitis reported on magnetic resonance imaging (MRI). Plaque Psoriasis (PP) - approve if pt has tried TWO of Enbrel, Humira, Otezla, Skyrizi, Stelara subcutaneous, Taltz, and Tremfya. Psoriatic Arthritis (PsA) - approve if pt has tried TWO of Enbrel, Humira, Otezla, Stelara subcutaneous, Taltz, Tremfya, and Xeljanz/XR. Rheumatoid Arthritis (RA) - approve if pt has tried TWO of Actemra subcutaneous, Enbrel, Humira, Rinvoq, and Xeljanz/XR. Spondyloarthritis (SpA) - approve if pt has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic disease-modifying antirheumatic drug (DMARD). Continuation (RA, AS, PsA, PP, CD) - approve if pt meets intial therapy requirements. Continuation (all others) - approve if pt has been taking Cimzia for at least 90 days. |

# Cometriq

**Products Affected**

- COMETRIQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Differentiated Thyroid Carcinoma. Non-Small Cell Lung Cancer. |
| **Exclusion Criteria** | Metastatic Castration-Resistant Prostate Cancer |
| **Required Medical Information** | Diagnosis, mutation results |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Medullary Thyroid Cancer - approve. Differentiated Thyroid Carcinoma (i.e., papillary, follicular, and Hürthle)- approve if refractory to radioactive iodine therapy. Non-Small Cell Lung Cancer - approve if pt has RET gene rearrangements. |

# Continuous Glucose Monitors

**Products Affected**

- DEXCOM G6 RECEIVER
- DEXCOM G6 SENSOR
- DEXCOM G6 TRANSMITTER
- FREESTYLE LIBRE 14 DAY READER
- FREESTYLE LIBRE 14 DAY SENSOR
- FREESTYLE LIBRE 2 READER
- FREESTYLE LIBRE 2 SENSOR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diabetes Mellitus |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, insulin use |
| **Age Restrictions** | Freestye Libre - 18 years of age or older. Freestyle Libre 2 - 4 years of age or older. Dexcom - 2 years of age or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Diabetes type 1 - Approve. Other Diabetes Types - Approve if patient is injecting insulin three times per day or using an insulin pump AND insulin dose requires frequent adjustment, per provider. |

# Copaxone

**Products Affected**

- *glatiramer subcutaneous syringe 20 mg/ml, 40 mg/ml*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use with other disease-modifying agents used for multiple sclerosis (MS). Non-relapsing forms of MS. |
| **Required Medical Information** | diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Multiple Sclerosis - pt has a relapsing form of MS. |

# Copiktra

**Products Affected**

- COPIKTRA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded, some medically accepted indications. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis, previous therapies |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 3 years |
| **Other Criteria** | CLL/SLL/Follicular Lymphoma/MALT Lymphoma/Marginal Zone Lymphoma - approve if the patient has tried two prior therapies. |

# Corlanor

**Products Affected**

- CORLANOR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Plus Inappropriate Sinus Tachycardia. |
| **Exclusion Criteria** | Stable Angina Pectoris, in patients without CHF |
| **Required Medical Information** | Previous use of a Beta-blocker, LVEF, sinus rhythm, and resting HR |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Chronic Heart Failure, Adults - approve if pt has a LVEF equal to or less than 35% currently or prior to initiation of Corlanor therapy AND pt has tried or is taking one beta blocker for heart failure or has a contraindication to its use. Heart Failure due to Dilated Cardiomyopathy, Children - approve. Inappropriate Sinus Tachycardia - approve. |

# Cotellic

**Products Affected**

- COTELLIC

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Central Nervous System Cancer. Histiocytic Neoplasm. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis. Mutation results. Other therapies tried. |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Melanoma - approve if pt has unresectable, advanced, or metastatic melanoma, has BRAF V600 mutation-positive disease, and Cotellic is being prescribed in combination with Zelboraf (vemurafenib). Central Nervous System Cancer - Approve if pt has BRAF V600 mutation-positive disease and the medication is being used for adjuvant treatment of pilocytic astrocytoma, pleomorphic xanthoastrocytoma, or ganglioglioma, or for recurrent disease of low-grade glioma, anaplastic glioma, or glioblastoma, or brain metastases due to melanoma AND the medication is prescribed in combination with Zelboraf (vemurafenib). Histiocytic Neoplasm - Approve if pt has BRAF V600 mutation-positive disease and has Langerhans cell histiocytosis and one of the following: multisystem disease, pulmonary disease, or central nervous system lesions. |

# Crysvita

**Products Affected**

- CRYSVITA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded |
| **Exclusion Criteria** | Chronic Kidney Disease (CKD), Severe Renal Impairment or End Stage Renal Disease, Epidermal Nevus Syndrome |
| **Required Medical Information** | Diagnosis, lab values |
| **Age Restrictions** | TIO - 2 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a endocrinologist or nephrologist |
| **Coverage Duration** | X-linked Hypophosphotemia - 1 year, Tumor-induced Osteomalacia - 6 months. Continuation - 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Tumor-Induced Osteomalacia - Approve if pt has a mesenchymal tumor that cannot be curatively resected or identified/localized AND, per the prescriber, the patient is currently exhibiting one or more signs or symptoms of tumor-induced osteomalacia AND pt has had a baseline (prior to any tumor-induced osteomalacia treatment) serum phosphorus level that was below the normal range for age AND Patient has had a baseline (prior to any tumor induced osteomalacia treatment) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender AND pt has tried, or has a contraindication to, oral phosphate and calcitriol therapy. Cont - approve if pt is continuing to derive benefit from Crysvita as determined by the prescriber.X-linked Hypophosphotemia (XLH) - Approve if pt has had a baseline (i.e., prior to any XLH treatment [e.g., Crysvita, oral phosphate/vitamin D therapy]) serum phosphorus level that was below the normal range for age AND pt either had a baseline (prior to any XLH treatment) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender OR pt has had a genetic test confirming the diagnosis of XLH via identification of a PHEX mutation AND If pt is greater than 18 years old, pt is currently exhibiting one or more signs or symptoms of X-linked hypophosphatemia per the prescriber and pt has tried, or has contraindications to, oral phosphate and calcitriol therapy. |

# Daliresp

**Products Affected**

- DALIRESP ORAL TABLET 250 MCG, 500 MCG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded |
| **Exclusion Criteria** | Asthma |
| **Required Medical Information** | Medications tried |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | COPD - approve if pt has severe COPD or very severe COPD, a history of exacerbations, and meets ONE of the following: pt has chronic bronchitis and has tried an inhaled long-acting beta2-agonist, an inhaled long-acting muscarinic antagonist, and an inhaled corticosteroid concomitantly OR pt has tried an inhaled long-acting muscarinic antagonist and long-acting beta2-agonist concomitantly and has a blood eosinophil level less than 100 cells/microliter. |

# Daurismo

**Products Affected**

- DAURISMO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis, medications that will be used in combination, comorbidities |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 3 years |
| **Other Criteria** | AML - approve if Daurismo will be used in combination with cytarabine AND the patient is greater than or equal to 75 years old OR the patient has comorbidities that preclude the use of intensive induction chemotherapy according to the prescribing physician. |

# Deferasirox

**Products Affected**

- *deferasirox*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Serum ferritin level |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Iron Overload, Chronic - Transfusion-Related - Approve if pt is receiving blood transfusions at regular intervals for a chronic condition and prior to starting chelating therapy, serum ferritin level was greater than 1,000 micrograms/liter (mcg/L). Continuation - Approve if the patient is benefiting from therapy, as confirmed by the prescriber. Iron Overload, Chronic - Non-Transfusion-Dependent Thalassemia Syndromes - Approve if prior to starting chelating therapy, serum ferritin level was greater than 300 micrograms/liter. Continuation - Approve if the patient is benefiting from therapy, as confirmed by the prescriber. |

# Deferiprone

**Products Affected**

- *deferiprone*
- FERRIPROX ORAL SOLUTION
- FERRIPROX ORAL TABLET 1,000 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Iron Overload, Chronic - Non-Transfusion-Dependent Thalassemia Syndromes. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Serum ferritin level |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Iron Overload, Chronic - Transfusion-Related Due to Thalassemia Syndromes, Sickle Cell Disease, or Other Anemias - Approve if prior to starting chelating therapy, serum ferritin level was greater than 1,000 micrograms/liter. Continuation - Approve if the patient is benefiting from Ferriprox therapy, as confirmed by the prescriber. Iron Overload, Chronic - Non-Transfusion-Dependent Thalassemia Syndromes - Approve if prior to starting chelating therapy, serum ferritin level was greater than 300 micrograms/liter. Continuation - Approve if the patient is benefiting from Ferriprox therapy, as confirmed by the prescriber. |

# Diacomit

**Products Affected**

- DIACOMIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Treatment-Refractory Seizures/Epilepsy (i.e., Lennox-Gastaut Syndrome, infantile spasms, tuberous sclerosis complex, Sturge-Weber syndrome, Doose syndrome, infection-related or anoxo-ischemic epilepsy syndromes, cortical malformation/dysplasia, epileptic encephalopathies associated with sodium channel mutations, and epilepsy with myoclonic absences). |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies |
| **Age Restrictions** | 2 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Dravet Syndrome, Initial- approve if the patient is taking concomitant clobazam OR the patient is unable to take clobazam due to adverse events as determined by the prescribing physician. Treatment-Refractory Seizures/Epilepsy, Initial - approve if the patient has tried at least two other antiepileptic drugs. Continuation- approve if the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescribing physician. |

# Dimethyl Fumarate

**Products Affected**

- *dimethyl fumarate*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded |
| **Exclusion Criteria** | Non-relapsing forms of multiple sclerosis. Concurrent use of other disease-modifying agents used for multiple sclerosis. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. |

# Dupixent

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use with another anti-interleukin monoclonal antibody (e.g. Cinqair, Nucala, Fasenra). Concurrent use with Xolair. Eosinophilic esophagitis. |
| **Required Medical Information** | Diagnosis, prescriber specialty, other medications tried and length of trials |
| **Age Restrictions** | Asthma- 6 years or older. Atopic Dermatitis- 6 years or older. Nasal Polyps- 18 years or older. |
| **Prescriber Restrictions** | Atopic Dermatitis - Prescribed by or in consultation with an allergist, immunologist or dermatologist. Asthma - prescribed by or in consultation with an allergist, immunologist or pulmonologist. Nasal Polyps - prescribed by or in consultation with an allergist, immunologist or otolaryngologist |
| **Coverage Duration** | AD Initial-4 months, Cont-1 year, Asthma/Nasal Polyps Initial-6 months, Cont-1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Asthma- Approve if pt meets the following criteria (i, ii, and iii):i. Pt meets ONE of the following criteria: has a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin (IL) therapy or Xolair OR has oral corticosteroid-dependent asthma, per the prescriber AND ii. has received combination therapy with BOTH an inhaled corticosteroid (ICS) and at least one additional asthma controller/maintenance medication (NOTE: An exception can be made if the patient has already received anti-IL-5 therapy or Xolair used concomitantly with an ICS. Combo ICS and LABA inhalers would also fulfill this requirement) AND iii. asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy or Xolair as defined by ONE of the following (a, b, c, d or e): a)experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b)experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department visit in the previous year OR c)has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d)has an FEV1/forced vital capacity (FVC) less than 0.80 OR e)The patient's asthma worsens upon tapering of oral corticosteroid therapy. Continuation-Approve if pt continues to receive therapy with an inhaled corticosteroid and has responded to Dupixent therapy as determined by the prescribing physician. Atopic Dermatitis-Initial-meets both a and b: a. has used at least one medium or higher potency prescription topical corticosteroid OR has atopic dermatitis affecting ONLY the face, eyes/eyelids, skin folds, and/or genitalia and has tried tacrolimus ointment AND b. Inadequate efficacy was demonstrated with these previously tried topical prescription therapies, according to the prescribing physician. Continuation-Approve if the pt has responded to Dupixent therapy as determined by the prescribing physician. Nasal Polyps-Initial-pt has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan AND has has received at |

| PA Criteria | Criteria Details |
|---|---|
| | least 3 months of therapy with an intranasal corticosteroid and will continue to receive therapy with an intranasal corticosteroid concomitantly with Dupixent AND pt has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell AND Pt meets one of the following: pt has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years, pt has a contraindication to systemic corticosteroid therapy, or pt has had prior surgery for nasal polyps. Continuation-approve if the pt continues to receive therapy with an intranasal corticosteroid AND pt has responded to Dupixent therapy as determined by the prescriber. |

# Eligard

**Products Affected**

- ELIGARD
- ELIGARD (3 MONTH)
- ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |

# Emgality

**Products Affected**

- EMGALITY PEN
- EMGALITY SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Combination use with other prophylactic CGRP agents. Acute treatment of migraines. |
| **Required Medical Information** | Diagnosis, number of migraine headaches per month, prior therapies tried |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Cluster Headaches - 6 months. Migraine Prevention - 1 year. |
| **Other Criteria** | Episodic Cluster Headache Treatment - Approve if pt has between one headache every other day and eight headaches per day and pt has tried at least one standard prophylactic (preventive) pharmacologic therapy for cluster headache and had inadequate efficacy or experienced an adverse event, according to the prescriber. Migraine Headache Prevention - Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND patient has tried at least two standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, beta-blocker), and has had inadequate responses to those therapies or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. Pt must also have also tried triptan therapy, unless contraindicated according to the prescriber, unless pt is currently taking a CGRP inhibitor for migraine headache prevention and has had a significant clinical benefit from the medication as determined by the prescriber. |

# Enbrel

**Products Affected**

- ENBREL MINI SUBCUTANEOUS CARTRIDGE 50 MG/ML (1 ML)
- ENBREL SUBCUTANEOUS RECON SOLN 25 MG (1 ML)
- ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5 ML
- ENBREL SUBCUTANEOUS SYRINGE 25 MG/0.5 ML (0.5), 50 MG/ML (1 ML)
- ENBREL SURECLICK SUBCUTANEOUS PEN INJECTOR 50 MG/ML (1 ML)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded plus Behcet's Disease, Graft-Versus-Host Disease, Pyoderma Gangrenosum, Scleritis (sterile corneal ulceration), Spondylarthritis, Still's Disease, and Uveitis. |
| **Exclusion Criteria** | Concurrent Use with a Biologic DMARD or Targeted Synthetic DMARD. Crohn's disease. Inflammatory myopathies (polymyositis, dermatomyositis, inclusion body myositis). Hidradenitis Suppurativa. Polymyalgia Rheumatica. Large Vessel Vasculitis (Giant Cell Arteritis, Takayasu's Arteritis). Wegener's Granulomatosis. |
| **Required Medical Information** | Diagnosis and previous therapies tried |
| **Age Restrictions** | PP - 4 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with: RA/AS/JIA/JRA/SpA/SD - rheumatologist. PP/PG - dermatologist. PsA - rheumatologist or dermatologist. Behcet's - rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist. GVHD - oncologist, hematologist, or a physician in a transplant center. Scleritis, Uveitis - ophthalmologist. |
| **Coverage Duration** | RA/AS/JIA/PP/PsA/BD/Scl/SpA/SD/UV-3mo GVHD-1mo PG-4mo. Cont:RA/AS/JIA/PP/PsA-3y GVHD-4m others-1yr |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | RA - pt has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) or biologic DMARD for at least 3 months. AS - approve.JIA/JRA - pt has tried one other agent for this condition or a biologic DMARD OR pt will be starting on Enbrel concurrently with methotrexate (MTX), sulfasalazine, or leflunomide OR pt has an absolute contraindication to MTX, sulfasalazine, or leflunomide OR pt has aggressive disease, as determined by the prescribing physician. PP initial - approve if the patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) or a biologic DMARD for at least 3 months, unless intolerant. PsA - approve.Behcet's - tried at least one conventional therapy or adalimumab or infliximab. GVHD approve if Patient has tried one conventional treatment or is currently receiving one of these medications. PG - approve if patient has tried one systemic corticosteroid OR one other immunosuppressant for at least 2 mo or was intolerant. Scleritis - pt has tried 1 other therapy (NSAID, IV corticosteroid, or immunosuppressant). SpA - The patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic DMARD OR The patient has axial spondyloarthritis with objective measures of inflammation (elevated CRD, sacroiliitis on MRI). Still's Disease - Patient has tried one corticosteroid AND one conventional synthetic DMARD for at least 2 months or was intolerant. Uveitis - The patient has tried one of the following therapies: periocular, intraocular, or systemic corticosteroids [for example, triamcinolone, betamethasone, methylprednisolone, prednisone] immunosuppressives (MTX, mycophenolate mofetil, cyclosporine, azathioprine, cyclophosphamide), adalimumab, or infliximab for this condition. Continuation thearpy - approve if the patient has had a response as determined by the prescriber. |

# Enspryng

**Products Affected**

- ENSPRYNG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded from coverage. |
| **Exclusion Criteria** | Concomitant use with Rituximab product, Soliris or Uplizna |
| **Required Medical Information** | Diagnosis, previous therapies tried, test results |
| **Age Restrictions** | NMOSD-18 years and older (initial and continuation) |
| **Prescriber Restrictions** | NMOSD-prescribed by or in consultation with a neurologist (initial and continuation) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Neuromyelitis Optica Spectrum Disorder-initial therapy-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and the patient has a history of at least 1 relapse (acute attack from neuromyelitis spectrum disorder) in the last 12 months. Patient is currently receiving or has previously tried two of the following systemic therapies including azathioprine, corticosteroid, mycophenolate mofetil, or rituximab (Note - An exception to the requirement for a trial of a systemic therapy can be made if the patient has already tried Soliris (eculizumab injection) or Uplizna (inebilizumab-cdon injection) for neuromyelitis optica spectrum disorder. Patients who have already tried Soliris or Uplizna for neuromyelitis optica spectrum disorder are not required to try another systemic agent.). Patient has a history of at least one relapse in the last 12 months or two relapses in the last 2 years. Continuation-approve if the diagnosis was confirmed by blood serum test for anti-aquaporin-4 antibody positive and the patient has had a clinical benefit from the use of Enspryng. |

# Epidiolex

**Products Affected**

- EPIDIOLEX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Treatment-Refractory Seizures/Epilepsy [specific rare conditions] (i.e. CDKL5 deficiency disorder, Dup15q, Aicardi, or Doose syndromes, febrile infection-related epilepsy syndromes, Sturge-Weber syndrome, lissencephaly, cortical malformation/dysplasia, and epilepsy with myoclonic absences). |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies |
| **Age Restrictions** | 1 year and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Dravet Syndrome - approve if pt has tried two other antiepileptic drugs OR one of Diacomit or clobazam. Lennox-Gaustaut Syndrome - pt has tried at least two other antiepileptic drugs OR one of lamotrigine, topiramate, Banzel, felbamate, clobazam. Tuberous Sclerosis Complex/ Treatment Refractory Seizures/Epilepsy - approve if pt has tried two other antiepileptic drugs. Continuation therapy - approve if pt is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescriber. |

# Epogen and Procrit

**Products Affected**

- EPOGEN INJECTION SOLUTION 10,000 UNIT/ML, 2,000 UNIT/ML, 20,000 UNIT/2 ML, 20,000 UNIT/ML, 3,000 UNIT/ML, 4,000 UNIT/ML

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Anemia due to myelodysplastic syndrome (MDS). Anemia Associated with Myelofibrosis. |
| **Exclusion Criteria** | Anemia associated with cancer in patinets not receiving myelosuppressive cancer chemotherapy. Anemia associated with AML, CML or other myeloid cancers. Anemia associated with radiotherapy for cancer. Athletic performance enhancement. Anemia due to acute blood loss. |
| **Required Medical Information** | Diagnosis, lab values |
| **Age Restrictions** | Anemia due to MDS - 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | CKD dialysis-3 yrs. CKD/MDS/HIV-1 yr. Chemo-6 months. Myelofibrosis-3 mo, cont.-1 yr. Surgery-1 mo |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Anemia due to CKD on dialysis - approve. Anemia due to CKD not on dialysis - For pts 18 years of age or older, must have a hemoglobin less than 10 g/dL (less than 11.5 g/dL if already receiving an erythropoiesis-stimulating agent[ESA]). If less than 18 years of age, must have a hemoglobin equal to or less than 11 g/dL (equal to or less than 12 g/dL if already receiving an ESA). Pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to Chemotherapy - Approve if pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA), is currently recieving myelosuppressive chemotherapy AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia and HIV on Zidovudine - Pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) OR has a serum erythropoietin level equal to or less than 500 mU/mL, pt is currently recieving zidovudine AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Reduction of Allogenic RBC Transfusions in Pts Undergoing Surgery - Hgb is less than 13 g/dL AND surgery is elective, nonvascular and noncardiac AND pt is not able or willing to donate autologus blood prior to surgery AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to MDS - Pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) OR has a serum erythropoietin level equal to or less than 500 mU/mL AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to Myelofibrosis - Pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) OR has a serum erythropoietin level equal to or less than 500 mU/mL AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. For pts already receiving an ESA, the pt has responded according to the prescriber as defined by a hemoglobin greater than 10 g/dL or an increase of greater than 2 g/dL. |

