

ACTEMRA SQ

Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	Interstitial lung disease-18 years and older (initial and continuation). GCA/RA-18 years and older (initial only). SJIA/PJIA-2 years and older (initial only).
Prescriber Restrictions	RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont)
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA) [A or B]: A) tried one of the following: Enbrel, preferred adalimumab product (see Example 1), Rinvoq or Xeljanz/XR (Note: trials with the following will also count: Cimzia, infliximab, Kevzara, golimumab SC/IV, non-preferred adalimumab product, Orencia), or B) heart failure or a previously treated lymphoproliferative disorder. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) [A or B]: A) tried one of the following: Enbrel, Rinvoq, Xeljanz, preferred adalimumab product. (Note: trials with Kevzara, infliximab, Orencia or a non-preferred adalimumab product will also count), or B) heart failure or a previously treated lymphoproliferative disorder. SYSTEMIC-ONSET JIA (SJIA) [one of A, B, or C]: A) tried one other systemic agent (e.g., corticosteroid [CS], conventional synthetic DMARD [e.g., MTX, leflunomide, sulfasalazine], or B) tried Kineret (anakinra) or Ilaris (canakinumab for SC injection), or C) one-month trial of an NSAID. GIANT CELL ARTERITIS: tried one systemic CS. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS (A and B): A) elevated acute phase reactants and B) diagnosis confirmed by high-resolution computed tomography.

PA Criteria	Criteria Details
	CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. Example 1: preferred adalimumab products include Hadlima, Simlandi.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ACTIMMUNE

Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Chronic granulomatous disease - prescribed by or in consultation with an immunologist, hematologist or infectious disease specialist. Malignant osteopetrosis- prescribed by or in consultation with an endocrinologist or hematologist.
Coverage Duration	1 year
Other Criteria	Chronic granulomatous disease - approve if diagnosis has been established by a molecular genetic test identifying a gene-related pathogenic variant linked to chronic granulomatous disease. Malignant osteopetrosis, severe - approve if pt has had radiographic (X-ray) imaging demonstrating skeletal features related to osteopetrosis or pt had a molecular genetic test identifying a gene-related pathogenic variant linked to severe, malignant osteopetrosis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ACYCLOVIR (TOPICAL