# Erivedge

**Products Affected**

- ERIVEDGE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Central Nervous System Cancer. |
| **Exclusion Criteria** | Basal Cell Carcinoma (Locally advanced or metastatic) that progressed while on Odomzo. Metastatic Colorectal Cancer. Ovarian Cancer. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Locally advanced basal cell carcinoma - approve if 1. the pt has recurrent basal cell carcinoma following surgery or radiation therapy or pt is not a candidate for surgery or radiation therapy. Continuation therapy - approve. Central Nervous System Cancer - approve if pt has tried at least one chemotherapy agent and has a mutation of the sonic hedgehog pathway according to prescriber. |

# Erleada

**Products Affected**

- ERLEADA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, other therapies |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Prostate Cancer - Non-Metastatic, Castration-Resistant - Approve if the medication is used in combination with a gonadotropin-releasing hormone (GnRH) analog or the pt has had a bilateral orchiectomy. Prostate Cancer - Metastatic, Castration-Sensitive - Approve if the medication is used in combination with a gonadotropin-releasing hormone (GnRH) analog or the pt has had a bilateral orchiectomy. |

# Erlotinib

**Products Affected**

- *erlotinib*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Bone Cancer. Renal Cell Carcinoma. |
| **Exclusion Criteria** | Biliary Cancer. Breast Cancer. Colorectal Cancer, metastatic. Glioblasatoma Multiforme. Head and Neck Cancer, Squamous Cell, Recurrent and/or Metastatic. Hepatocellular Carcinoma (HCC), Advanced. Occult Primary/Cancer of Unknown Primary Site (CUP). Renal Cell Carcinoma (RCC), Advanced - Clear Cell Histology. |
| **Required Medical Information** | Diagnosis, mutation results, previous therapies tried |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC) - Approve if pt has metastatic epidermal growth factor receptor (EGFR) mutation-positive disease AND pt has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. Pancreatic cancer - approve if the medication is used in combination with gemcitabine. Bone Cancer - approve if pt has chordoma and has tried at least one previous therapy. Recal Cell Carcinoma (RCC) - Approve if the pt has relapsed or has Stage IV non-clear cell histology RCC. |

# Esbriet

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concomitant use with Ofev. |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | prescribed by or in consultation with a pulmonologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Idiopathic Pulmonary Fibrosis - Approve if pt has forced vital capacity (FVC) greater than 40% of predicted value and the diagnosis is confirmed by either findings on high-resolution computed tomography which indicate usual interstitial pneumonia or a surgical lung biopsy which demonstrates usual interstitial pneumonia. Continuation - Approve if pt has experienced a beneficial response to therapy over the last year while receiving Esbriet. |

# Everolimus (antineoplastic)

**Products Affected**

- AFINITOR ORAL TABLET 10 MG
- *everolimus (antineoplastic) oral tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Differentiated Thyroid Carcinoma, Ednometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST), Classical Hodkin Lymphoma, Meningioma, Soft Tissue Sarcoma - Perivascular Epitheloid Cell Tumors (PEComa), Recurrent Angiomyolipoma, Lymphangioleiomyomatosis. Thymomas and Thymic Carcinomas. Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL). |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, hormone receptor status, prior therapies |
| **Age Restrictions** | Breast cancer/NE tumors/RCC/TSC with RA/TC/EC/GIST/CHL/Meningioma/STS/TTC/WM/LPL - 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Breast Cancer - Approve if pt has recurrent or Stage IV, hormone receptor Positive (HR+) disease and human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND pt has tried at least one prior endocrine therapy (anastrazole, letrozole, or tamoxifen), AND pt meets one of the following: pt is a postmenopausal female OR male OR pt is pre-or perimenopausal and is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., leuprolide, triptorelin, goserelin), or has had surgical bilateral oophorectomy or ovarian irradiation AND pt meets one of the following: if pt is a male and if everolimus will be used in combination with exemestane, then the patient is receiving a GnRH agonist OR everolimus will be used in combination with exemestane, fulvestrant or tamoxifen AND the pt has not had disease progression while on everolimus. Advanced, Unresectable or Metastatic Carcinoid Tumors - Approve. Renal Cell Carcinoma (RCC) - Pt has relapsed or stage IV disease. If using for clear cell disease, the pt has tried a systemic therapy previously (e.g. axitinib, pazopanib, sunitinib, cabozantinib, sorafenib). Tuberous Sclerosis Complex (TSC)-Associated Renal Angiomyolipoma - approve. TSC-Associated Subependymal Giant Cell Astrocytoma (SEGA) - Approve if SEGA cannot be curatively resected. TSC-Associated Partial Onset Seizure - approve. Differentiated Thyroid Carcinoma -Approve if refractory to radioactive iodine therapy. Endometrial Carcinoma - Pt has recurrent, metastatic, or high-risk disease and Afinitor will be used in combination with letrozole. GIST - Pt has tried imatinib or avapritinib, sunitinib, regorafenib, ripretinib and Afinitor will be used in combination with imatinib, sunitinib, or regorafenib. Classical Hodgkin Lympoma - approve. Meningioma - approve. Soft Tissue Sarcoma - Perivascular Epitheloid Cell Tumors, Recurrent Angiomyolipoma, Lymphangioleiomyomatsosis - Approve. Thymomas and Thymic Carcinomas - approve if pt has tried chemotherapy. WM/LPL - Approve if pt has not responded to primary therapy (e.g.bortezomib with dexamethasone, bendamustine, rituximab |
| | combination therapy, or carfilzomib with rituximab and dexamethasone) or pt has progressive or relapsed disease. |

# Everolimus (immunosuppressant)

**Products Affected**

- *everolimus (immunosuppressive)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |

# Evrysdi

**Products Affected**

- EVRYSDI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded |
| **Exclusion Criteria** | Patient has Complete Paralysis of All Limbs. Patient has Permanent Ventilator Dependence. |
| **Required Medical Information** | Diagnosis, SMA exam results, genetic testing results, pregnancy status, weight |
| **Age Restrictions** | Initial - 2 months up to 25 years of age. Continuation - pt was less than 25 years when Evrysdi was started |
| **Prescriber Restrictions** | prescribed by or in consultation with a physician who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders |
| **Coverage Duration** | 4 months |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Spinal Muscular Atrophy (SMA) - Approve if baseline motor ability assessment that suggests spinal muscular atrophy (based on age, motor ability, and development) is provided from one of the following exams [documentation required]: Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) [Item 22], Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), Hammersmith Functional Motor Scale Expanded (HFMSE), Hammersmith Infant Neurological Exam Part 2 (HINE-2), Motor Function Measure-32 Items (MFM-32), Revised Upper Limb Module (RULM) test, or World Health Organization motor milestone scale AND pt has had a genetic test confirming the diagnosis of SMA with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene reported as at least one of the following: homozygous deletion, homozygous mutation, or compound heterozygous mutation [documentation required] AND has two to four survival motor neuron 2 (SMN2) gene copies [documentation required] AND according to the prescriber, the patient has objective signs consistent with spinal muscular atrophy Types 1, 2, or 3 [documentation required] AND for pts currently receiving or who have received prior treatment with Spinraza, the prescriber attests that further therapy with Spinraza will be discontinued AND pt has not received Zolgensma in the past AND females of current reproductive potential must have the prescriber confirm BOTH of the following: pt is not currently pregnant and effective contraception will be utilized during treatment and for 1 month after the last Evrysdi dose AND dosing of Evrysdi meets ONE of the following based on the current (within the past 1 month) kg weight (a, b, or c): a) 0.2 mg/kg once daily if the patient is 2 months to less than 2 years of age OR b) 0.25 mg/kg once daily for patients greater than 2 years of age who weigh less than 20 kg OR c) 5 mg once daily for patients greater than 2 years of age who weigh more than 20 kg. Continuation - must meet initial criteria AND according to the prescriber, the patient has responded to Evrysdi and continues to have benefit from |
| | ongoing Evrysdi therapy by the most recent (within the past 4 months) objective measurement and/or assessment tool. |

# Farydak

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Pancreatic cancer |
| **Required Medical Information** | previous therapies tried |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Multiple Myeloma - Approve if pt has previousy tried bortezomib injection and at least one immunomodulatory drug (i.e., thalidomide capsules, Revlimid [lenalidomide capsules], or Pomalyst [pomalidomide capsules]), and the medication will be taken in combination with bortezomib injection and dexamethasone. |

# Fasenra

**Products Affected**

- FASENRA
- FASENRA PEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | COPD. Concurrent use of Fasenra with Another Anti-Interleukin Monoclonal Antibody or Xolair. Hypereosinophilic Syndrome. |
| **Required Medical Information** | Diagnosis, labs, previous and current medications, spirometry results |
| **Age Restrictions** | 12 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, or pulmonologist |
| **Coverage Duration** | Asthma - 6 months initial, 1 year continuation. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Asthma - Approve if pt has a blood eosinophil count greater than 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin-5 therapy AND pt has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid and one additional asthma controller or asthma maintenance medication AND pt has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following: two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR one or more asthma exacerbations requiring hospitalization or an Emergency Department visit in the previous year OR pt has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR pt has an FEV1/forced vital capacity (FVC) less than 0.80 OR pt has asthma that worsens upon tapering of oral corticosteroid therapy. Continuation - Approve if pt has already recieved 6 months of Fasenra, continues to recieve therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler, and has responded to therapy as determined by the prescriber. |

# Filgrastim

**Products Affected**

- GRANIX
- NIVESTYM
- ZARXIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | "All FDA-approved indications not otherwise excluded. Acute lymphocytic leukemia (ALL). Cytokine Release Syndrome Associated with Chimeric Antigen Receptor (CAR) T-Cell Therapy. Drug induced agranulocytosis or neutropenia. Myelodysplastic syndromes (MDS). Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Radiation-Induced Neutropenia." |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Cancer/AML/MDS/ALL-oncologist or a hematologist. Cancer patients w/ BMT or PBPC -oncologist, hematologist, or a physician who specializes in transplantation. SCN, AA - hematologist. HIV/AIDS neutropenia - infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. RS - physician who has expertise in treating acute radiation syndrome. RIN - oncologist, radiologist, or radiation oncologist. |
| **Coverage Duration** | chemo/SCN/AML-6 mo. HIV/AIDS-4 mo.MDS-3 mo. Drug induced A/N,AA,ALL,BMT-3 mo. PBPC-1mo. Others-12mo. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Cancer patients receiving chemotherapy - Approve if pt meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection). Cytokine Release Syndrome Associated with Chimeric Antigen Receptor (CAR) T-Cell Therapy - Approve if pt has neutropenia. Radiation-Induced Neutropenia - Approve fi pt is not currently receiving chemotherapy. |

# Fintepla

**Products Affected**

- FINTEPLA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 2 years and older (initial therapy) |
| **Prescriber Restrictions** | Prescribed by or in consultation with an neurologist (initial therapy) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Dravet Syndrome - Approve if pt has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex or Diacomit. Dravet Syndrome - Continuation - Approve if the pt is responding to therapy as determined by the prescriber. |

# Firazyr

**Products Affected**

- *icatibant*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded |
| **Exclusion Criteria** | prophylaxis of HAE attacks |
| **Required Medical Information** | Diagnosis, lab results |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an allergist/immunologist or a physican that specializes in the treatment of HAE or related disorders. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency (Type I or Type II) - Treatment of Acute Attacks: Initial - pt has HAE type 1 or 2 as confrimed by low levels of functional C1-INH protein (less than 50% of normal) at baseline AND pt has lower than normal serum C4 levels at baseline. Continuation - pt has treated previous acute HAE type 1 or 2 attacks with icatibant and according to the prescriber, the pt has had a favorable response with icatibant treatment |

# Fotivda

**Products Affected**

- FOTIVDA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, other therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Renal Cell Carcinoma (RCC) - Approve if the patient has relapsed or Stage IV disease and has tried at least two other systemic regimens. |

# Gavreto

**Products Affected**

- GAVRETO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | NSCLC-18 years or older, Thyroid Cancer-12 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC) - Approve if pt has metastatic disease and rearranged during transfection (RET) fusion-positive disease. Thyroid Cancer - Approve if patient has rearranged during transfection (RET)- fusion positive disease and either the pt has anaplastic thyroid cancer OR the disease requires treatment with systemic therapy and the pt either has medullary thyroid cancer or radioactive iodine-refractory disease. |

# Gilenya

**Products Affected**

- GILENYA ORAL CAPSULE 0.5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS). Non-relapsing forms of MS. |
| **Required Medical Information** | diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Multiple Sclerosis - pt has a relapsing form of MS. |

# Gilotrif

**Products Affected**

- GILOTRIF

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis of metastatic Non-Small Cell Lung Cancer (NSCLC) |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months |
| **Other Criteria** | Patient must have epidermal growth factor receptor (EGFR) exon 19 deletion as detected by a Food and Drug Administration (FDA)-approved test OR the patient does not have exon 21 (L858R) substitution as detected by an FDA-approved test. |

# Glatopa

**Products Affected**

- GLATOPA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Given in combination with another disease-modifying agent used for MS (such as, Rebif, Betaseron, Tysabri, Gilenya, Aubagio, and Tecfidera) |
| **Required Medical Information** | Diagnosis of Multiple Sclerosis (MS) or patient has experienced an attack and is at risk for MS. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. |
| **Coverage Duration** | Authorization will be for 3 years |
| **Other Criteria** | |

# Glucagon-Like Peptide -1 Agonists

**Products Affected**

- BYDUREON BCISE
- BYETTA SUBCUTANEOUS PEN INJECTOR 10 MCG/DOSE(250 MCG/ML) 2.4 ML, 5 MCG/DOSE (250 MCG/ML) 1.2 ML
- OZEMPIC SUBCUTANEOUS PEN INJECTOR 0.25 MG OR 0.5 MG(2 MG/1.5 ML), 1 MG/DOSE (2 MG/1.5 ML), 1 MG/DOSE (4 MG/3 ML)
- RYBELSUS
- SOLIQUA 100/33
- TRULICITY
- VICTOZA 2-PAK
- VICTOZA 3-PAK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 3 years |
| **Other Criteria** | |

# Gonadotropin-Releasing Hormone Agonists - Injectable Long-Acting Products

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Abnormal Uterine Bleeding. Breast Cancer. Gender Dysphoric/Gender-Incongruent Persons, Persons Undergoing Gender Reassignment. Head and Neck Cancer - Salivary Gland Tumors. Ovarian Cancer. Preservation of Ovarian Function/Fertility in Patients Undergoing Chemotherapy. Prophylaxis or Treatment of Uterine Bleeding in Patients with Hematologic Malignancy, or Undergoing Cancer Treatment, or Prior to Bone Marrow/Stem Cell Transplantation (BMT/SCT). |
| **Exclusion Criteria** | Hirsutism. Menstrual Migraine. Premenstrual Syndrome (PMS). Polycystic Ovarian Syndrome (PCOS). |
| **Required Medical Information** | Diagnosis, concurrent medications |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Cancer/Ovarian Function/Bleeding due to Cancer - prescribed by or in consultation with an oncologist. Gender - prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients. |
| **Coverage Duration** | Endometriosis/Cancer/Ovarian Function/Bleeding due to Cancer/Gender/ - 1 year. Uterine Leiomyomata |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Endometriosis - approve if pt has tried a contraceptive, an oral progesterone, or depo-medroxyprogesterone injection, unless contraindicated. Uterine Leiomyomata - approve. Prostate/Breast/Ovarian cancer - approve. Preservation of Ovarian Function/Fertility in Patients Undergoing Chemotherapy/Prophylaxis or Treatment of Uterine Bleeding in Patients with Hematologic Malignancy, or Undergoing Cancer Treatment, or Prior to Bone Marrow/Stem Cell Transplantation - approve. Abnormal Uterine Bleeding - approve. Head and Neck Cancer - Salivary Gland Tumors - approve if pt has advanced salivary gland tumors with distant metastases and androgen receptor (AR)-positive disease. |

# Growth Hormone

**Products Affected**

- GENOTROPIN
- GENOTROPIN MINIQUICK
- NORDITROPIN FLEXPRO
- ZORBTIVE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Short Bowel Syndrome in Adults. |
| **Exclusion Criteria** | Acute Critical Illness Due to Complications Following Surgery, Multiple Accidental Trauma, or with Acute Respiratory Failure. Aging, To Improve Functional Status in Elderly Patients, and Somatopause. Athletic Ability Enhancement. Central Precocious Puberty. Chronic Fatigue Syndrome. Congenital Adrenal Hyperplasia (CAH). Constitutional Delay of Growth and Puberty (CDGP). Corticosteroid-Induced Short Stature. Fibromyalgia. Human Immunodeficiency Virus (HIV)-Infected Patients with Alterations in Body Fat Distribution. Infertility. Obesity. Osteoporosis. |
| **Required Medical Information** | Diagnosis, lab results [documentation required], vitals |
| **Age Restrictions** | NGHDSS - 5 years or younger. Children Born Small for Gestational Age or with Intrauterine Growth Restriction (initial) - 2 years or older. SBS - 18 years or older. |
| **Prescriber Restrictions** | GHD, Noonan, PWS, SHOX, born small - eval by endocrinologist. CKD - eval by endocrinologist or a nephrologist. |
| **Coverage Duration** | NGHDSS (initial) - 6 months. SBS (initial and cont) - 1 mo. All others - 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | GHD in Children or Adolescents - approve if pt has had 2 inadequate GH stim tests OR pt has had at least 1 inadequate GH stim test and has at least 1 risk factor for GHD. GHD in pts who have undergone brain radiation or have congenital hypopituitarism - approve if evaluated by endocrinologist AND 1 inadequate GH stim test OR deficiency in at least 1 other pituitary hormone. GHD in panhypopituitarism - approve if structural confirmation of dx OR pt has 3 or more pituitary hormone deficiencies OR pt has had 1 inadequate GH stim test. GHD in pts who have had a removal of the pituitary gland - approve. GHD Cont - approve if height has increased by more than 2 cm/year in the most recent year AND for pts greater than 12, the epiphyses are open AND for pts greater than 18, mid-parental height has not been attained. Non-GHD Short Stature (NGHDSS) - Approve if pts height is less than 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender AND has a growth rate less than 4 cm/year or velocity less than the 10th pcnt AND w/o therapy, pt's predicted height is less than 63 in (m) or less than 59 in (f) AND the epiphyses are open AND pt does not have constitutional delay. NGHDSS Cont - For pts on initial 6 mo trial, approve if the annual growth rate has doubled. For pts 5-12 yrs, approve if height has increased by 2 cm/yr AND for pts 12-18 yrs, the epiphyses are open AND for pts older than 18 yrs, approve if mid-parental height has not been attained.GHD in Adults or Transition Adolescents - Approve if endocrinology certifies that somatropin is not being prescribed for anti-aging therapy or to enhance athletic ability or for body building AND GHD must be childhood onset or adult onset that results from one of the following: pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, tumor treatment, TBI, or subarachnoid hemorrhage AND pt has known cause OR 3+ pituitary deficiences and IGF-1 below normal range with external causes for low IGF-1 excluded OR pt has had a negative response to GH stim tests. CKD - approve if pt has or had CKD defined by an abnormal CrCl. Noonan - approve if |

| PA Criteria | Criteria Details |
| --- | --- |
| | height is less than 5th percentile. Prader-Willi Syndrome - approve. Cont - Child's height has increased by 2 cm/yr AND epiphyses are open AND adults must not use for anti-aging or for athletic performance.Short Stature Homeobox (SHOX) - approve if pt has SHOX deficiency AND epiphyses are open AND height is less than 3rd percentile. Born small - approve if pt was born 2 SD below mean birth wt/ht AND height remains less than 5th percentile.Turner - approve. Cont - approve if height increased by 2 cm/hr and epiphyses are open. SBS - approve if pt is receiving nutritional support. Cont - approve if prescriber attests to response. |

# Haegarda

**Products Affected**

- HAEGARDA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concomitant use with other HAE prophylactic therapies. Patients may concomitantly use medications for the treatment of acute HAE attacks. |
| **Required Medical Information** | diagnosis, lab values |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Hereditary Angioedema (HAE) - HAE type 1 or type 2 as confirmed by low levels of functional C1-INH protein (less than 50% of normal) at baseline AND lower than normal serum C4 levels at baseline. Continuation therapy - patient is currently receiving Haegarda for HAE type 1 or type 2 prophylaxis AND according to the prescriber, the patient has had a favorable clinical response (e.g., decrease in number of HAE acute attack frequency, decrease in HAE attack severity, decrease in duration of HAE attacks) since initiating Haegarda prophylactic therapy compared with baseline. |

# Hemlibra

**Products Affected**

- HEMLIBRA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | lab results, other medications tried |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hemophilia specialist |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Hemophilia A with Factor VIII Inhibitors - Approve if pt is using Hemlibra for routine prophylaxis to prevent or reduce the frequency of bleeding episodes AND either has had a positive Factor VIII inhibitor titer greater than 5 Bethesda Units OR has had a positive Factor VIII inhibitor titer less than or equal to 5 Bethesda Units with an anamnestic response (current or past) to Factor VIII product dosing or experienced an inadequate clinical response (current or past) to increased Factor VIII product dosing. Presciber also attests that the patient will not be undergoing immune tolerance induction therapy while receiving Hemlibra, that if the patient is currently receiving a bypassing agent for prophylaxis, the bypassing agent therapy will be discontinued the day prior to initiation of Hemlibra and prophylactic use of bypassing agents will not occur while using Hemlibra, AND if the pt is currently receiving a Factor VIII product for prophylactic use, the Factor VIII product will be discontinued within the initial 4-week loading dose period with Hemlibra and that prophylactic use of Factor VIII products will not occur while using Hemlibra. Continuation - prescriber must make Factor VIII and bypassing agent attestations and the pt must have experienced a beneficial response, according to prescriber.Hemophilia A without Factor VIII Inhibitors - Approve if pt is using Hemlibra for routine prophylaxis to prevent or reduce the frequency of bleeding episodes AND has severe to moderate severe disease as defined by pretreatment Factor VIII levels less than 2% of normal OR has moderate to mild disease as defined by pretreatment Factor VIII levels greater than 2% to less than 40% of normal and meets one of the following criteria: pt has experienced a severe, traumatic, or spontaneous bleeding episode as determined by the prescriber, has hemophilia-related joint damage, has experienced a joint bleed, or has a specific joint that is subject to recurrent bleeding (presence of a target joint), or is in a perioperative situation and/or has an additional clinical scenario regarding bleeding/bleeding risk in which the prescriber determines the use of Hemlibra is warranted. Prescriber also attests that |
| | prophylactic use of bypassing agent will not occur while using Hemlibra, that if pt is receiving a Factor VIII product for prophylactic use, therapy will be discontinued within the initial 4-week loading dose period with Hemlibra, and prophylactic use of Factor VIII products will not occur while using Hemlibra. Continuation - prescriber must make Factor VIII and bypassing agent attestations and the pt must have experienced a beneficial response, according to prescriber. |

# Humira

**Products Affected**

- HUMIRA
- HUMIRA PEN
- HUMIRA PEN CROHNS-UC-HS START
- HUMIRA PEN PSOR-UVEITS-ADOL HS
- HUMIRA(CF)
- HUMIRA(CF) PEDI CROHNS STARTER
- HUMIRA(CF) PEN
- HUMIRA(CF) PEN CROHNS-UC-HS
- HUMIRA(CF) PEN PEDIATRIC UC
- HUMIRA(CF) PEN PSOR-UV-ADOL HS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded plus Behcet's Disease, Pyoderma Grangrenosum, Sarcoidosis, Scleritis (Sterile Conreal Ulceration), Spondyloarthritis. |
| **Exclusion Criteria** | Concurrent use with biologic DMARD or targeted synthetic DMARD (does not include methotrexate, hydroxychloroquine, sulfasalazine, and leflunomide). Polymyalgia rheumatica. |
| **Required Medical Information** | Diagnosis and previous medications tried |
| **Age Restrictions** | CD - 6 years or older. PP - 18 years or older. UC - 5 years or older. |
| **Prescriber Restrictions** | RA/JIA/JRA/AS/SpA - rheumatologist. PsA - rheumatologist or dermatologist. PP/PG/HS - dermatologist. UC/CD - gastroenterologist. Uveitis/Scleritis - ophthalmologist. Sarcoidosis - pulmonologist, ophthalmologist, or dermatologist. Bechet's - rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist. |
| **Coverage Duration** | Initial - 3 mo. Initial PG - 4 mo. Cont RA/AS/CD/JIA/JRA/HS/PP/PsA/UC/UV - 3 yr. Cont others - 1 yr. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | RA- pt has tried ONE conventional DMARD (e.g., MTX, hydroxychloroquine, sulfasalazine, or leflunomide) for at least 3 months OR the patient has tried one biologic (e.g. adalimumab, infliximab products, tociluzumab) for at least 3 months. AS- approve. CD- the patient has tried or is taking corticosteroids (CS) or CS are contraindicated OR pt has tried one other agent for CD (eg, azathioprine, 6-MP, MTX, certolizumab, adalimumab, ustekinumab, vedolizumab) or the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas or the patient has had ileocolonic resection. JIA/JRA- tried another agent (eg, MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide OR pt has absolute contraindication to MTX, sulfasalazine, or leflunomide OR pt has aggressive disease. HS- pt has tried at least one other therapy for HS (intralesional or oral CS, systemic abx, isotretinoin). PP- pt has tried at least ONE systemic therapy (e.g., MTX, CSA, acitretin, or PUVA) for at least 3 months, unless intolerant OR the patient has tried at least one biologic for at least 3 months (e.g., etanercept, infliximab, secukinumab, ustekinumab) OR the patient has a contraindication to MTX as determined by the prescriber. PsA - approve. UC- pt has tried ONE systemic agent (e.g., 6-mercaptopurine, azathioprine, CSA, tacrolimus, or a corticosteroid) or one biologic agent (e.g., infliximab, golimumab, vedolizumab), OR the patient has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. UV- approve if patient has tried ONE of the following therapies: periocular, intraocular, or systemic corticosteroids, immunosuppressives (MTX, mycophenolate mofetil, cyclosporine, azathioprine, cyclophosphamide) Enbrel (etanercept SC injection), or Remicade. Bechet's- Pt has tried at least one conventional therapy (CS, immunosuppressants, entanercept, infliximab). PG- approve if pt has tried one systemic corticosteroid OR |

| PA Criteria | Criteria Details |
|---|---|
| | Patient has tried one other immunosuppressant for at least 2 months or was intolerant to one of these agents. Sarcoidosis - approve if pt has tried at least 1 corticosteroid for this condition AND has tried at least one immunosuppressive agent. Scleritis- approve if pt has tried 1 therapy (NSAID, IV corticosteroid, or immunosuppressive agent). SpA- approve if pt has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional drug DMARD OR pt has axial spondyloarthritis AND has objective signs of inflammation (elevated CRP, sacroiliitis on MRI). Continuation for all - pt has had a response, as determined by prescriber. |

# Hycamtin

**Products Affected**

- HYCAMTIN ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |

# Hyqvia

**Products Affected**

- HYQVIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | |

# Ibandronate

**Products Affected**

- *ibandronate intravenous*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Treatment of postmenopausal osteoporosis, must meet ONE of the following 1. T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, or total hip, 2. has had osteoporotic fracture, 3. had a T-score (current or at any time in the past) at or below -2.0 at the lumbar spine, femoral neck, or total hip and the physician believes the patient is at high risk for fracture AND has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of bone mineral density (BMD), lack of BMD increase), had an osteoporotic fracture while receiving oral bisphosphonate therapy, or experienced intolerability to an oral bisphosphonate (e.g., severe GI-related adverse effects) OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid). |

# Ibrance

**Products Affected**

- IBRANCE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All-FDA approved indications not otherwise excluded.<br>Liposarcoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Breast Cancer - approve if pt has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer when the pt meets ONE of the following: Pt is postmenopausal and Ibrance will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) or has had surgical bilateral oophorectomy or ovarian irradiation AND Ibrance will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant. Breast Cancer in Men - approve if pt has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer and pt is receiving a gonadotropin-releasing hormone (GnRH) AND Ibrance will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant. Lipsarcoma - Approve if pt patient has well-differentiated/dedifferentiated liposarcoma (WD-DDLS). |

# Iclusig

**Products Affected**

- ICLUSIG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Myeloid/Lymphoid Neoplasms with Eosinophilia. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies |
| **Age Restrictions** | Chronic Myeloid Leukemia, Acute Lymphoblastic Leukemia - 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 Years |
| **Other Criteria** | Acute Lymphoblastic Leukemia - approve if pt has Philadelphia chromosome-positive acute lymphoblastic leukemia and has tried at least two other tyrosine kinase inhibitors for Philadelphia chromosome-positive acute lymphoblastic leukemia. (e.g., imatinib and dasatinib). Chronic Myeloid Leukemia - approve if pt has Philadelphia chromosome positive chronic myeloid leukemia and has tried at least two other tyrosine kinase inhibitors for Philadelphia chromosome-positive chronic myeloid leukemia. (e.g., imatinib, dasatinib, or nilotinib). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if tumor has an ABL1 or FGFR1 rearrangement. |

# Idhifa

**Products Affected**

- IDHIFA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from coverage. |
| **Exclusion Criteria** | |
| **Required Medical Information** | mutation results |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Acute Myeloid Leukemia (AML) - approve if the disease is isocitrate dehydrogenase-2 (IDH2)-mutation positive as detected by an approved test. |

# Imatinib

**Products Affected**

- *imatinib*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. All FDA approved indications not otherwise excluded. Chordoma. Fibromatosis (Desmoid Tumors). Graft Versus Host Disease, Chronic. Kaposi Sarcoma. Metastatic Melanoma. Myeloid/Lymphoid Neoplasms with Eosinophilia. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis. Mutation results. |
| **Age Restrictions** | ASM/DP/HS/MDD - 18 or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Graft Versus Host Disease, Chronic - 1 year. All others - 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Acute Lymphoblastic Leukemia - approve if pt has Philadelphia chromosome-positive acute lymphoblastic leukemia. Aggressive Systemic Mastocytosis (AMS) - approve. Chronic Myeloid Leukemia - approve if pt has Philadelphia chromosome-positive chronic myeloid leukemia. Dermatofibrosarcoma Protuberans (DP) - approve. Gastrointestinal Stromal Tumors - approve. Hypereosinophilic Syndrome and/or Chronic Eosinophilic Leukemia (HS) - approve. Myelodysplastic/Myeloproliferative Disease (MDD) - approve if condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements. Chordoma - approve. Fibromatosis (Desmoid Tumors) - approve if pt has advanced, aggressive, or unresectable fibromatosis (desmoid tumors). Graft Versus Host Disease, Chronic - approve if pt has tried at least one conventional systemic treatment for graft versus host disease. Kaposi Sarcoma - approve if pt has tried at least one medication and has relapsed or refractory disease. Metastatic Melanoma - approve if pt has c-Kit-positive advanced/recurrent or metastatic melanoma. Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if pt has tumor has an ABL1, FIP1L1-PDGFRA or PDGFRB rearrangement. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor - Approve if pt has tried Turalio (pexidartinib capsules) or cannot take Turalio, according to the prescriber. |

# Imbruvica

**Products Affected**

- IMBRUVICA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. B-Cell Lymphoma. Central Nervous System Lymphoma (Primary). Hairy Cell Leukemia. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | GVHD - 1 year. All others - 3 years. |
| **Other Criteria** | Chronic Lymphocytic Leukemia (CLL) - Approve. Graft-Versus-Host Disease, Chronic (GVHD) - Approve if pt has tried at least one conventional systemic treatment for graft-versus-host disease. Mantle Cell Lymphoma - Approve if pt has tried at least one systemic regimen or imbruvica is used in combination with rituximab prior to induction therapy. Marginal Zone Lymphoma (MZL) - Approve if pt tried at least one systemic regimen. Small Lymphocytic Lymphoma - Approve. Waldenström Macroglobulinemia - Approve. B-Cell Lymphoma (BCL) - Approve if pt has tried at least one systemic regimen. Central Nervous System Lymphoma (Primary) (CNSL) - Approve if pt has tried at least one therapy and according to the prescriber, the patient is not a candidate for or is intolerant to high-dose methotrexate. Hairy Cell Leukemia (HCL) - Approve if pt has tried at least two systemic regimens. |

# Immune Globulin

**Products Affected**

- GAMMAGARD LIQUID
- PRIVIGEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | For Vivaglobin, Hizentra prescribed with one of the following physician specialists: an allergist/immunologist, immunologist, otolaryngologist (ear nose and throat [ENT] physician), pulmonologist, or an infectious disease specialist |
| **Coverage Duration** | Authorization will be for 12 months. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For Gammunex-C, Gammaked, Gammagard liquid given SC and Vivaglobin, Hizentra, needs to be used for the treatment of a primary humoral or combined immune deficiency, which includes common variable immunodeficiency (CVID), X-linked agammaglobulinemia, severe combined immunodeficiencies (SCID), Wiskott-Aldrich syndrome, hyper-IgM syndromes (X-linked or autosomal recessive), other combined immunodeficiencies with significant hypogammaglobulinemia or antibody production defect, and unspecified hypogammaglobulinemia. For Gammunex-C, Gammked, Gammagard, other IVIG given IV, need documented diagnosis, prescriber specialty. For Vivaglobin, Hizentra, diagnoses Common variable immunodeficiency (CVID) and Unspecified hypogammaglobulinemia patient has documented history of significant recurrent or persistent, severe bacterial infections (such as recurrent pneumonias, frequent episodes of bacterial infections such as sinusitis, otitis, bronchitis, skin structure infections, or infections of the gastrointestinal tract) according to the prescribing physician that are not responding to antibiotics or prophylactic antibiotics or member has interfering hypersensitivities, other disorders increasing susceptibility to infection need to have been sought out and treated if exist, patient has reduced IgG level or reduced IgG1 and IgG3 levels or IgG1 reduction. Other immune deficiencies for Hizentra, Vivaglobin, patient has frequent and severe infections. |

# Inlyta

**Products Affected**

- INLYTA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded.<br>Differentiated Thyroid Carcinoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Advanced Renal Cell Carcinoma - Approve. Differentiated Thyroid Cancer (examples include papillary, follicular, and Hürthle cell thyroid carcinoma) - Approve if patient is refractory to radioactive iodine therapy. |

# Inqovi

**Products Affected**

- INQOVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded from coverage |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |

# Inrebic

**Products Affected**

- INREBIC

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from coverage. Myeloid/Lymphoid neoplasms with Eosinophilia. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, mutation results |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF - Approve if pt has intermediate-2 or high-risk disease. Myeloid/Lymphoid neoplasms with Eosinophilia - Approve if the tumor has a JAK2 rearrangement. |

# Iressa

**Products Affected**

- IRESSA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Metastatic NSCLC - Approve if the pt has epidermal growth factor receptor (EGFR) exon 19 deletions OR has exon 21 (L858R) substitution mutations as detected by an FDA-approved test. |

# Isturisa

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Patients with Endogenous Cushing's Syndrome. Patients with Endogenous Cushing's Syndrome awaiting surgery or awaiting a response after radiotherapy. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prior surgeries |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's disease/syndrome |
| **Coverage Duration** | Cushing's Disease/Syndrome- 1 yr. Patients awaiting surgery or response after radiotherapy- 4 months |
| **Other Criteria** | Cushing's Disease - Approve if the patient is not a candidate for surgery or surgery has not been curative. Endogenous Cushing's Syndrome - Approve if, according to the prescriber, the patient is not a candidate for surgery or surgery has not been curative AND pt has tried one of the following: ketoconazole tablets, Korlym, Metopirone, Lysodren, Signifor, or Signifor LAR for the treatment of endogenous Cushing's syndrome OR is currently receiving Isturisa. Endogenous Cushing's Syndrome, pts awaiting surgery or pts awaiting therapeutic response after radiotherapy - approve. |

# Ivermectin

**Products Affected**

- *ivermectin oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Ascariasis. Gnathostomiasis. Enterobiasis. Hookworm-related cutaneous larva migrans. Mansonella ozzardi infection. Mansonella streptocerca infection. Pediculosis. Scabies. Trichuriasis. Wucheria bancrofti infection. |
| **Exclusion Criteria** | Coronavirus disease 2019 (COVID-19) |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Please see approval durations in other criteria. |
| **Other Criteria** | Onchocerciasis - Approve for 1 dose. Strongyloidiasis - Approve for 2 doses. Ascariasis- Approve for 1 dose. Gnathostomiasis - Approve for 1 dose. Enterobiasis - Approve for 2 doses. Hookworm-related cutaneous larva migrans - Approve for 1 dose. Mansonella ozzardi infection - Approve for 1 dose. Mansonella streptocerca infection - Approve for 1 dose. Pediculosis - Approve for 3 doses if pt has infection causes by head, body, or pubic lice. Scabies - Approve for 2 doses if pt has classic scabies, treatment-resistant scabies, or pt is unable to tolerate topical treatment. Approve for 3 doses if pt has crusted scabies. Approve for 1 dose if pt is using ivermectin for prevention and/or control of scabies. Trichuriasis - Approve for 3 doses. Wucheria bancrofti infection - Approve for 1 dose. |

# Jakafi

**Products Affected**

- JAKAFI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Acute Lymphoblastic Leukemia. Atypical Chronic Myeloid Leukemia. Chronic Monomyelocytic Leukemia-2. Graft versus Host Disease, Chronic. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Previous therapies tried. Mutation results. |
| **Age Restrictions** | GVHD - 12 years or older. MF/PV/CML-2 - 18 years or older. ALL - 21 years or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Graft versus Host Disease, Acute - Approve if pt has tried one systemic corticosteroid. Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF - approve. Polycythemia Vera (PV) - approve if pt has tried hydroxyurea. Acute Lymphoblastic Leukemia (ALL) - Approve if the mutation/pathway is Janus Associated Kinase-related. Atypical Chronic Myeloid Leukemia - approve if pt has a Janus Associated Kinase mutation. Chronic Monomyelocytic Leukemia-2 - approve if pt is also receiving a hypomethylating agent. Graft versus Host Disease, Chronic - Approve if pt has tried one conventional systemic treatment for graft versus host disease. |

# Jynarque

**Products Affected**

- JYNARQUE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use of Samsca. Hyponatremia. |
| **Required Medical Information** | Diagnosis, renal function |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Autosomal Dominant Polycystic Kidney Disease - Approve if pt has rapidly-progressing autosomal dominant polycystic kidney disease (e.g., reduced or declining renal function, high or increasing total kidney volume [height adjusted]) and the pt does not have Stage 5 chronic kidney disease (glomerular filtration rate less than 15 mL/min/1.73 m2 or receiving dialysis). |

# Kadcyla

**Products Affected**

- KADCYLA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Non-Small Cell Lung Cancer. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 years |
| **Other Criteria** | Breast Cancer - approve if HER2-positive AND cancer is recurrent or metastatic OR Kadcyla will be used as adjuvant therapy. Non-Small Cell Lung Cancer - approve if HER2-positive. |

# Kalydeco

**Products Affected**

- KALYDECO ORAL GRANULES IN PACKET 50 MG, 75 MG
- KALYDECO ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | CF pts who are Homozygous for the phe508del (F508del) Mutation in the CFTR gene. CF pts with unknown CFTR gene mutation. Combination therapy with Orkambi, Symdeko, or Trikafta. |
| **Required Medical Information** | |
| **Age Restrictions** | 4 months and older |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a pulmonologist or physician or specializes in the treatment of CF |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Cystic Fibrosis (CF) - Patient has at least ONE of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, S945L, S977F, F1052V, K1060T, A1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, D1270N, G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, G1349D, 2789+5G-A, 3272-26A-G, 3849+10kbC-T, 711+3A-G, E831X, R117H, A120T, A234D, A349V, D192G, D924N, E882K, F311L, F311delF508C, F508C,S1251N, G178E, G194R, G314E, G576A, G970D, G1249R, H939R, H1375P, I148T, I175V, I807M, I1027T, I1139V, L320V, L967S, L997F, L1480P, M152V, M9521, M952T, Q237E, Q237H, Q359R, Q1291R, R75Q, R117G, R117L, R117P, R170H, R347L, R553Q, R668C, R792G, R933G, R1162L, R1283M, S589N, S737F, S1159F, S1159P, T338I, T1053I, V232D, V562I, V754M, V1293G, W1282R, Y1014C, or Y1032C. |

# Kesimpta

**Products Affected**

- KESIMPTA PEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded from coverage. |
| **Exclusion Criteria** | Concurrent use with other disease modifying agents used for multiple sclerosis. Non-relapsing forms of multiple sclerosis. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. |

# Kisqali

**Products Affected**

- KISQALI
- KISQALI FEMARA CO-PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Breast cancer in men. |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, hormone receptor status, concurrent therapies |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Breast Cancer - approve if pt has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer when the pt meets ONE of the following: Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) or has had surgical bilateral oophorectomy or ovarian irradiation AND Kisqali will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant. Breast Cancer in Men - approve if pt has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer and pt is receiving a gonadotropin-releasing hormone (GnRH) AND Kisqali will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant. |

# Koselugo

**Products Affected**

- KOSELUGO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Neurofibromatosis Type 1 - approve if the patient is 2 to 18 years of age OR the patient is 19 years of age or older and has been previously started on therapy with Koselugo prior to becoming 19 years of age, AND prior to starting Koselugo the patient has symptomatic, inoperable plexiform neurofibromas, according to the prescriber. |

# Ledipasvir-Sofosbuvir

**Products Affected**

- *ledipasvir-sofosbuvir*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Recurrent HCV post-liver transplant. |
| **Exclusion Criteria** | Combination use with other direct acting antivirals, excluding ribavirin. |
| **Required Medical Information** | Genotype, prescriber specialty, other medications tried or those that will be used in combination with requested medication, cirrhosis status. |
| **Age Restrictions** | 3 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD. |
| **Coverage Duration** | Approval duration will be applied consistent with AASLD/ISDA guidance |
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance |

# Lemtrada

**Products Affected**

- LEMTRADA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Lemtrada should not be given in combination with other disease-modifying agents used for MS (e.g., Betaseron, Extavia, Rebif, Copaxone, Avonex, Plegridy, Glatopa, Gilenya, Aubagio, Tecfidera, Tysabri or Zinbryta). Clinically isolated syndrome. Non-relapsing forms of MS. Pts infected with HIV. |
| **Required Medical Information** | The patient has a relapsing form of MS (relapsing forms of MS are RRMS, SPMS with relapses, and PRMS) |
| **Age Restrictions** | 17 years of age or older. |
| **Prescriber Restrictions** | Lemtrada is prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of MS. |
| **Coverage Duration** | Initial - 5 days. Continuation - 3 days. |
| **Other Criteria** | According to the prescriber, pt has experienced inadequate efficacy or significant intolerance to two disease-modifying agents used for multiple sclerosis OR pt has highly active or agreesive MS meeting one of the following:(1) Patient has demonstrated rapidly-advancing deterioration(s) in physical functioning (e.g., loss of mobility/or lower levels of ambulation, severe changes in strength or coordination) [documentation required], (2) Disabling relapse(s) with suboptimal response to systemic corticosteroids [documentation required], (3) MRI findings suggest highly-active or aggressive multiple sclerosis (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions) [documentation required],(4)Manifestations of multiple sclerosis-related cognitive impairment [documentation required]. Continuation therapy - at least 1 year has elapsed from the last dose of any prior Lemtrada treatment course. |

# Lenvima

**Products Affected**

- LENVIMA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Medullary thyroid carcinoma. Thymic Carcinoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies tried |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Endometrial Carcinoma - Approve if pt has advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) and is used in combination with Keytruda, after pt has tried at least one systemic therapy and is not a candidate for curative surgery or radiation. Hepatocellular Cancer - Approve if pt has unresectable or metastatic disease. Renal Cell Cancer - Approve if pt has advanced disease and pt either using Lenvima in combinatino with Keytruda OR Lenvima is being used with everolimus and pt either has clear cell histology and has tried one antiangiogenic therapy or pt has non-clear cell histology. Thyroid Carcinoma, Differentiated (papillary, follicular, and Hürthle cell) - Approve if disease is refractory to radioactive iodine therapy. Thymic Carcinoma - Approve if pt has tried at least one chemotherapy regimen. Medullary Thyroid Carcinoma - Approve if pt has tried at least one systemic therapy. |

# Letairis/Tracleer

**Products Affected**

- *ambrisentan*
- *bosentan*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | The patient has a diagnosis of PAH (WHO Group 1) |
| **Age Restrictions** | |
| **Prescriber Restrictions** | For Pulmonary Arterial Hypertension (PAH) or Chronic Thromboembolic Pulmonary Hypertension (CTEPH) must be prescribed by or in consultation with a cardiologist or a pulmonologist |
| **Coverage Duration** | Authorization will be for 12 months. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For PAH patient must have had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). For Digital Ulcers/Systemic Sclerosis approve if patient has tried two other therapies for this condition such as calcium channel blockers (CCBs) [e.g., amlodipine, felodipine, nifedipine], alpha-adrenergic blockers (e.g., prazosin), nitroglycerin, phosphodiesterase type 5 (PDE5) inhibitors (e.g., sildenafil tablets, Levitra [vardenafil tablets]), or angiotensin converting enzyme (ACE) inhibitors OR the patient has tried one vasodilator/prostanoid therapy (e.g., epoprostenol injection, alprostadil injection). For Chronic Thromboembolic Pulmonary Hypertension (CTEPH) approve if he patient meets ONE of the following: The patient has tried Adempas OR The patient has a specific contraindication to use of Adempas according to the prescribing physician (e.g., the patient is receiving nitrates or nitric oxide donors, the patient is receiving a phosphodiesterase inhibitor [e.g., Revatio, Adcirca], the patient is hypotensive or is at risk for hypotension) OR The patient is currently receiving Tracleer for CTEPH. |

# Long Acting Opioids

**Products Affected**

- BELBUCA
- *buprenorphine*
- *fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr*
- *methadone oral concentrate*
- *methadone oral solution 10 mg/5 ml, 5 mg/5 ml*
- *methadone oral tablet 10 mg, 5 mg*
- *morphine oral capsule,extend.release pellets 100 mg, 20 mg, 30 mg, 50 mg, 60 mg, 80 mg*
- *morphine oral tablet extended release 100 mg, 15 mg, 200 mg, 30 mg, 60 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded worded as pain severe enough to require daily, around-the-clock, long-term opioid treatment. Plus patients with a cancer diagnosis, patients in a hospice program/end-of-life care/palliative care. |
| **Exclusion Criteria** | Acute (ie, non-chronic) pain |
| **Required Medical Information** | Pain type (chronic vs acute), prior pain medications/therapies tried,concurrent pain medications/therapies. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | For pain severe enough to require daily, around-the-clock, long-term opioid treatment (with no cancer diagnosis and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naive (buprenorphine products are excluded from this requirement), AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patients history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), unless unavailable in the state, AND 4) the prescribing physician has discussed risks (e.g., addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (i.e., FDA labeled use) prior to reviewing for quantity exception. |

# Lonsurf

**Products Affected**

- LONSURF

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Colon and Rectal Cancer - approve if pt has been previously treated with a fluoropyrimidine (e.g., capecitabine, 5-fluorouracil [5-FU]) AND oxaliplatin AND irinotecan AND if the pt's tumor or metastases are KRAS and/or NRAS mutation negative then Erbitux or Vectibix has been tried. Gastric or Gastroesophageal Junction Adenocarcinoma - Approve for if pt has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma. |

# Lorbrena

**Products Affected**

- LORBRENA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Non-Small Cell Lung Cancer which is ROS1 Rearrangement positive. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, mutation results, previous therapies |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | NSCLC - Approve if the patient has ALK-positive metastatic NSCLC OR pt has ROS1 rearrangement-positive disease and has tried at least one of Xalkori (crizotinib capsules), Zykadia (ceritinib capsules), or Rozlytrek (entrectinib capsules). |

# Lynparza

**Products Affected**

- LYNPARZA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Breast Cancer - approve if pt has metastatic, germline BRCA mutation-positive breast cancer AND has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting AND meets one of the following: 1) pt has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease and has been treated with prior endocrine therapy or is considered inappropriate for endocrine therapy OR 2) pt has triple negative disease (i.e., ER-negative, PR-negative, and HER2-negative). Ovarian Cancer - Treatment - approve if pt has a germline BRCA-mutation as confirmed by an approved test has progressed on three or more prior lines of chemotherapy OR pt has a BRCA mutation (germline) as confirmed by an approved test and is currnetly receiving Lynparza. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance, Monotherapy - Approve if pt has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test and is in complete or partial response to first-line platinum-based chemotherapy regimen OR pt is in complete or partial response after at least two platinum-based chemotherapy regimens. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance, Combination Therapy - approve if being used in combination with bevacizumab AND pt has homologous recombination deficiency (HRD)-positive disease as confirmed by an approved test (which includes pts with BRCA mutation-positive disease) AND pt is in complete or partial response to first-line platinum-based chemotherapy regimen. Pancreatic Cancer - Maintenance Therapy - Patient has a germline BRCA mutation-positive metastatic disease and the disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen. Prostate Cancer - Castration-Resistant - approve if pt has metastatic disease AND the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or pt has had a bilateral orchiectomy AND Patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed |
| | by an approved test (HRR gene mutations include BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, or RAD54L) AND pt does not have a PPP2R2A mutation AND pt has been previously treated with abiraterone or Xtandi (enzalutamide capsules). |

# Lysosomal Storage Disease Enzyme Replacement Therapies

**Products Affected**

- ALDURAZYME
- CEREZYME INTRAVENOUS RECON SOLN 400 UNIT
- ELAPRASE
- ELELYSO
- FABRAZYME
- LUMIZYME
- VIMIZIM
- VPRIV

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Lumizyme Initial must meet all of the following: The member has a diagnosis of late-onset (noninfantile)Pompe disease, The member's diagnosis of late-onset Pompe disease is based on both of the following:Acid alpha-glucosidase (GAA) enzyme assay that shows reduced enzyme activity at less than 40 percent of the lab-specific normal mean value AND Confirmation by a second GAA enzyme activity assay in a separate sample (from purified lymphocytes, fibroblast, or muscle) or by GAAgene sequencing, The member is 8 years of age or older, The member has a forced vital capacity (FVC) 30 percent to 79 percent of predicted value while in the sitting position, The member has a postural drop in FVC (in liters) of 10 percent or more from upright to supine position, The member has the ability to walk 40 meters on a six minutewalk test (assistive devices permitted), AND The member has muscle weakness in the lower extremities.Continuation: The clinical criteria for approval of a subsequent PA request for Lumizyme are both of the following:The member is ambulatory (assistive devices permitted) The member is not ventilator dependent.Note: The prescriber should indicate the member's ambulation and ventilator status on the PA request. |

# Makena

**Products Affected**

- *hydroxyprogest(pf)(preg presv)*
- *hydroxyprogesterone cap(ppres)*
- *hydroxyprogesterone capr(bulk)*
- *hydroxyprogesterone caproate*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Hx of threatened preterm birth. Infertility. Pts pregnant with multiple gestations (twins, or other multiples). Pregnant pt with short cervix without a hx of a prior Singleton Spontaneous Preterm Birth. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Reduce Risk of Preterm Birth - 5 months. |
| **Other Criteria** | Reduce Risk of Preterm Birth - Pt is pregnant with singleton pregnancy with history of single spontaneous preterm birth prior to 37 weeks gestation and treatment will begin in pts who are at least 16 weeks of gestation, according to prescriber. NOTE: In cases where there was an inaccuracy in dating the pregnancy, a one-month authorization may be granted to patients who have already received 21 injections and are less than 37 weeks pregnant. |

# Mavyret

**Products Affected**

- MAVYRET ORAL PELLETS IN PACKET
- MAVYRET ORAL TABLET 100-40 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Criteria will be applied consistent with current AASLD/IDSA guidance and, if not available, FDA labeling. |
| **Exclusion Criteria** | HCV with moderate or severe hepatic impairment. Concomitant use with any other direct-acting antiviral. Life expectancy less than 1 year due to non-liver related comorbidities. Pediatric patients less than 3 years old. |
| **Required Medical Information** | Genotype, prescriber specialty, other medications tried or used in combination with requested medication |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD/IDSA guidance or FDA label |
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance and, if not available, FDA labeling. |

# Mayzent

**Products Affected**

- MAYZENT
- MAYZENT STARTER PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from coverage |
| **Exclusion Criteria** | Non-relapsing forms of multiple sclerosis. Concurrent use of other disease-modifying agents used for multiple sclerosis. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. |

# Megestrol

**Products Affected**

- *megestrol oral suspension 400 mg/10 ml (10 ml), 400 mg/10 ml (40 mg/ml)*
- *megestrol oral tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Coverage is not provided for weight gain for cosmetic reasons. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 months |
| **Other Criteria** | |

# Mekinist

**Products Affected**

- MEKINIST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Biliary Tract Cancer. Central Nervous System Cancer. Histiocytic Neoplasm. Ovarian/Fallopian Tube/Primary Peritoneal Cancer. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, mutation results, other therapies tried |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Melanoma - Approve if pt has unresectable, advanced (including stage III or stage IV disease), or metastatic melanoma and BRAF V600 mutation-positive disease. Non-Small Cell Lung Cancer - Approve if pt has BRAF V600E mutation-positive disease and the medication is prescribed in combination with Tafinlar (dabrafenib). Anaplastic Thyroid Carcinoma - Approve if pt has locally advanced or metastatic anaplastic disease, BRAF V600 mutation-positive disease, and the medication will be taken in combination with Mekinist Tafinlar (dabrafenib), unless intolerant. Biliary Tract Cancer - Approve if pt has tried at least one systemic chemotherapy regimen, has BRAF V600 mutation-positive disease, and the medication will be taken in combination with Tafinlar (dabrafenib). Central Nervous System Cancer - Approve if pt has BRAF V600 mutation-positive disease and the medication is being used for adjuvant treatment of pilocytic astrocytoma, pleomorphic xanthoastrocytoma, or ganglioglioma, or for recurrent disease of low-grade glioma, anaplastic glioma, or glioblastoma, or brain metastases due to melanoma AND the medication is prescribed in combination with Tafinlar (dabrafenib). Histiocytic Neoplasm - Approve if pt has BRAF V600 mutation-positive disease and has Langerhans cell histiocytosis and one of the following: multisystem disease, pulmonary disease, or central nervous system lesions OR pt has Erdheim-Chester disease OR pt has Rosai-Dorfman disease. Ovarian/Fallopian Tube/Primary Peritoneal Cancer - Approve if pt has recurrent disease and the medication is used for low-grade serous carcinoma. |

# Mektovi

**Products Affected**

- MEKTOVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, BRAF V600 mutations |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Melanoma - Approve if pt has unresectable, advanced, or metastatic melanoma which is BRAF V600 mutation-positive, and the medication will be used in combination with Braftovi (encorafenib). |

# Natpara

**Products Affected**

- NATPARA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Acute post-surgical hypoparathyroidism. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Chronic hypoparathyroidism - Before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL and 25-hydroxyvitamin D stores are sufficient per the prescribing physician AND as per product labeling, patient cannot be well-controlled on calcium supplements and active forms of vitamin D alone. Continuation - The patient cannot be well-controlled on calcium supplements and active forms of vitamin D alone, pt's 25-hydroxyvitamin D stores are sufficient during Natpara therapy, according to the prescriber, and pt is responding to Natpara therapy, according to the prescriber. |

# Nerlynx

**Products Affected**

- NERLYNX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use of Nerlyx with other medications for adjuvant or neoadjuvant treatment of HER2-positive breast cancer (e.g. Herceptin, Perjeta) |
| **Required Medical Information** | Diagnosis, HER2 status, Herceptin treatment status |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Adjuvant therapy - 1 year. Advanced or Metastatic disease - 3 years. |
| **Other Criteria** | Breast Cancer, adjuvant therapy - approve if pt has HER2 positive breast cancer AND the medication is requested for extended adjuvant therapy after the patient has completed 1 year of adjuvant therapy with trastuzumab intravenous products OR pt has tried adjuvant therapy with trastuzumab intravenous products and could not tolerate 1 year of therapy, according to the prescriber. Breast Cancer, advanced or metastatic - approve if pt has HER2 positive breast cancer AND the medication will be used in combination with capecitabine AND pt has tried at least two prior anti-HER2 based regimens in the metastatic setting. |

# Nexavar

**Products Affected**

- NEXAVAR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Acute Myeloid Leukemia. Bone Cancer. Gastrointestinal Stromal Tumor. Myeloid/Lymphoid Neoplasms with Eosinophilia. Ovarian, Fallopian Tube, Primary Peritoneal Cancer. Soft Tissue Sarcoma. Thyroid Cancer, Medullary. |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, previous therapies tried, mutation results |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Hepatocellular Cancer - Approve if pt has unresectable or metastatic disease. Renal Cell Cancer - Approve if pt has relapesed or advanced disease AND has clear cell histology AND has tried at least one systemic therapy. Thyroid Carcinoma, Differentiated - Approve if pt has differentiated thyroid carcinoma (papillary, follicular, and Hürthle cell) and the disease is refractory to radioactive iodine therapy. Acute Myeloid Leukemia - Approve if pt has FLT3-ITD mutation-positive disease as detected by an approved test and will use Nexavar in combination with azacitidine or decitabine. Bone Cancer - Approve if pt has recurrent chordoma OR pt has osteosarcoma and has tried one systemic chemotherapy regimen. Gastrointestinal Stromal Tumor - Approve if pt has previously tried Sutent, Stivarga, Qinlock, and either imatinib or Avyakit. Myeloid/Lymphoid Neoplasms with Eosinophilia - Approve if pt has an FLT3 rearrangement. Ovarian, Fallopian Tube, Primary Peritoneal Cancer - Approve if pt has platinum-resistant disease and Nexavar will be used in combination with topotecan. Soft Tissue Sarcoma - Approve if pt has one of the following diagnoses: angiosarcoma, desmoid tumors, or solitary fibrous Tumor/Hemangiopericytoma. Thyroid Cancer, Medullary - Approve if pt has tried at least one systemic therapy. |

# Nexletol

**Products Affected**

- NEXLETOL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | lab results, prior therapies tried |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Atherosclerotic Cardiovascular Disease (ASCVD) -approve if pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND pt has tried a high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) AND ezetimibe concomitantly for greater than or equal to 8 continuous weeks and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Heterozygous Familial Hypercholesterolemia (HeFH) - approve if pt meets one of the following - The patient has an untreated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 190 mg/dL (prior to treatment with antihyperlipidemic agents) OR the patient has genetic confirmation of HeFH by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 or low-density lipoprotein receptor adaptor protein 1 gene OR the patient has been diagnosed with HeFH meeting one of the following diagnostic criteria thresholds - the prescriber used the Dutch Lipid Network criteria and the patient has a score greater than 5 OR the prescriber used the Simon Broome criteria and the patient met the threshold for definite or possible familial hypercholesterolemia OR the patient has clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma) AND the pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) AND ezetimibe concomitantly for greater than or equal to 8 continuous weeks and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin |
| | intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. |

# Nilutamide

**Products Affected**

- *nilutamide*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Prostate cancer-approve if nilutamide is used concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist. |

# Ninlaro

**Products Affected**

- NINLARO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Systemic Light Chain Amyloidosis. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, other medication use |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Multiple Myeloma - Approve if Ninlaro will be taken in combination with Revlimid (lenalidomide capsules) and dexamethasone OR pt has received at least one prior regimen for multiple myeloma OR Ninlaro will be used following autologous stem cell transplantation (ASCT). Systemic Light Chain Amyloidosis - Approve if pt has tried at least one other regimen for this condition. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma - Approve if Ninlaro will be used in combination with a rituximab product and dexamethasone. |

# Nubeqa

**Products Affected**

- NUBEQA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Prostate Cancer (Non-Metastatic, Castration-Resistant) - approve if the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR pt has had a bilateral orchiectomy. |

# Nucala

**Products Affected**

- NUCALA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Atopic dermatitis. COPD. Concurrent use with another Anti-Interleukin monoclonal antibody. Concurrent use with Xolair. Eosinophilic esophagitis, eosinophilic gastroenteritis, or eosinophilic colitis. |
| **Required Medical Information** | Diagnosis, lab results, previous medication use |
| **Age Restrictions** | Asthma - 6 years of age and older. EGPA/NP - 18 years of age and older. Hypereosinophilic syndrome - 12 years of age and older. |
| **Prescriber Restrictions** | Asthma - Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. EGPA/Hypereosinophilic Syndrome - Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist. NP - prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist. |
| **Coverage Duration** | Asthma/EGPA/NP initial-6mo. Hypereosinophilic syndrome - 8mo. Continuation therapy - 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Asthma - pt has a blood eosinophil level of greater than 150 cells per mL within the previous 6 weeks or within 6 weeks prior to treatment with any AL-5 therapy AND pt has received at least 3 consecutive months of ICS and at least one additional asthma controller/maintenance medication AND pts asthma is uncontrolled or was uncontrolled prior to starting any anti-interleukin therapy as defined by ONE of the following: two or more exacerbations requiring systemic corticosteroids (CS), one exacerbation which required an ED visit or hospitalization in the previous year, FEV1 of less than 80 percent predicted, or pt has CS dependent asthma. Eosinophilic Granulomatosis with Polyangiitis (EGPA) [formerly known as Churg-Strauss Syndrome] - pt has has active, non-severe disease and a blood eosinophil level of greater than 150 cells per mL within the previous 6 weeks or within 6 weeks prior to treatment with any AL-5 therapy AND pt has received at least 4 weeks of CS. Hypereosinophilic Syndrome (HS) - pt has had HS for greater than 6 months AND has FIP1L1-PDGFRa-negative disease AND according to the prescriber, the patient does NOT have an identifiable non-hematologic secondary cause of HS AND prior to initiating therapy with any anti-interleukin-5 therapy, the patient has/had a blood eosinophil level of greater than 1,000 cells per mL AND pt has tried at least one other treatment for hypereosinophilic syndrome for a minimum of 4 weeks. Nasal Polyps (NP) - Approve if pt has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan and has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell. Pt has received at least 3 months of therapy with an intranasal corticosteroid and will continue to receive therapy with an intranasal corticosteroid concomitantly with Nucala AND pt has either received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years, has a contraindication to systemic corticosteroid therapy, or has had prior surgery for nasal polyps. |
| | Continuation (all) - pt has received at least 6 months of Nucala (8mo for HS) and is responding to therapy as determined by prescriber. Continuation (NP) - Pt must also continue to receive therapy with an intranasal corticosteroid. |

# Nuedexta

**Products Affected**

- NUEDEXTA ORAL CAPSULE 20-10 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Heroin detoxification. Levodopa-Induced Dyskinesia in Parkinson's Disease. Neuropathic Pain. Psychosis-Related Aggression. Treatment-Resistant Depression. |
| **Required Medical Information** | diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Treatment of Pseudobulbar Affect - Approve if pt has pseudobulbar affect associated with a chronic neurological condition. |

# Nurtec ODT

**Products Affected**

- NURTEC ODT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Combination therapy with Aimovig, Ajovy, Emgality, or Vyepti if Nurtec is being taken for the preventive treatment of episodic migraine. |
| **Required Medical Information** | Diagnosis, other therapies used |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Migraine, acute treatment - Pt has tried at least one triptan therapy or has a contraindication to triptans according to the prescriber. Preventive Treatment of Episodic Migraine - Approve if pt has at least 4 but less than 15 migraine headache days per month, AND has tried at at least two standard prophylactic pharmacologic therapies, each from a different pharmacologic class, but had inadequate efficacy or experienced adverse effects severe enough to warrant discontinuation, AND pt has either tried a triptan (or has a contraindication to triptans according to the prescriber) or pt is currently taking Nurtec ODT and has had a significant clinical benefit from the medication as determined by the prescriber. |

# Ocaliva

**Products Affected**

- OCALIVA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Alcoholic liver disease. Nonalcoholic Fatty Liver Disease, including Nonalcoholic Fatty liver or Nonalcoholic Steatohepatitis. |
| **Required Medical Information** | Diganosis, lab results, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician |
| **Coverage Duration** | Initial - 6 months. Continuation - 1 year |
| **Other Criteria** | Primary Biliary Cholangitis - Approve if pt has a diagnosis of primary biliary cholangitis as defined by TWO of the following: alkaline phosphatase is elevated above the upper limit of normal as defined by normal laboratory reference values, positive anti-mitochondrial antibodies or other primary biliary cholangitis-specific auto-antibodies including, sp100 or gp210, if anti-mitochondrial antibodies are negative, or histologic evidence of primary biliary cholangitis from a liver biopsy AND pt either has been receiving ursodiol therapy for greater than 1 year and has had an inadequate response or is unable to tolerate ursidiol therapy, according to the prescriber AND pt either does not have cirrhosis or has compensated cirrhosis without evidence of portal hypertension. Continuation - Approve if pt either does not have cirrhosis or has compensated cirrhosis without evidence of portal hypertension AND pt has responded to Ocaliva as determined by the prescriber. |

# Ocrevus

**Products Affected**

- OCREVUS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis. |
| **Required Medical Information** | diagnosis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a physician who specializes in the treatment of MS and/or a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Multiple Sclerosis (MS), Relapsing Forms - approve if pt has a relapsing form of multiple sclerosis (e.g. clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease). MS, Primary Progressive - approve. |

# Odactra

**Products Affected**

- ODACTRA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use with subcutaneous allergen immunotherapy (i.e.allergy shots) or other sublingual (SL) allergen immunotherapy. |
| **Required Medical Information** | Diagnosis, results of skin test or in vitro test |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT]) physician specialist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | House Dust Mite-Induced Allergic Rhinitis - Approve if the diagnosis of house dust mite-induced allergic rhinitis is confirmed by a positive skin test response to house dust mite allergen extracts or a positive in vitro test (i.e., a blood test for allergen-specific IgE antibodies) for house dust mite AND the patient has previously tried an oral antihistamine and a nasal corticosteroid. |

# Ofev

**Products Affected**

- OFEV

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded. |
| **Exclusion Criteria** | Combination use with pirfenidone (Esbriet). |
| **Required Medical Information** | diagnosis |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | IPF/ILDCF - prescribed by or in consultation with a pulmonologist. ILDSS - prescribed by or in consultation with a pulmonologist or a rheumatologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Idiopathic Pulmonary Fibrosis (IPF) - Approve if pt has forced vital capacity (FVC) greater than or equal to 40 percent of the predicted value AND diagnosis must be confirmed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or a surgical lung biopsy demonstrating UIP. Interstitial Lung Disease, Chronic Fibrosing with a Progressive Phenotype (ILDCF) - approve if the FVC is greater than or equal to 40% of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10% of lung volume on high-resolution computed tomography AND according to the prescriber the patient has clinical signs of progression. Interstitial Lung Disease Associated with Systemic Sclerosis (ILDSS) - approve if FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by HRCT. Continuation (all) - approve if pt has experienced a beneficial response to therapy over the last year while receiving Ofev. |

# Omnipod

**Products Affected**

- OMNIPOD DASH 5 PACK POD
- OMNIPOD INSULIN MANAGEMENT
- OMNIPOD INSULIN REFILL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diabetes mellitus, type 1. Diabetes mellitus, type 2, insulin dependent. |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, insulin use |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Diabetes mellitus, type 1 - approve. Diabetes mellitus, type 2, insulin dependent - approve if pt is using at least three injections of insulin per day. Continuation - approve. |

# Ongentys

**Products Affected**

- ONGENTYS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Parkinson's Disease - approve if pt is currently receiving carbidopa/levodopa therapy. |

# Onureg

**Products Affected**

- ONUREG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Acute Myeloid Leukemia (AML) - Approve if the medication is used for post-remission maintenance therapy, the pt is not able to complete intensive consolidation chemotherapy, the pt has declined or is not fit or eligible for allogeneic hematopoietic stem cell transplant, and the pt meets one of the following: pt has poor- or intermediate-risk cytogenics, pt is minimal residual disease positive, pt has treatment-related acute myeloid leukemia other than core binding factor, or pt has complete response to previous intensive induction chemotherapy. |

# Opsumit

**Products Affected**

- OPSUMIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | PAH WHO group, right heart catherization |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PAH - must be prescribed by or in consultation with a cardiologist or a pulmonologist. |
| **Coverage Duration** | Authorization will be for 1 years. |
| **Other Criteria** | Pulmonary arterial hypertension (PAH) WHO Group 1 patients not currently on Opsumit or another agent indicated for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1 patients currently on Opsumit or another agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization. |

# Orgovyx

**Products Affected**

- ORGOVYX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 Year |
| **Other Criteria** | Prostate Cancer - Approve. |

# Oriahnn

**Products Affected**

- ORIAHNN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded |
| **Exclusion Criteria** | Heavy Menstrual Bleeding not associated with Uterine Fibroids |
| **Required Medical Information** | Diagnosis, previous therapies, test results |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health |
| **Coverage Duration** | 2 years |
| **Other Criteria** | Uterine Fibroids (Leiomyomas) - Approve if pt is premenopausal and experiencing heavy menstrual bleeding associated with the uterine fibroids which have been confirmed by a pelvic ultrasound, including transvaginal ultrasonography or sonohysterography, hysteroscopy, or magnetic resonance imaging. Pt must also have tried at least one other therapy for the medical management of heavy menstrual bleeding, and pt has not previously received 24 months or longer of therapy with Oriahnn or Myfembree. |

# Orilissa

**Products Affected**

- ORILISSA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Endometriosis - Approve if pt has tried an oral contraceptive, an oral progesterone, a depo-medroxyprogesterone injection, or a gonadotropin-releasing hormone agonist for endometriosis. Continuation - approve. |

# Orkambi

**Products Affected**

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Cystic Fibrosis heterozygous for the F508del Mutation. Combination use with Kalydeco, Symdeko, or Trikafta. |
| **Required Medical Information** | |
| **Age Restrictions** | 2 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of CF. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Cystic Fibrosis - Approve if pt is homozygous for the F508del mutation in the CFTR gene. |

# Orladeyo

**Products Affected**

- ORLADEYO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concomitant Use with Other HAE Prophylactic Therapies |
| **Required Medical Information** | diagnosis, lab results |
| **Age Restrictions** | 12 years or older |
| **Prescriber Restrictions** | prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Prophylaxis - Approve if pt has HAE type I or type II as confirmed by low levels of functional C1-INH protein (less than 50% of normal) and lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required]. Continuation - Approve if pt has a diagnosis of HAE type I or II [documentation required] and according to the prescriber, the patient has had a favorable clinical response since initiating Orladeyo prophylactic therapy compared with baseline. |

# Otezla

**Products Affected**

- OTEZLA (4)-30 MG(19)
- OTEZLA STARTER ORAL TABLETS,DOSE PACK 10 MG (4)-20 MG (4)-30 MG (47), 10 MG (4)-20 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use with a biologic DMARD or targeted synthetic DMARD. Ankylosing spondylitis. Rheumatoid arthritis. |
| **Required Medical Information** | Diagnosis, previous medications tried |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | PP - prescribed by or in consultation with a dermatologist. PsA, Behcet's - prescribed by or in consultation with a rheumatologist or a dermatologist. |
| **Coverage Duration** | Initial - 4 months. Continuation PP, PsA - 3 years. Continuation Behcet's - 1 year. |
| **Other Criteria** | Plaque Psoriasis - Approve if patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light (PUVA) for at least 3 months, unless intolerant OR The patient has a contraindication to MTX, as determined by the prescribing physician OR the patient has already had a 3 month trial or previous intolerance to at least one biologic DMARD indicated for PP (e.g. Humira, Enbrel, Remicade, Cimzia, Stelara, Cosentyx, Taltz, Ilumya, Skyrizi, Tremfya). Psoriatic Arthritis - Approve. Behcet's - The patient has oral ulcers or other mucocutaneous involvement AND has tried at least one systemic therapy (e.g., colchicine, systemic corticosteroids, azathioprine, thalidomide, interferon alpha, tumor necrosis factor inhibitors (e.g., adalimumab [Humira], etanercept [Enbrel], certolizumab pegol [Cimzia], golimumab [Simponi/Aria], or infliximab products [Inflectra, Remicade, Renflexis]). Continuation therapy - Pt has had a response, as determined by the prescribing physician. |

# Oxervate

**Products Affected**

- OXERVATE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Treatment duration of greater than 16 weeks |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or an optometrist. |
| **Coverage Duration** | 8 weeks |
| **Other Criteria** | Neurotrophic keratitis - Initial - Approve. Continuation - Approve if pt has previously received 8 weeks or less of treatment per affected eye(s) and pt has a recurrence of neurotrophic keratitis. |

# Palforzia

**Products Affected**

- PALFORZIA (LEVEL 1)
- PALFORZIA (LEVEL 2)
- PALFORZIA (LEVEL 3)
- PALFORZIA (LEVEL 4)
- PALFORZIA (LEVEL 5)
- PALFORZIA (LEVEL 6)
- PALFORZIA (LEVEL 7)
- PALFORZIA (LEVEL 8)
- PALFORZIA (LEVEL 9)
- PALFORZIA (LEVEL 10)
- PALFORZIA (LEVEL 11 UP-DOSE)
- PALFORZIA INITIAL DOSE
- PALFORZIA LEVEL 11 MAINTENANCE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded |
| **Exclusion Criteria** | |
| **Required Medical Information** | Lab results |
| **Age Restrictions** | 4-17 years old OR 18 years or older and has previously been started on therapy with Palforzia prior to becoming 18 years of age |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist or immunologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Per prescriber, the patient has a history of an allergic reaction to peanut that met each of the following: the patient demonstrated signs and symptoms of a significant allergic reaction (e.g. hives, swelling, wheezing, hypotension, and gastrointestinal symptoms) AND this reaction occurred within a short period of time following a known ingestion of peanut or peanut-containing food AND the prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector AND patient has a positive skin prick test (SPT) response to peanut with a wheal diameter 3 mm or larger than the negative control AND patient has a positive in vitro test (i.e., a blood test) for peanut-specific IgE (psIgE) with a level 0.35 kUA/L or greater AND per the prescriber, Palforzia will be used in conjunction with a peanut-avoidant diet. |

# Palynziq

**Products Affected**

- PALYNZIQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, lab results |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a metabolic disease specialist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Phenylketonuria - Initial therapy - Approve if the pt has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., restriction of dietary phenylalanine and protein intake, prior treatment with Kuvan). Continuation - Approve if the pt meets one of the following conditions: Pt is continuing to titrate Palynziq to an effective maintenance dose, per the prescriber AND if the pt is receiving a dose of Palynziq 60 mg once daily, the treatment duration at this dose has not exceeded 16 weeks OR pt's blood phenylalanine concentration is less than or equal to 600 micromol/L or the pt has achieved at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline AND pt is not receiving concomitant therapy with sapropterin (Kuvan, generic). |

# Pegfilgrastim

**Products Affected**

- FULPHILA
- UDENYCA
- ZIEXTENZO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Peripheral Blood Progenitor Cell Transplantation in Patients with Cancer. |
| **Exclusion Criteria** | Myelodysplastic Syndrome. |
| **Required Medical Information** | Diagnosis, other therapies |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Cancer pts receiving chemotherapy - prescribed by or in consultation with an oncologist or hematologist. RS - prescribed by or in consultation with a physician with expertise in treating acute radiation syndrome. PBPC - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in tranplantation. |
| **Coverage Duration** | Cancer pts receiving chemo - 6 months, RS - 1 month, PBPC - 1 dose |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Cancer in a Patient Receiving Myelosuppressive Chemotherapy - Approve if pt is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, age greater than or equal to 65 years), history of previous chemotherapy or radiation therapy, pre-existing neutropenia, open wounds or active infection, poor performance status, OR the patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. Radiation Syndrome (RS) (Hematopoietic Syndrome of Acute Radiation Syndrome) - Approve. Peripheral Blood Progenitor Cell Transplantation in Patients with Cancer (PBPC) - Approve. |

# Pemazyre

**Products Affected**

- PEMAZYRE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis,  prior therapies |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test AND the patient has been previously treated with at least one systemic therapy regimen |

# Penicillamine

**Products Affected**

- *penicillamine*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |

# Phosphodiesterase-5 Inhibiors for PAH

**Products Affected**

- *sildenafil (pulm.hypertension) intravenous*
- *sildenafil (pulm.hypertension) oral tablet*
- *tadalafil (pulm. hypertension) oral tablet 20 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded and Raynaud phenomenon. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PAH - The agent is prescribed by, or in consultation with, a cardiologist or a pulmonologist. |
| **Coverage Duration** | 3 years. |
| **Other Criteria** | Pulmonary Arterial Hypertension (PAH) [World Health Organization {WHO} Group 1]: the patient has a diagnosis of PAH (WHO Group 1) AND The patient has had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1) OR patient is currently Receiving the Requested Phosphodiesterase Type 5 (PDE5) inhibitor (i.e., Revatio tablets, Revatio suspension or Adcirca) or Another Agent Indicated for WHO Group 1. Raynaud - oral sildenafil and tadalfil only. The patient must have previously tried and failed CCB therapy. |

# Piqray

**Products Affected**

- PIQRAY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded from coverage. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Breast Cancer - Approve if pt is a postmenopausal female, a male, or a premenopausal female who is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) analog or has had surgical bilateral oophorectomy or ovarian irradiation AND has advanced or metastatic hormone receptor (HR)-positive disease, human epidermal growth factor receptor 2 (HER2)-negative disease, and PIK3CA-mutated breast cancer as detected by an approved test AND has progressed on or after at least one prior endocrine-based regimen AND Piqray will be used in combination with fulvestrant injection. |

# Plegridy

**Products Affected**

- PLEGRIDY INTRAMUSCULAR
- PLEGRIDY SUBCUTANEOUS PEN INJECTOR 125 MCG/0.5 ML, 63 MCG/0.5 ML- 94 MCG/0.5 ML
- PLEGRIDY SUBCUTANEOUS SYRINGE 125 MCG/0.5 ML, 63 MCG/0.5 ML- 94 MCG/0.5 ML

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Non-relapsing forms of multiple sclerosis. Concurrent use of other disease-modifying agents used for multiple sclerosis. |
| **Required Medical Information** | diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. |

# Pomalyst

**Products Affected**

- POMALYST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. All FDA-approved indications not otherwise excluded. Central Nervous System Lymphoma. POEMS Syndrome. Systemic Light Chain Amyloidosis. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | KS/MM/POEMS/SLCA - 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Kaposi Sarcoma (KS) - approve if pt is HIV negative OR if pt is HIV positive and continues to receive highly active antiretroviral therapy. Multiple Myeloma (MM) - Approve if pt has received at least one other Revlimid (lenalidomide tablets)-containing regimen. Central Nervous System Lymphoma - approve if pt has relapsed or refractory disease. POEMS Syndrome - approve if Pomalyst is in combination with dexamethasone. Systemic Light Chain Amyloidosis (SLCA) - approve if Pomalyst is in combination with dexamethasone and pt has tried at least one other regimen. |

# Praluent

**Products Affected**

- PRALUENT PEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use of Juxtapid, Kynamro or Repatha. |
| **Required Medical Information** | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history |
| **Age Restrictions** | 18 years of age and older. |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Provider attests that the patient has tried statins and/or ezetimibe and was unable to meet LDL goals after 8 weeks with maximally tolerated therapy or is intolerant of both. |

# Prolastin C

**Products Affected**

- PROLASTIN-C

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | |

# Promacta

**Products Affected**

- PROMACTA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded.<br>Thrombocytopenia in Myelodysplastic Syndrome (MDS) |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, lab results |
| **Age Restrictions** | |
| **Prescriber Restrictions** | AA/IT - Prescribed by or in consultation with a hematologist.<br>THCV - prescribed by or in consultation with a gastroenterologist, hepatologist, or ID. TMDS - prescribed by or in consultation with a hematologist or an oncologist. |
| **Coverage Duration** | THCV - 1 year. AA - 4 months. IT, TMDS - 3 months.<br>Continuation (all) - 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Aplastic Anemia (AA) - approve if the pt has low platelet counts at baseline (e.g., less than 30,000/mL) AND the patient has tried one immunosuppressant therapy OR pt will be using Promacta in combination with standard immunosuppressive therapy. Immune Thrombocytopenia (IT) - Approve if pt meets both 1) pt has a platelet count of less than 30,000/mL or less than 50,000/mL and pt is at risk for bleeding according to prescriber. 2) Pt has tried at least one other therapy or has undergone splenectomy. Thrombocytopenia in Patients with Chronic Hepatitis C (THCV) - approve if pt has low platelet count at baseline (e.g. less than 75,000/mL) AND pt will be receiving interferon-based therapy for HCV. TMDS - Approve if pt has low to intermediate risk MDS and pt either has platelet count of less than 30,000/mL or less than 50,000/mL and pt is at risk for bleeding according to prescriber. AA Continuation - approve if pt demonstrates a beneficial clinical response according to prescriber. CIT, TMDS Cont. - approve if pt demonstrates a beneficial clinical response according to prescriber and pt remains at risk for bleeding complications. |

# Qinlock

**Products Affected**

- QINLOCK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, other therapies tried |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Gastrointestinal stromal tumor (GIST) - Approve if pt has been previously treated with Strivarga, Sutent, and either imatinib or Ayvakit. |

# Rebif

**Products Affected**

- REBIF (WITH ALBUMIN)
- REBIF REBIDOSE
- REBIF TITRATION PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded. |
| **Exclusion Criteria** | Non-relapsing forms of multiple sclerosis. Concurrent use of other disease-modifying agents used for multiple sclerosis. |
| **Required Medical Information** | diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. |
| **Coverage Duration** | 3 years. |
| **Other Criteria** | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. |

# Repatha

**Products Affected**

- REPATHA SURECLICK
- REPATHA SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use of Juxtapid or Praluent. |
| **Required Medical Information** | diagnosis, lab values, other therapies tried |
| **Age Restrictions** | ASCVD/Primary Hyperlipidemia - 18 years or older, HoFH/HeFH - 10 years or older |
| **Prescriber Restrictions** | ASCVD/HoFH/HeFH - Prescribed by or in consultation with a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Primary hyperlipidemia/Secondary Prevention for ASCVD/Heterozygous Familial Hyperlimipidemia (HeFH)/Homozygous Familial Hyperlimipidemia (HoFH) - approve if provider attests that the patient has tried statins and/or ezetimibe and was unable to meet LDL goals after 8 weeks with maximally tolerated therapy or is intolerant of both. |

# Retacrit

**Products Affected**

- RETACRIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded worded as anemia associated with chronic renal failure (CRF), including patients on dialysis and not on dialysis, and worded as anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Anemia due to myelodysplastic syndrome (MDS). Plus anemia in patients with HIV(with or without zidovudine). Patients using for perisurgical adjuvant therapy. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | CKD and MDS - Authorization will be for 6 months, Perisurgical - 1 month, Other - 4 months |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Confirmation of adequate iron stores at initiation of therapy (eg, prescribing information recommends supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation is less than 20%). CRF anemia in patients on and not on dialysis. Hemoglobin (Hb) of less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children to start. Hb less than or equal to 11.5 g/dL for adults or 12 g/dL or less for children if currently on epoetin alfa or Aranesp. Anemia w/myelosuppressive chemotx. pt must be currently receiving myelosuppressive chemo and Hb 10.0 g/dL or less to start. Hb less than or equal to 12.0 g/dL if currently on epoetin alfa or Aranesp. MDS, approve if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. Currently receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV (with or without zidovudine), Hb is 10.0 g/dL or less or endogenous erythropoetin levels are 500 munits/mL or less at tx start. Currently on EA approve if Hb is 12.0 g/dL or less. Perisurgical adjuvant therapy, patient is undergoing hip or knee surgery, has Hgb between 10 and 13 g/dL, is not a candidate for autologous blood transfusion. |

# RETEVMO

**Products Affected**

- RETEVMO ORAL CAPSULE 40 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded.<br>Anaplastic Thyroid Cancer. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Medullary Thyroid Cancer/Thyroid Cancer-12 years or older.<br>NSCLC/Anaplastic Thyroid Cancer - 18 years or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC) - Approve if the pt has metastatic disease and the tumor is RET fusion-positive. Medullary Thyroid Cancer - Approve if the pt has advanced or metastatic RET-mutant disease and the disease requires treatment with systemic therapy. Thyroid Cancer - Approve if the patient has advanced or metastatic RET fusion positive disease, the disease is radioactive iodine-refractory (if radioactive iodine is appropriate), and the disease requires treatment with systemic therapy. Anaplastic Thyroid Cancer - Approve if the pt has RET fusion-positive anaplastic thyroid cancer. |

# Revcovi

**Products Affected**

- REVCOVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For initial therapy, the patient has failed or is not a candidate for bone marrow transplantation (BMT). For continuation of therapy, provider attests that disease is stable or has improved on therapy |

# Revlimid

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. B Cell Lymphomas. Kaposi Sarcoma. Castleman's Disease. Central Nervous System Lymphoma. Classical Hodgkin Lymphoma. Langerhans Cell Histiocytosis. Myelofibroisis. Peripheral T-Cell Lymphomas. POEMS Syndrome. Systemic Light Chain Amyloidosis. T-Cell Leukemia/Lymphoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies tried, other medications, lab results |
| **Age Restrictions** | FL/MCL/MZL/MM/MDS/BCL/CHL/MF/PTCL/POEMS/SLCA/TCL - 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Follicular Lymphoma (FL) - approve if pt is using Revlimid in combination with rituximab or pt has tried at least one other regimen. Mantle Cell Lymphoma (MCL) - Approve if pt is using Revlimid in combination with rituximab or pt has tried at least two other regimens. Marginal Zone Lymphoma (MZL) - is using Revlimid in combination with rituximab or pt has tried at least one other regimen. Multiple Myeloma (MM) - approve. Myelodysplastic Syndrome (MDS) - approve if pt has symptomatic anemia, has transfusion-dependent anemia, or has anemia that is not controlled with an erythroid stimulating agent. B-Cell Lymphomas, Other (BCL) - Approve if pt has tried at least one other regimen. Kaposi Sarcoma - approve if pt has relapsed or refractory disease and has tried at least one other medication. Castleman's Disease - apporve if pt has relapsed/refractory or progressive disease. Central Nervous System Lymphoma - approve if prescriber attests that pt has relapsed or refractory disease. Classical Hodgkin Lymphoma (CHL) - approve if pt has tried at least one other regimen. Langerhans Cell Histiocytosis - approve if pt has multifocal skin disease. Myelofibrosis (MF) - approve if pt has anemia, according to prescriber AND either pt has serum erythropoietin levels greater than 500 mU/mL OR pt has serum erythropoietin levels less than 500 mU/mL and has experienced no response or loss of response to an erythropoiesis-stimulating stimulating agent. Peripheral T-Cell Lymphomas - approve if pt has tried at least one other regimen. POEMS syndrome - approve if Revlimid is used in combination with dexamethasone. Systemic Light Chain Amyloidosis (SLCA) - Approve if Revlimid is used in combination with dexamethasone. T-Cell Leukemia/Lymphoma - approve if pt has tried one other regimen. |

# Rinvoq

**Products Affected**

- RINVOQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use with a biologic or with a targeted synthetic DMARD. Concurrent use with other potent immunosuppressants. COVID-19. |
| **Required Medical Information** | Diagnosis, previous therapies tried |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | RA - prescribed by or in consultation with a rheumatologist. |
| **Coverage Duration** | Initial - 3 months. Continuation - 3 years. |
| **Other Criteria** | RA- approve if the patient has tried one conventional synthetic DMARD or biologic DMARD for at least 3 months. Continuation Therapy - patient has had a response, as determined by the prescriber. |

# Rituxan Hycela

**Products Affected**

- RITUXAN HYCELA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Hairy Cell Leukemia. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma. |
| **Exclusion Criteria** | Granulomatosis with Polyangiitis (Wegener's granulomatosis) or Microscopic Polyangiitis. Pemphigus Vulgaris. Rheumatoid Arthritis. |
| **Required Medical Information** | Diagnosis, previous rituximab use |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if pt has already received at least one full dose of rituximab intravenous AND Rituxan Hycela is administered under the care of a healthcare professional. |

# Rozlytrek

**Products Affected**

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Solid Tumors - 12 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Non-Small Cell Lung Cancer - Approve if the patient has ROS1-positive metastatic disease. Solid Tumors - Approve if pt's tumor has neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity AND pt has progressed following treatment or there are no satisfactory alternative therapies. |

# Rubraca

**Products Affected**

- RUBRACA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, mutation results, previous therapies tried |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - For treatment, approve if pt has a BRCA-mutation (germline or somatic) as confirmed by an approved test and has progressed on two or more prior lines of chemotherapy. For maintenance therapy, approve if pt is in complete or partial response after at least two platinum-based chemotherapy regimens. Prostate Cancer - Castration-Resistant - Approve if pt has metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or pt has had a bilateral orchiectomy AND pt has been previously treated with at least one androgen receptor-directed therapy AND pt has been previously treated with at least one taxane-based chemotherapy or is not a candidate or is intolerant to taxane-based chemotherapy, according to the prescriber. |

# Rufinamide

**Products Affected**

- *rufinamide*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Treatment-Refractory Seizures/Epilepsy |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 1 year or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Lennox-Gastaut Syndrome - Approve if pt has tried and/or is concomitantly receiving at least two other antiepileptic drugs. Treatment-Refractory Seizures/Epilepsy - Approve if pt has tried and/or is concomitantly receiving at least two other antiepileptic drugs. Continuation (all) - Approve if pt is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescriber. |

# Rydapt

**Products Affected**

- RYDAPT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Myeloid or Lymphoid Neoplasms with Eosinophilia. |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, mutation results |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Acute Myeloid Leukemia (AML) - approve if pt is FLT3-mutation positive AML as detected by an approved test AND pt is receiving Rydapt in one of the following settings: induction therapy in combination with cytarabine and daunorubicin OR after standard-dose cytarabine induction/reinduction, along with cytarabine and daunorubicin OR post remission or consolidation therapy in combination with cytarabine OR maintenance therapy. Aggressive Systemic Mastocytosis (ASM) - approve. Systemic Mastocytosis Associated with Acute Hematologic Neoplasm (SM-AHN) - approve. Mast Cell Leukemia (MCL) - approve. Myeloid or Lymphoid Neoplasms with Eosinophilia - approve if pt has an FGFR1 rearrangement or an FLT3 rearrangement. |

# Samsca

**Products Affected**

- SAMSCA ORAL TABLET 15 MG, 30 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use with Jynarque. Pt has autosomal dominant polycystic kidney disease or requires intervetnion to raise serum sodium urgently to prevent or treat serious neurological symptoms. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 30 days |
| **Other Criteria** | The patient has a serum sodium less than 125 mEq/L at baseline, OR The patient has less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (e.g., nausea, vomiting, headache, lethargy, confusion), OR The patient has already been started on Samsca and has received less than 30 days of therapy. |

# Signifor

**Products Affected**

- SIGNIFOR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Endogenous Cushing's Syndrome - Patient Awaiting Surgery. Endogenous Cushing's Syndrome - Patient Awaiting Therapeutic Response After Radiotherapy. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years and older (initial therapy) |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist or a physician or specializes in the treatment of Cushing's syndrome (initial therapy) |
| **Coverage Duration** | Initial - 4 months, Continuation - 1 year. Awaiting surgery or response after radiotherapy-4 months |
| **Other Criteria** | Cushings disease, initial - Approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Cushings disease, continuation - Approve if the patient has already been started on Signifor and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response. Endogenous Cushing's Syndrome - Patient Awaiting Surgery or Awaiting Therapeutic Response After Radiotherapy - Approve. |

# Skyrizi

**Products Affected**

- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.83 ML
- SKYRIZI SUBCUTANEOUS SYRINGE KIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from coverage. |
| **Exclusion Criteria** | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) |
| **Required Medical Information** | Diagnosis, Previous medication use |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | PP- Prescribed by or in consultation with a dermatologist |
| **Coverage Duration** | Initial therapy - 3 months, Continuation therapy - 3 years |
| **Other Criteria** | Initial Therapy- pt has tried at least one traditional systemic agent (MTX, cyclosporine, acitretin, PUVA) or a biologic DMARD for at least 3 months, unless intolerant OR has a contraindication to MTX as determined by prescriber. Cont therapy - approve if pt has responded, according to prescriber. |

# Sodium Phenylbutyrate

**Products Affected**

- *sodium phenylbutyrate*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | |

# Sofosbuvir-Velpatasvir

**Products Affected**

- *sofosbuvir-velpatasvir*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Combination use with other direct acting antivirals, excluding ribavirin. Life expectancy less than 12 months due to non-liver related comorbidities. |
| **Required Medical Information** | Genotype, prescriber specialty, other medications tried or used in combination with requested medication. |
| **Age Restrictions** | 3 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Other Criteria** | Criteria will be applied according to AASLD guidelines. |

# Solaraze

**Products Affected**

- *diclofenac sodium topical gel 3 %*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Actinic Cheilitis. Disseminated Superficial Actinic Porokeratosis. |
| **Exclusion Criteria** | Osteoarthritis |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Actinic Keratoses - Approve. Actinic Cheilitis (Actinic Keratoses of the Lips) - Approve. Disseminated Superficial Actinic Porokeratosis - Approve if pt has tried at least two other therapies used for the management of disseminated superficial actinic porokeratosis. Note: Examples of therapies for management of disseminated superficial actinic porokeratosis include topical 5-fluorouracil (5-FU), imiquimod, topical corticosteroids, topical vitamin D3 analogs, topical or oral retinoids, cryotherapy, photodynamic therapy, and laser. |

# Somatuline Depot

**Products Affected**

- SOMATULINE DEPOT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Pheochromocytoma and Paraganglioma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous treatments/therapies |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Acromegaly - prescribed by or in consultation with an endocrinologist. Carcinoid syndrome, Neuroendocrine Tumors - prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. Pheochromocytoma and Paraganglioma - prescribed by or in consultation with an endocrinologist, oncologist, or neurologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Acromegaly - Approve if the pt has a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets one of the following: has had an inadequate response to surgery and/or radiotherapy, is not an appropriate candidate for surgery and/or radiotherapy, or the pt is experiencing negative effects due to tumor size (e.g., optic nerve compression). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas) - Approve. Carcinoid Syndrome - Approve. Pheochromocytoma and Paraganglioma - Approve. |

# Somavert

**Products Affected**

- SOMAVERT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Treatment of Excess Growth Hormone Associated with McCune-Albright Syndrome (MAS) |
| **Required Medical Information** | Diagnosis, previous therapy, concomitant therapy |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Acromegaly - approve if pt meets ONE of the following:  has had an inadequate response to surgery and/or radiotherapy, is NOT an appropriate candidate for surgery and/or radiotherapy, or is experiencing negative effects due to tumor size (e.g., optic nerve compression) AND patient has a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal (ULN) based on age and gender for the reporting laboratory. |

# Spravato

**Products Affected**

- SPRAVATO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications |
| **Exclusion Criteria** | |
| **Required Medical Information** | Prior therapies tried |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | Prescribed by a psychiatrist |
| **Coverage Duration** | SI - 2 months. TRD - 6 months. |
| **Other Criteria** | Major Depressive Disorder with Acute Suicidal Ideation or Behavior (SI) - Pt has major depressive disorder that is considered to be severe, according to the prescriber AND pt is concomitantly receiving at least one oral antidepressant AND pt has no history of psychosis or the prescriber believes that the benefits of Spravato outweigh the risks. Treatment-Resistant Depression - Pt has demonstrated nonresponse (greater than 25% improvement in depression symptoms or scores) to at least two different antidepressants, each from a different pharmacologic class, according to the prescriber AND each antidepressant was used at therapeutic dosages for at least 6 weeks in the current episode of depression, according to the prescriber AND pt is concomitantly receiving at least one oral antidepressant AND pt has no history of psychosis OR the prescriber believes that the benefits of Spravato outweigh the risks AND pts history of controlled substance prescriptions has been checked using the state prescription drug monitoring program, according to the prescriber. |

# Sprycel

**Products Affected**

- SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Chondrosarcoma or Chordoma. Gastrointestinal Stromal Tumor. Myeloid/Lymphoid Neoplasms with Eosinophilia. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies |
| **Age Restrictions** | Chondrosarcoma or Chordoma, Gastrointestinal Stromal Tumor, Meyloid/Lymphoid Neoplasms with Eosinophilia - 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Acute Lymphoblastic Leukemia - approve if pt has Philadelphia chromosome-positive acute lymphoblastic leukemia. Chronic Myeloid Leukemia - approve if pt has Philadelphia chromosome positive chronic myeloid leukemia. Chondrosarcoma or Chordoma - approve. Gastrointestinal Stromal Tumor - approve if pt has previously tried imatinib or avapritinib, sunitinib, regorafinib, and ripretinib. Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if tumor has an ABL1 rearrangement. |

# Stelara

**Products Affected**

- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5 ML
- STELARA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use of another biologic or targeted synthetic DMARD. Ankylosing Spondylitis. |
| **Required Medical Information** | Diagnosis, previous therapies tried. |
| **Age Restrictions** | PP- 6 years or older. All other indications - 18 years or older. |
| **Prescriber Restrictions** | PP - prescribed by or in consultation with a dermatologist. PsA - prescribed by or in consultation with a rheumatologist or dermatologist. CD/UC - prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | Inital - 3 months. Continuation - 3 years. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Crohn's Disease (CD) - Approve if pt has received a single induction dose with Stelara IV within 2 months of initiating therapy with Stelara SC and meets one of the following: pt has tried or is currently taking corticosteroids, or corticosteroids are contraindicated OR the pt has tried one conventional systemic therapy for Crohns disease (e.g., azathioprine, 6-mercaptopurine, or methotrexate) or pt has already tried a biologic OR pt has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR pt had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). Plaque Psoriasis (PP) - Approve if pt has tried at least at least one traditional systemic agent for psoriasis (e.g., methotrexate, cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant OR the patient has already has a 3-month trial or previous intolerance to at least one biologic (e.g., etanercept, secukinumab, adalimumab, infliximab, brodalumab, ixekizumab, or guselkumab) OR The patient has a contraindication to methotrexate, as determined by the prescribing physician. Psoriatic Arthritis (PsA) - Approve. Ulcerative Colitis (UC) - Approve if pt has had a trial of one systemic agent for UC (e.g., 6MTP, azathioprine, cyclosporine, tacrolimus, corticosteroids, adalimumab, infliximab, golimumab, or vedolizumab) AND will receive a single induction dose with Stelara IV within 2 months of initiating therapy with Stelara SC. Continuation for all - patient has had a response to therapy as determined by prescriber. |

# Stivarga

**Products Affected**

- STIVARGA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded. Glioblastoma. Osteosarcoma. Soft Tissue Sarcoma |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prior therapies tried, mutations |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Colon and Rectal Cancer - pt has advanced or metastatic disease AND has been previously treated with a fluoropyrimidine (e.g., capecitabine, 5-fluorouracil [5-FU]) AND oxaliplatin AND irinotecan AND if the pt's tumor or metastases are wild-type RAS (KRAS and/or NRAS negative), then Erbitux (cetuximab injection for intravenous infusion) or Vectibix (panitumumab injection for intravenous infusion) has also been tried. Gastrointestinal Stromal Tumor (GIST) - approve if pt has previously tried sunitinib and either imatinib or avapritinib. Hepatocellular Carcinoma - approve if pt has been previously treated with at least one tyrosine kinase inhibitor (e.g. Nexavar, Lenvima). Glioblastoma - approve if pt has recurrent disease. Osteosarcoma - approve if pt has relapsed/refractory or metastatic disease AND Stivarga is used as subsequent therapy. Soft Tissue Sarcoma - approve if pt has advanced or metastatic disease AND one of the following: Non-adipocytic extremity/body wall, head/neck, or retroperitoneal/intra-abdominal sarcoma OR Pleomorphic rhabdomyosarcoma OR Angiosarcoma OR Solitary fibrous tumor. |

# Strensiq

**Products Affected**

- STRENSIQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, genetic testing results |
| **Age Restrictions** | |
| **Prescriber Restrictions** | prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of hypophosphatasia or related disorders |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Hypophosphatasia - Infantile- and Juvenile-Onset - Approve if pt has a diagnosis supported by one of the following: molecular genetic testing documenting tissue non-specific alkaline phosphatase (ALPL) gene mutation, low baseline serum alkaline phosphatase activity, or an elevated level of a tissue non-specific alkaline phosphatase substrate (i.e., serum pyridoxal 5'-phosphate, serum or urinary inorganic pyrophosphate, urinary phosphoethanolamine) AND one of the following: pt currently has a history of clinical manifestations consistent with hypophosphatasia (e.g. skeletal abnormalities, premature tooth loss, muscle weakness, poor feeding, failure to thrive, respiratory problems, vitamin B6-dependent seizures) or pt has a family history (parent or sibling) of hypophosphatasia without current clinical manifestations of hypophosphatasia AND disease onset was before 19 years of age. |

# Supprelin LA

**Products Affected**

- SUPPRELIN LA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |

# Sutent

**Products Affected**

- *sunitinib oral capsule 12.5 mg, 25 mg, 37.5 mg, 50 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Bone Cancer. Meningioma. Myeloid/Lymphoid Neoplasms with Eosinophilia. Soft Tissue Sarcoma. Thymic Carcinoma. Differentiated Thyroid Carcinoma. Medullary Thyroid Carcinoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, mutation results, previous therapies tried |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Gastrointestinal stromal tumors (GIST) - Approve if pt has tried imatinib or avapritinib. Neuroendocrine Tumors of the Pancreas - Approve if pt has advanced or metastatic disease. Renal Cell Cancer - Approve if pt has clear cell histology with either a high risk recurrence following nephrectomy and Sutent is being used as adjuvant therapy OR pt has relapsed or advanced disease. Bone Cancer - Approve if pt has recurrent chordoma. Meningioma - Approve if pt has recurrent or progressive disease. Myeloid/Lymphoid Neoplasms with Eosinophilia - Approve if the tumor has an FLT3 rearrangement. Soft Tissue Sarcoma - Approve if the pt has Alveolar Soft Part Sarcoma, Angiosarcoma, or Solitary Fibrous Tumor/Hemangiopericytoma. Thymic Carcinoma - Approve if pt has tried at least one systemic chemotherapy regimen. Thyroid Carcinoma, Differentiated - Approve if pt has differentiated thyroid carcinoma which is refractory to radioactive iodine therapy. Thyroid Carcinoma, Medullary - Approve if pt has tried at least one systemic therapy. |

# Sylatron

**Products Affected**

- SYLATRON SUBCUTANEOUS KIT 200 MCG, 300 MCG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Systemic mastocytosis, myeloproliferative neoplasms |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Melanoma-approve if the patient has microscopic or gross nodal involvement and has had a complete lymphadenectomy within the past 84 days. Systemic mastocytosis-approve if the patient has aggressive systemic mastocytosis OR systemic mastocytosis with an associated hematologic malignancy OR osteopenia/osteoporosis with refractory bone pain and/or decreasing bone mineral density on bisphosphonate therapy. Myeloproliferative neoplasms-approve if the patient has symptomatic low-risk myelofibrosis or polycythemia vera or essential thrombocythemia. |

# Symdeko

**Products Affected**

- SYMDEKO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | CF pts with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco, or Trikafta. |
| **Required Medical Information** | Diagnosis, specific CFTR gene mutations |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or a physician whospecializes in CF |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | CF - approve if pt is homozygous for F508del mutation or has at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A-G, S945L, S977F, F1052V, E831X, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G-A, 3272-26A-G, 3849 + 10kbC-T, A120T, A234D, A349V, A554E, A1006E, D192G, D443Y, D443Y,G57A,R668C, D614G, D836Y, D924N, D979V, I618T, I807M, I980K, I1027T, I1139V, I1269N, I1366N, L15P, L320V, R170H, R258G, R334L, R334Q, R347L, R347P, R352W, R553Q, R668C, R751L, V1293G, E60K, E92K, E116K, E403D, E558V, E822K, F191V, F311del, F311L, F508C, F508C,S1251N, F575Y, L346P, L967S, L997F, L1324P, L1335P, L1480P, M152V, M265R, M9521, R1066H, R1070Q, R1162L, R1283M, R1283S, S549N, S549R, S589N, S737F, S912L, F1016S, F1099L, G126D, G178E, G178R, G194R, G194V, G314E, G551D, G551S, G576A, G576A,R668C, M952T, P5L, P205S, Q98R, Q237E, Q237H, Q359R, Q1291R, R31L, S1251N, S1255P, T3381, T1036N, T10531, V201M, V232D, V5621, V754M, V1153E, G622D, G970D, G1069R, G1244E, G1249R, G1349D, H939R, H1054D, H1375P, I148T, I175V, I336K, I601F, R74Q, R74W,D1270N, R74W,V201M, R74W,V201M,D1270N, R75Q, R117G, R117H, R117L, R117P, W1282R, Y109N, Y161S, Y1014C, Y1032C, R792G, R933G, S1159F, S1159P, or V1240G. |

# Tabrecta

**Products Affected**

- TABRECTA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has metastatic disease AND the tumor is positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping, as detected by an approved test. |

# Tafinlar

**Products Affected**

- TAFINLAR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Biliary Tract Cancer. Central Nervous System Cancer. Histiocytic Neoplasm. Differentiated Thyroid Carcinoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, mutation results, other therapies tried |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Melanoma - Approve if pt has unresectable, advanced (including stage III or stage IV disease), or metastatic melanoma and BRAF V600 mutation-positive disease. Non-Small Cell Lung Cancer - Approve if pt has BRAF V600E mutation-positive disease. Anaplastic Thyroid Carcinoma - Approve if pt has locally advanced or metastatic anaplastic disease, BRAF V600 mutation-positive disease, and the medication will be taken in combination with Mekinist (trametinib), unless intolerant. Biliary Tract Cancer - Approve if pt has tried at least one systemic chemotherapy regimen, has BRAF V600 mutation-positive disease, and the medication will be taken in combination with Mekinist (trametinib). Central Nervous System Cancer - Approve if pt has BRAF V600 mutation-positive disease and the medication is being used for adjuvant treatment of pilocytic astrocytoma, pleomorphic xanthoastrocytoma, or ganglioglioma, or for recurrent disease of low-grade glioma, anaplastic glioma, or glioblastoma, or brain metastases due to melanoma AND the medication is prescribed in combination with Mekinist (trametinib). Histiocytic Neoplasm - Approve if pt has BRAF V600 mutation-positive disease and has Langerhans cell histiocytosis and one of the following: multisystem disease, pulmonary disease, or central nervous system lesions OR pt has Erdheim-Chester disease. Differentiated Thyroid Carcinoma - Approve if pt has differentiated thyroid carcinoma that is refractory to radioactive iodine therapy and is BRAF mutation-positive. |

# Tagrisso

**Products Affected**

- TAGRISSO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | NSCLC - prior therapies and EGFR T790M mutation |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | exon 21 L858R mutation - up to 3 years (total). All others - 3 years |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC), Epidermal Growth Factor Receptor (EGFR) Mutation-Positive - Approve if the medication is used as adjuvant therapy after tumor resection and the tumor is positive for EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an approved test OR pt has metastatic EGFR T790M mutation-positive NSCLC as detected by an approved test and has progressed on one of the EGFR-tyrosine kinase inhibitors (e.g. Iressa, Vizimpro, or Gilotrif) OR pt has metastatic disease with EGFR exon 19 deletions as detected by an approved test OR pt has metastatic disease with EGFR exon 21 L858R mutations as detected by an approved test. |

# Taltz

**Products Affected**

- TALTZ AUTOINJECTOR
- TALTZ AUTOINJECTOR (2 PACK)
- TALTZ AUTOINJECTOR (3 PACK)
- TALTZ SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use of biologic or targeted synthetic DMARDS. Inflammatory bowel disease (Crohn's, ulcerative colitis). |
| **Required Medical Information** | Diagnosis and previous therapies tried |
| **Age Restrictions** | PP- 6 years or older. |
| **Prescriber Restrictions** | AS/NRAS - prescribed by or in consultation with a rheumatologist. PP- prescribed by or in consultation with a dermatologist. PsA- prescribed by or in consultation with a rheumatologist or dermatologist. |
| **Coverage Duration** | Initial - 3 months. Continuation - 3 years. |
| **Other Criteria** | Ankylosis Spondylitis - approve. Non-Radiographic Axial Spondyloarthritis - approve if pt has objective signs of inflammation (elevated CRP, sacroiliitis on MRI). Plaque Psoriasis - approve if pt has tried at least one traditional systemic agent (MTX, cyclosporine, acitretin, PUVA, or a biologic DMARD) for psoriasis for at least 3 months, unless intolerant OR the pt has a contraindication to MTX, as determined by prescriber. Psoriatic Arthritis - approve. Continuation therapy - approve if the pt has responded to therapy according to prescriber. |

# Talzenna

**Products Affected**

- TALZENNA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, BRCA mutation status, HER2 status |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Locally-advanced or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive AND human epidermal growth factor receptor 2 (HER2) negative disease |

# Targretin

**Products Affected**

- TARGRETIN TOPICAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | prescribed by or in consultation with an oncologist or dermatologist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | |

# Tasigna

**Products Affected**

- TASIGNA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Acute Lymphoblastic Leukemia. Gastrointestinal Stromal Tumor. Myeloid/Lymphoid Neoplasms with Eosinophilia. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies tried |
| **Age Restrictions** | Acute Lymphoblastic Leukemia, Gastrointestinal Stromal Tumor, Meyloid/Lymphoid Neoplasms with Eosinophilia - 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Chronic Myeloid Leukemia - approve if pt has Philadelphia chromosome positive chronic myeloid leukemia. Acute Lymphoblastic Leukemia - approve if pt has Philadelphia chromosome-positive acute lymphoblastic leukemia and has tried at least one other tyrosine kinase inhibitors for Philadelphia chromosome-positive acute lymphoblastic leukemia. (e.g., imatinib and dasatinib). Gastrointestinal Stromal Tumor - approve if pt has tried imatinib or avapritinib, sunitinib, regorafinib, and ripretinib. Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if tumor has an ABL1 rearrangement. |

# Tazverik

**Products Affected**

- TAZVERIK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from coverage. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 16 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Epitheliod Sarcoma-approve if the patient has metastatic or locally advanced disease and the patient is not eligible for complete resection. Follicular Lymphoma - approve if pt has relapsed or refractory disease AND pt meets one of the following: tumor is positive for an EZH2 mutation and pt has tried at least two prior systemic therapies OR according to the prescriber, there are no appropriate alternative therapies. |

# Tepmetko

**Products Affected**

- TEPMETKO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, mutation results |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Non-Small Cell Lung Cancer - Approve if pt has metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping alterations. |

# Teriparatide

**Products Affected**

- *teriparatide*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use with other medications for osteoporosis (Prolia, oral bisphosphonates, calcitonin nasal spray, Tymlos, and Evenity). Osteoporosis prevention. |
| **Required Medical Information** | diagnosis, other therapies tried, lab results |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Hypoparathyroidism - prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | up to 2 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Glucocorticoid-Induced Osteoporosis, Treatment - approve if pt is either initiating or continuing systemic glucocorticoids and meets one of the following: pt has tried zoledronic acid injection OR has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy or experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber or has experienced significant intolerance to an oral bisphosphonate OR pt cannot take an oral bisphosphonate due to difficulty swallowing or inability to remain upright, or pt has a pre-existing gastrointestinal medical condition OR pt has severe renal impairment, chronic kidney disease, or has had an osteoporotic fracture or a fragility fracture. Use of teriparatide exceeding 2 years during a patient's lifetime will only be approved if the patient is at high risk for fracture as determined by the prescriber. Osteoporosis, Treatment for a Postmenopausal Patient and Osteoporosis, (to Increase Bone Mass) in Men with Primary or Hypogonadal Osteoporosis - Approve if pt has had a T-score at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% radius, has had an osteoporotic fracture or a fragility fracture, or has low bone mass and is at risk for fracture. Pt also meets one of the following: pt has tried ibandronate injection (Postmenopausal pts only) or zoledronic acid injection OR has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy or experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber or has experienced significant intolerance to an oral bisphosphonate OR pt cannot take an oral bisphosphonate due to difficulty swallowing or inability to remain upright, or pt has a pre-existing gastrointestinal medical condition OR pt has severe renal impairment, chronic kidney disease, or has had an osteoporotic fracture or a fragility fracture. Use of teriparatide |
| | exceeding 2 years during a patient's lifetime will only be approved if the patient is at high risk for fracture as determined by the prescriber. Hypoparathyroidism - Approve if pt has tried Natpara or Natpara is unavailable. |

# Tetrabenazine

**Products Affected**

- *tetrabenazine*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Hyperkinetic dystonia. Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | CHD/HD/TS - prescribed by or in consultation with a neurologist. TD - prescribed by or in consultation with a neurologist or psychiatrist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Chorea associated with Huntington's Disease (CHD) - approve if diagnosis of Huntington's disease is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36). Hyperkinetic Dystonia (HD) - approve. Tardive Dyskinesia (TD) - approve. Tourette Syndrome and Related Tic Disorders (TS) - approve. |

# Thalomid

**Products Affected**

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Castleman's Disease. Discoid Lupus Erythematosus or Cutaneous Lupus Erythematosus. Kaposi Sarcoma. Langerhans Cell Histiocytosis. Myelofibrosis. Prurigo Nodularis. Recurrent Aphthous Ulcers or Aphthous Stomatitis. Rosai-Dorfman Disease. |
| **Exclusion Criteria** | Cancer Cachexia. Crohn's Disease. |
| **Required Medical Information** | Diagnosis, previous therapies tried, other medications, lab results |
| **Age Restrictions** | Multiple Myeloma, Myelofibrosis - 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Erythema nodosum Leprosum - approve. Multiple Myeloma - approve if Thalomid is being taken in combination with at least two other medications. Castleman's Disease - approve if pt relapsed/refractory or progressive disease OR pt has multi-centric Castleman's Disease and is negative for the human immunodeficiency virus and human herpesvirus-8. Discoid Lupus Erythematosus or Cutaneous Lupus Erythematosus - approve if pt has tried at least two other medications. Kaposi Sarcoma - approve if pt has tried at least one other medication. Langerhans Cell Histiocytosis - approve if pt has multifocal skin disease. Myelofibrosis - approve if pt has anemia, according to prescriber AND either pt has serum erythropoietin levels greater than 500 mU/mL OR pt has serum erythropoietin levels less than 500 mU/mL and has experienced no response or loss of response to an erythropoiesis-stimulating stimulating agent. Prurigo Nodularis - approve if pt has tried at least two other medications. Recurrent Aphthous Ulcers or Aphthous Stomatitis - approve if pt has tried at least two other medications. Rosai-Dorfman Disease - approve if pt has cutaneous disease. |

# Tibsovo

**Products Affected**

- TIBSOVO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Cholangiocarcinoma. Chondrosarcoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, mutation results |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Acute Myeloid Leukemia (AML) - approve if disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. Cholangiocarcinoma - approve if disease is isocitrate dehydrogenase-1 (IDH1) mutation positive AND pt has been previously treated with at least one chemotherapy regimen. Chondrosarcoma - approve if disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. |

# Tiopronin

**Products Affected**

- *tiopronin*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist, urologist, or physician who specializes in the treatment of cystinuria. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Cystinuria - Approve if diagnosis of cystinuria has been confirmed based on laboratory testing and the patient has had an inadequate response to high fluid intake, dietary modification, and urinary alkalization, according to the prescriber. |

# Tobramycin (nebulized)

**Products Affected**

- *tobramycin inhalation*
- *tobramycin with nebulizer*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Bronchiectasis, Non-Cystic Fibrosis. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Bronchiectasis - 18 years or older |
| **Prescriber Restrictions** | CF - prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis. Bronchiectasis - prescribed by or in consultation with a pulmonologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Cystic Fibrosis (CF) - Approve if pt has Pseudomonas aeruginosa in culture of the airway. Bronchiectasis, Non-Cystic Fibrosis - Approve if pt has Pseudomonas aeruginosa in culture of the airway. |

# Topical Testosterone

**Products Affected**

- ANDRODERM
- *testosterone transdermal gel*
- *testosterone transdermal gel in metered-dose pump 10 mg/0.5 gram /actuation, 12.5 mg/ 1.25 gram (1 %), 20.25 mg/1.25 gram (1.62 %)*
- *testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram), 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)*
- *testosterone transdermal solution in metered pump w/app*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Plus Endrocrinologic masculization, delayed puberty (induction of puberty), or hypogonadism (primary or secondary). |
| **Exclusion Criteria** | Not covered if used to enhance athletic performance. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Female-to-male gender reassignment - prescribed by, or in consultation with, an endocrinologist or a physician who specializes in the treatment of transgender patients. |
| **Coverage Duration** | Authorization will be for 12 months |
| **Other Criteria** | Must not be used in male patients with carcinoma of the breast OR known or suspected carcinoma of the prostate. For First-Testosterone MC or First-Testosterone products must have tried one of the FDA-approved topical testosterone products [for example: Androderm, AndroGel, Axiron, testosterone 10mg/actuation gel (Fortesta), Striant, or testosterone gel 1% (Testim, Vogelxo)] for the current condition prior to approval. |

# Transmucosal Fentanyl

**Products Affected**

- *fentanyl citrate buccal lozenge on a handle 1,200 mcg, 1,600 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months |
| **Other Criteria** | For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate). |

# Tremfya

**Products Affected**

- TREMFYA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from coverage. |
| **Exclusion Criteria** | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) |
| **Required Medical Information** | Diagnosis, Previous medication use |
| **Age Restrictions** | PP - 18 years of age and older |
| **Prescriber Restrictions** | PP- Prescribed by or in consultation with a dermatologist. PsA - Prescribed by or in consultation with a rheumatologist or dermatologist. |
| **Coverage Duration** | Initial - 3 months, Continuation - 3 years |
| **Other Criteria** | Plaque Psoriasis (PP) - Approve if patient has tried at least one traditional or biologic systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, psoralen plus ultraviolet A light [PUVA], an adalimumab product [e.g., Humira], an etanercept product [e.g., Enbrel], Cimzia [certolizumab pegol SC injection], Cosentyx [secukinumab SC injection], Ilumya [tildrakizumab SC injection], an infliximab product [e.g., Remicade, Inflectra, Renflexis], Siliq [brodalumab SC injection], Stelara [ustekinumab SC injection], or Taltz [ixekizumab SC injection]) for at least 3 months, unless intolerant OR the patient has a contraindication to methotrexate (MTX), as determined by the prescriber. Psoriatic Arthritis (PsA) - Approve. Continuation (all) - Approve if pt has responded, as determined by the prescriber. |

# Trikafta

**Products Affected**

- TRIKAFTA ORAL TABLETS, SEQUENTIAL 100-50-75 MG(D) /150 MG (N), 50-25-37.5 MG (D)/75 MG (N)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded |
| **Exclusion Criteria** | Patients with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco or Symdeko. |
| **Required Medical Information** | Diagnosis, specific CFTR gene mutations, concurrent medications |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Cystic Fibrosis (CF) - Patient has at least one copy of one of the following mutations in the cystic fibrosis conductance regulator gene: F508del, 3141del9, E822K, G1069R, L967S, R117L, S912L, 546insCTA, F191V, G1244E, L997F, R117P, S945L, A46D, F311del, G1249R, L1077P, R170H, S977F, A120T, F311L, G1349D, L1324P, R258G, S1159F, A234D, F508C, H139R, L1335P, R334L, S1159P, A349V, F508C,S1251N, H199Y, L1480P, R334Q, S1251N, A455E, H939R, M152V, R347H, S1255P, A554E, F575Y, H1054D, M265R, R347L, T338I, A1006E, F1016S, H1085P, M952I, R347P, T1036N, A1067T, F1052V, H1085R, M952T, R352Q, T1053I, D110E, F1074L, H1375P, M1101K, R352W, V201M, D110H, F1099L, I148T, P5L, R553Q, V232D, D192G, G27R, I175V, P67L, R668C, V456A, D443Y, G85E, I336K, P205S, R751L, V456F, D443Y,G576A,R668C, G126D, I502T, P574H, R792G, V562I, D579G, G178E, I601F, Q98R, R933G, V754M, D614G, G178R, I618T, Q237E, R1066H, V1153E, D836Y, G194R, I807M, Q237H, R1070Q, V1240G, D924N, G194V, I980K, Q359R, R1070W, V1293G, D979V, G314E, I1027T, Q1291R, R1162L, W361R, D1152H, G463V, I1139V, R31L, R1283M, W1098C, D1270N, G480C, I1269N, R74Q, R1283S, W1282R, E56K, G551D, I1366N, R74W, S13F, Y109N, E60K, G551S, K1060T, R74W,D1270N, S341P, Y161D, E92K, G576A, L15P, R74W,V201M, S364P, Y161S, E116K, G576A,R668C, L165S, R74W,V201M,D1270N, S492F, Y563N, E193K, G622D, L206W, R75Q, S549N, Y1014C, E403D, G628R, L320V, R117C, S549R, Y1032C, E474K, G970D, L346P, R117G, S589N, E588V, G1061R, L453S, R117H, or S737F. |

# Triptodur

**Products Affected**

- TRIPTODUR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded and gender dysphoria. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Gender dysphoria - less than 18 years old |
| **Prescriber Restrictions** | Gender dysphoria - Prescribed by or in consultation with an expert in gender dysphoria and transgender medicine |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Gender dysphoria - patient has reached or passed through Tanner stage 2 |

# TUKYSA

**Products Affected**

- TUKYSA ORAL TABLET 150 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Breast Cancer-approve if the patient has advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine. |

# Turalio

**Products Affected**

- TURALIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded.<br>Histiocytic Neoplasms. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, mutation results |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis) - Approve if the tumor is not amenable to improvement with surgery, according to the prescriber.<br>Histiocytic Neoplasms - Approve if pt has a colony stimulating factor 1 receptor (CSF1R) mutation and has one of the following conditions: Langerhans cell histiocytosis, Erdheim-Chester disease, or Rosai-Dorfman disease. |

# Tykerb

**Products Affected**

- *lapatinib*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Bone Cancer - Chordoma. Colon or Rectal Cancer. |
| **Exclusion Criteria** | Cervical Cancer. Gastric, Esophageal, or Gastroesophageal Adenocarcinoma Cancer. Head and Neck, Squamous Cell Carcinoma. Renal Cell Carcinoma (RCC). Urothelial Carcinoma. |
| **Required Medical Information** | Diagnosis, hormone receptor status |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Breast Cancer, Human Epidermal Growth Factor Receptor 2 Positive (HER2+) - approve if pt has advanced or metastatic breast cancer and the following criteria are met: pt has received prior therapy with trastuzumab AND the medication will be used in combination with capecitabine OR the medication will be used in combination with trastuzumab OR approve if pt has hormone receptor-positive (estrogen- and/or progesterone-positive) metastatic breast cancer and the following criteria are met: pt is a postmenopausal woman, a premenopausal or perimenopausal woman and is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, surgical bilateral oophorectomy, or ovarian irradiation, or pt is a man and is receiving a gonadotropin-releasing hormone (GnRH) agonist AND the medication will be used in combination with an aromatase inhibitor (e.g. letrozole, anastrozole, or exemestane). Bone Cancer - Chordoma - approve if pt has epidermal growth-factor receptor (EGFR)-positive recurrent disease. Colon or Rectal Cancer - Approve if pt has unresectable advanced or metastatic disease that is human epidermal receptor2 (HER2)-amplified and with wild-type RAS AND the medication is used as subsequent therapy in combination with trastuzumab AND pt has not been previously treated with a HER2-inhibitor (e.g. traztuzumab, Nerlyx, Kadcyla, Perjeta). |

# Tymlos

**Products Affected**

- TYMLOS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use with other medications for osteoporosis (Prolia , oral bisphosphonates, intravenous bisphosphonates , calcitonin nasal spray, teriparatide, and Evenity). Osteoporosis Prevention. |
| **Required Medical Information** | diagnosis, BMD results |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Up to 2 years (total) |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Osteoporosis Treatment for a Postmenopausal Patient - Approve if pt has had a T-score at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% radius, has had an osteoporotic fracture or a fragility fracture, or has low bone mass and is at risk for fracture. Pt also meets one of the following: pt has tried ibandronate injection or zoledronic acid injection OR has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy or experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber or has experienced significant intolerance to an oral bisphosphonate OR pt cannot take an oral bisphosphonate due to difficulty swallowing or inability to remain upright, or pt has a pre-existing gastrointestinal medical condition OR pt has severe renal impairment, chronic kidney disease, or has had an osteoporotic fracture or a fragility fracture. Use of Tymlos and/or teriparatide subcutaneous injection (Forteo) does not exceed 2 years during a patient's lifetime. |

# Tysabri

**Products Affected**

- TYSABRI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent Use of Tysabri with an Immunosuppressant Agent in Patients with Crohn's Disease. Current Use of Tysabri with Other Disease-Modifying Agents or immunosuppressants used for MS. Non-relapsing forms of MS. Ulcerative Colitis. |
| **Required Medical Information** | diagnosis, previous medications tried |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | MS - Prescribed by or in consultation with a neurologist or physician who specializes in the treatment of MS. CD - Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | MS - 1 year. CD - 3 mo.  continuation - 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Multiple Sclerosis - pt has a relapsing form of multiple sclerosis AND according to the prescriber the patient has experienced inadequate efficacy or significant intolerance to one disease-modifying agent used for MS OR according to the prescriber the patient has highly-active or aggressive multiple sclerosis by meeting one of the following (pt demonstrated rapidly-advancing deterioration(s) in physical functioning (e.g., loss of mobility/or lower levels of ambulation, severe changes in strength or coordination) [documentation required] OR Disabling relapse(s) with suboptimal response to systemic corticosteroids [documentation required] OR MRI findings suggest highly-active or aggressive multiple sclerosis (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions) [documentation required] OR Manifestations of multiple sclerosis-related cognitive impairment [documentation required]. MS cont - approve if pt has relapsing form of MS.Crohn's disease - Approve if pt has moderately to severely active CD AND pt has tried at least two biologics for CD. CD Cont - approve if pt has had a response as determined by the prescriber. |

# Ukoniq

**Products Affected**

- UKONIQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, other therapies tried. |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Follicular Lymphoma - Approve if pt has received at least three prior lines of systemic therapy. Marginal Zone Lymphoma - Approve if pt has received at least one prior anti-CD20-based regimen. |

# Uptravi

**Products Affected**

- UPTRAVI ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Confirmation of right heart catheterization (select populations), medication history |
| **Age Restrictions** | |
| **Prescriber Restrictions** | prescribed by or in consultation with a cardiologist or a pulmonologist |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Pulmonary Arterial Hypertension (PAH) (World Health Organization [WHO] Group 1) - Pt has had a right heart catheterization to confirm the diagnosis of WHO group 1 PAH (documentation required for new starts only). Patient has tried or is currently receiving at least one oral medication for PAH from one of the three following different categories each for greater than 60 days:  one phosphodiesterase type 5 (PDE5) inhibitor, one endothelin receptor antagonist (ERA), or Adempas (riociguat tablets) ORpatient is currently receiving, or has a history of receiving, one prostacyclin therapy for PAH |

# Valchlor

**Products Affected**

- VALCHLOR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Adults with T-cell leukemia/lymphoma |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Cutaneous Lymphomas (Note-includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders)-approve. Adult T-Cell Leukemia/Lymphoma-approve if the patient has chronic/smoldering subtype of adult T-cell leukemia/lymphoma. |

# Venclexta

**Products Affected**

- VENCLEXTA
- VENCLEXTA STARTING PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Mantle Cell Lymphoma. Multiple Myeloma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previously tried therapies, mutation status |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Acute myeloid Leukemia (AML) - Approve if Venclexta is used in combination with either azacitidine, decitabine, or cytarabine. Chronic Lymphocytic Leukemia (CLL) - Approve. Small Lymphocytic Leukemia (SLL) - Approve. Mantle Cell Lymphoma - Approve if pt has tried at least one systemic regimen. Multiple Myeloma - Approve if pt has t (11,14) translocation, has tried at least one systemic therapy for multiple myeloma, and Venclexta is used in combination with dexamethasone. |

# Verzenio

**Products Affected**

- VERZENIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, hormone receptor status, concurrent therapies |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Breast Cancer - approve if pt has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer when the pt meets ONE of the following: 1) Pt is postmenopausal and Verzenio will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR Verzenio will be used as monotherapy and pt's breast cancer has progressed on at least one prior endocrine therapy and pt has tried chemotherapy for metastatic breast cancer 2) pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) or has had surgical bilateral oophorectomy or ovarian irradiation AND Verzenio will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR Verzenio will be used as monotherapy and pt's breast cancer has progressed on at least one prior endocrine therapy and pt has tried chemotherapy for metastatic breast cancer. Breast Cancer in Men - approve if pt has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer and pt is receiving a gonadotropin-releasing hormone (GnRH) AND Kisqali will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR Verzenio will be used as monotherapy and pt's breast cancer has progressed on at least one prior endocrine therapy and pt has tried chemotherapy for metastatic breast cancer. |

# Vitrakvi

**Products Affected**

- VITRAKVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis, NTRK gene fusion status |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Solid tumors - approve if the tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity AND there are no satisfactory alternative treatments or the patient has disease progression following treatment. |

# Vizimpro

**Products Affected**

- VIZIMPRO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, tumor mutation results |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC) - Approve if pt has metasatic disease and has either epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutations as detected by an approved test. |

# Vosevi

**Products Affected**

- VOSEVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Chronic Hepatitis C Virus Genotype 1b, 2, 4, 5, or 6. Patients already started on Vosevi. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Genotype, prescriber specialty, other medications tried or used in combination with requested medication |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician |
| **Coverage Duration** | 12 weeks |
| **Other Criteria** | Chronic Hepatitis C Virus (HCV) Genotype 1b, 2, 4, 5, or 6 - Approve if pt either does not have cirrhosis or has compensated cirrhosis AND pt had a prior null response, prior partial response, or relapse after prior treatment with an HCV direct-acting antiviral (DAA) regimen containing either an NS5A inhibitor or Sovaldi + a non-NS5a inhibitor. Chronic HCV, Genotype 1a or 3 - Approve if pt either does not have cirrhosis or has compensated cirrhosis AND pt had a prior null response, prior partial response, or relapse after prior treatment with an HCV direct-acting antiviral regimen containing an NS5A inhibitor or had a prior null response, prior partial response, or relapse after prior treatment with an HCV DAA regimen containing Sovaldi + a non-NS5A inhibitor. |

# Votrient

**Products Affected**

- VOTRIENT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Bone Cancer. Gastrointestinal Stromal Tumor. Ovarian Cancer. Differentiated Thyroid Carcinoma. Medullary Thyroid Carcinoma. Uterine Sarcoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previously tried therapies |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Renal Cell Cancer - Approve if pt has relapsed or advanced disease. Soft Tissue Sarcoma - Approve if pt does not have gastrointestinal stromal tumor, has advanced or metastatic disease, and has one of the following: alveolar soft part sarcoma, angiosarcoma, desmoid tumors (aggressive fibromatosis), pleomorphic rhabdomyosarcoma, retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive, soft tissue sarcoma of the extremity/superficial trunk or head/neck, including synovial sarcoma, or solitary fibrous tumor/hemangiopericytoma. Bone Cancer - Approve if pt has chondrosarcoma and either has metastatic disease or the prescriber indicates pt has widespread disease. Gastrointestinal Stromal Tumor (GIST) - Approve if pt has tried imatinib or avapritinib, sunitinib, regorafinib, and ripretinib. Ovarian Cancer - Approve if pt has persistent or recurrent disease. Thyroid Carcinoma, Differentiated - Approve if pt has differentiated thyroid carcinoma which is refractory to radioactive iodine therapy. Thyroid Carcinoma, Medullary - Approve if pt has tried at least one systemic therapy. Uterine Sarcoma (e.g., endometrial stromal sarcoma, undifferentiated uterine sarcoma, uterine leiomyosarcomas) - Approve if pt has recurrent, advanced, or metastatic disease. |

# Vumerity

**Products Affected**

- VUMERITY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA approved indications not otherwise excluded. |
| **Exclusion Criteria** | Non-relapsing forms of multiple sclerosis. Concurrent use of other disease-modifying agents used for multiple sclerosis. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. |

# Vyndaqel/Vyndamax

**Products Affected**

- VYNDAMAX
- VYNDAQEL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from coverage. |
| **Exclusion Criteria** | Concomitant Use With Onpattro or Tegsedi. Concurrent Use of Vyndaqel and Vyndamax. Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR) |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis - approve if the diagnosis was confirmed by a technetium pyrophosphate scan (i.e., nuclear scintigraphy) OR Amyloid deposits are identified on cardiac biopsy OR pt had genetic testing which, according to the prescriber, identified a transthyretin (TTR) mutation, in addition to diagnostic cardiac imaging which has demonstrated cardiac involvement AND pt has heart failure, but does not have New York Heart Association class IV disease. |

# Xalkori

**Products Affected**

- XALKORI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. NSCLC with High Level MET Amplification or MET Exon 14 Skipping Mutation. Soft Tissue Sarcoma - Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. |
| **Exclusion Criteria** | |
| **Required Medical Information** | diagnosis, mutation results |
| **Age Restrictions** | Anaplastic Large Cell Lymphoma - pt is between 1 and 21 years of age. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC) - approve if pt has metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC. Non-Small Cell Lung Cancer (NSCLC) with ROS1 Rearrangement - approve if pt has recurrent or metastatic disease. Anaplastic Large Cell Lymphoma - Approve if pt has anaplastic lymphoma kinase (ALK)-positive disease AND has received at least one prior systemic treatment regimen. Non-Small Cell Lung Cancer (NSCLC) with High Level MET Amplification or MET Exon 14 Skipping Mutation - approve. Soft Tissue Sarcoma - Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation - approve. |

# Xeljanz

**Products Affected**

- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET
- XELJANZ XR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Concurrent use with Biologic or Targeted Synthetic DMARDs. Concurrent use with other potent immunosuppressants (azathioprine, tacrolimus, cyclosporine, mycophenolate). COVID-19. Renal Transplantation. |
| **Required Medical Information** | Diagnosis, other therapies tried |
| **Age Restrictions** | PsA/RA/UC - 18 years or older |
| **Prescriber Restrictions** | RA/JIA-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a dermatologist or rheumatologist. UC-prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | RA/JIA/JRA/PsA-Initial 3 months. UC-Initial 4 months. Continuation - 1 yr. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Juvenile Idiopathic Arthritis (JIA) - approve if pt has tried one other medication for this condition (MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD) OR has aggressive disease, as determined by prescriber. Psoriatic Arthritis (PSA) - The patient has tried one conventional or biologic DMARD for at least 3 months (MTX, leflunomide, and sulfasalazine) AND Xeljanz will be used concomitantly with MTX or another conventional synthetic DMARD, unless contraindicated. Rheumatoid Arthritis (RA) - patient has tried one conventional synthetic or biologic DMARD for at least 3 months (e.g., methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine). Ulcerative Colitis (UC) - approve if pt has had a trial of at least one tumor necrosis factor inhibitor (examples include adalimumab, infliximab, golimumab). Continuation for UC - approve if pt has responded to therapy, per prescriber AND pt has been established on Xeljanz for at least 90 days OR pt has already tried Humira, infliximab, or Simponi. Continuation for all except UC - approve if pt has responded to therapy, per prescriber. |

# Xenleta

**Products Affected**

- XENLETA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D plus patients already started on Xenleta for a covered use. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 month |
| **Other Criteria** | Community Acquired Pneumonia: Diagnosis must be confirmed via chest radiograph AND The member has a documented intolerance, adverse reaction, or resistance to at least two formulary alternatives from different antibiotic classes approved for CAP (macrolides, fluoroquinolones, beta-lactam, tetracycline (doxycycline)). |

# Xermelo

**Products Affected**

- XERMELO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | previous therapies tried |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Carcinoid Syndrome Diarrhea - Initial - Approve if pt has been on a long-acting somatostatin analog (SSA) therapy for at least 3 consecutive months, and while on a SSA, the patient continues to have at least four bowel movements per day, and Xermelo will be used concomitantly with a SSA. Continuation - approve if the patient is continuing to take Xermelo concomitantly with a long-acting somatostatin analog therapy for carcinoid syndrome diarrhea. |

# Xifaxan

**Products Affected**

- XIFAXAN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Helicobacter Pylori Infection |
| **Required Medical Information** | other medications used |
| **Age Restrictions** | Hepatic Encephalopathy/IBSD - 18 years or older. Traveler's Diarrhea - 12 years or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Hepathic Encephalopathy - 6 mo. IBSD/SIBO - 14 days. Traveler's Diarrhea - 3 days. |
| **Other Criteria** | Hepatic Encephalopathy - Approve if pt has previously had overt hepatic encephalopathy, according to the prescriber, and Xifaxin will be used concomitantly with lactulose, unless pt has a contraindication or significant intolerance to treatment with lactulose (550mg tablets only). Irritable Bowel Syndrome with Diarrhea (IBSD) - approve (550mg tablets only). Traveler's Diarrhea - Approve if pt is afebrile and does not have blood in the stool (200mg tablets only). Small Intestine Bacterial Overgrowth (SIBO) - approve if SIBO is diagnosed by glucose hydrogen breath test, lactulose hydrogen breath test, or small bowel aspiration and culture. |

# Xolair

**Products Affected**

- XOLAIR SUBCUTANEOUS RECON SOLN
- XOLAIR SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.5 ML

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | Atopic Dermatitis. Concurrent use with an interleukin (IL) antagonist monoclonal antibody (eg., Cinqair, Dupixent, or Nucala). Eosinophilic Gastroenteritis, Eosinophilic Esophagitis, or Eosinophilic Colitis. Latex Allergy in Health Care Workers with Occupational Latex Allergy. Peanut and Other Food Allergies. |
| **Required Medical Information** | Diagnosis, other medications tried. |
| **Age Restrictions** | Asthma - 6 years and older. Urticaria - 12 years and older. Nasal Polyps - 18 years and older. |
| **Prescriber Restrictions** | Asthma - prescribed by or in consultation with an allergist, immunologist, or pulmonologist. Chronic Idiopathic Urticaria - prescribed by or in consultation with an allergist, immunologist, or dermatologist. Nasal Polyps - prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist. |
| **Coverage Duration** | Initial Asthma/Urticaria - 4 mo. Initial Polyps - 6 mo. Cont therapy for all - 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Asthma - approve if pt has baseline immunoglobulin E (IgE) level greater than 30 IU/mL AND a baseline positive skin test or a blood test for allergen-specific IgE for one or more perennial aeroallergens (e.g. house dust mite, animal dander, cockroach, feathers, and mold spores) and/or for one or more seasonal aeroallergens (e.g. grass, pollen, and weeds) AND has received at least 3 consecutive months of combination therapy with BOTH an inhaled corticosteroid (ICS) and at least one additional asthma controller/maintenance medication (e.g. inhaled long-acting beta2-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, theophylline, anti-IL-4/13 [e.g. Dupixent]) AND has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following: a)Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, b)Patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department visit in the previous year, c)Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted, d)Patient has an FEV1/forced vital capacity (FVC) less than 0.80, e)Patient has asthma that worsens upon tapering of oral corticosteroid therapy. Continuation - approve if pt is concomitantly using an ICS and has responded to therapy as determined by the prescriber. Chronic Idiopathic Urticaria (Chronic Spontaneous Urticaria) - Approve if pt has/had urticaria for greater than 6 weeks (prior to treatment with Xolair), with symptoms present more than 3 days per week despite daily non-sedating H1 antihistamine therapy with doses that have been titrated up to a maximum of four times the standard FDA-approved dose. Continuation - approve if pt has responded to therapy as determined by the prescriber. Nasal Polyps - Approve if pt has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan AND has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or |

| PA Criteria | Criteria Details |
|---|---|
| | reduction/loss of smell AND has a baseline immunoglobulin E (IgE) level greater than 30 IU/mL AND pt has received at least 3 months of therapy with an intranasal corticosteroid and will continue to receive therapy with an intranasal corticosteroid concomitantly with Xolair AND pt meets one of the following: Pt has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years, pt has a contraindication to systemic corticosteroid therapy, or pt has had prior surgery for nasal polyps. Continuation - approve if pt has already received at least 6 months of therapy with Xolair and is concomitantly using a nasal corticosteroid and has responded to therapy as determined by the prescriber. |

# Xospata

**Products Affected**

- XOSPATA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, FLT3-mutation status |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | AML - approve if the patient has relapsed or refractory disease AND the disease is FLT3-mutation positive as detected by an approved test. |

# Xpovio

**Products Affected**

- XPOVIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from coverage. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, Prior therapies |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Diffuse Large B-Cell Lymphoma - approve if pt has been treated with at least two prior systemic therapies. Multiple Myeloma - approve if the medication will be taken in combination with dexamethasone AND pt meets one of the following: pt has tried at least four prior regimens for multiple myeloma OR pt has tried at least one prior regimen for multiple myeloma and the medication will be taken in combination with bortezomib OR pt has tried at least one prior regimen for multiple myeloma and the medication will be taken in combination with Darzalex (daratumumb infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules). |

# Xtandi

**Products Affected**

- XTANDI ORAL CAPSULE
- XTANDI ORAL TABLET 40 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, other therapies |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Prostate Cancer - Castration-Resistant - Approve if the medication is used in combination with a gonadotropin-releasing hormone (GnRH) analoghte pt has had a bilateral orchiectomy. Prostate Cancer - Metastatic, Castration-Sensitive - Approve if the medication is used in combination with a gonadotropin-releasing hormone (GnRH) analoghte pt has had a bilateral orchiectomy. |

# Xuriden

**Products Affected**

- XURIDEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, lab results |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a metabolic specialist, geneticist or physician specializing in the condition being treated |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Hereditary orotic aciduria (Orotic aciduria Type 1)-Approve if the patient has molecular genetic testing confirming mutation in the UMPS gene or clinical diagnosis supported by first degree family relative (i.e., parent or sibling) with hereditary orotic aciduria and urinary orotic acid level above the normal reference range for the reporting laboratory. |

# Yondelis

**Products Affected**

- YONDELIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies tried |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization is for 12 months |
| **Other Criteria** | |

# Zejula

**Products Affected**

- ZEJULA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Maintenance) - Approve if the patient has had a complete or partial response after a platinum-based chemotherapy regimen. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Treatment) - Approve if the patient has tried at least 3 prior chemotherapy regimens AND pt has homologous recombination deficiency (HRD)-positive disease as confirmed by an approved test.[Note: HRD-positive disease includes patients with BRCA mutation-positive disease.] |

# Zelboraf

**Products Affected**

- ZELBORAF

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Central Nervous System Cancer. Hairy Cell Leukemia. Histiocytic Neoplasm. Non-Small Cell Lung Cancer. Differentiated Thyroid Carcinoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, mutation results, other therapies tried |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Erdheim-Chester Disease - Approve if pt has BRAF V600 mutation-positive disease. Melanoma - Approve if pt has unresectable, advanced, or metastatic melanoma and BRAF V600 mutation-positive disease. Central Nervous System Cancer - Approve if pt has BRAF V600 mutation-positive disease and the medication is being used for adjuvant treatment of pilocytic astrocytoma, pleomorphic xanthoastrocytoma, or ganglioglioma, or for recurrent disease of low-grade glioma, anaplastic glioma, or glioblastoma, or brain metastases due to melanoma AND the medication is prescribed in combination with Cotellic (cobimetinib). Hairy Cell Leukemia - Approve if pt has tried at least one other systemic therapy for hairy cell leukemia. Histiocytic Neoplasm - Approve if pt has BRAF V600 mutation-positive disease and has Langerhans cell histiocytosis and one of the following: multisystem disease, pulmonary disease, or central nervous system lesions. Non-Small Cell Lung Cancer - Approve if pt has BRAF V600E mutation-positive disease. Differentiated Thyroid Carcinoma - Approve if pt has differentiated thyroid carcinoma that is refractory to radioactive iodine therapy and is BRAF mutation-positive. |

# Zokinvy

**Products Affected**

- ZOKINVY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, test results |
| **Age Restrictions** | 1 year and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a geneticist or pediatric cardiologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Hutchinson-Gilford Progeria Syndrome - Approve if the pt has a body surface area greater than or equal to 0.39 m2 and genetic testing demonstrates a confirmed pathogenic mutation in the LMNA gene consistent with Hutchinson-Gilford Progeria Syndrome. Progeroid laminopathies. Approve if the pt has a body surface area greater than or equal to 0.39 m2 and has Heterozygous LMNA mutation with progerin-like protein accumulation or Homozygous or compound heterozygous ZMPSTE24 mutations. |

# Zolinza

**Products Affected**

- ZOLINZA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve. |

# Zortress

**Products Affected**

- ZORTRESS ORAL TABLET 1 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | |

# Zydelig

**Products Affected**

- ZYDELIG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Marginal Zone Lymphoma. |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previously tried therapies |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Chronic Lymphocytic Leukemia (CLL) - Approve if pt has tried at least two systemic therapies. Follicular Lymphoma - Approve if pt has tried at least two systemic therapies. Small Lymphocytic Leukemia (SLL) - Approve if pt has tried at least two systemic therapies. Marginal Zone Lymphoma (Marginal Zone Lymphoma includes Gastric MALT Lymphoma, Nongastric MALT Lymphoma, Nodal Marginal Zone Lymphoma, and Splenic Marginal Zone Lymphoma) - Approve if pt has tried at least two systemic therapies. |

# Zykadia

**Products Affected**

- ZYKADIA ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Non-Small Cell Lung Cancer with ROS1 Rearrangement. Soft Tissue Sarcoma - Inflammatory Myofibroblastic Tumor (IMT). |
| **Exclusion Criteria** | |
| **Required Medical Information** | mutation results |
| **Age Restrictions** | |
| **Prescriber Restrictions** | 18 years or older |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Non-Small Cell Lung Cancer - Apporve if pt has metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC as detected by an approved test. Non-Small Cell Lung Cancer with ROS1 rearrangement - Approve if pt has ROS1 rearrangement-positive NSCLC and is receiving Zykadia as first-line treatment. Soft Tissue Sarcoma - Inflammatory Myofibroblastic Tumor (IMT) - Approve if pt has IMT with anaplastic lymphoma kinase (ALK) translocation. |

# Zytiga

**Products Affected**

- *abiraterone oral tablet 250 mg, 500 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded. Plus Prostate Cancer - Regional Risk Group |
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 years |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Prostate Cancer - Metastatic, Castration-Resistant (mCRPC) - approve if the medication is used in combination with prednisone AND pt meets ONE of the following criteria: The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog (e.g. Lupron, Lupron Depot, Trelstar, Zoladex, Vantas, Firmagon, Orgovyx) OR Patient has had a bilateral orchiectomy. Prostate Cancer -Metastatic, Castration-Sensitive (mCSPC) - approve if the medication is used in combination with prednisone AND pt has high-risk disease (e.g., evidence of measurable visceral metastases, lesions on bone scan, total Gleason score 8 or more) as confirmed by the prescribing physician AND meets ONE of the following criteria: The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog (e.g. Lupron, Lupron Depot, Trelstar, Zoladex, Vantas, Firmagon, Orgovyx) OR Patient has had a bilateral orchiectomy. Prostate Cancer - Regional Risk Group - approve if the medication is used in combination with prednisone AND pt has regional lymph node metastases and no distant metastases AND meets ONE of the following criteria: The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog (e.g. Lupron, Lupron Depot, Trelstar, Zoladex, Vantas, Firmagon, Orgovyx) OR Patient has had a bilateral orchiectomy. |

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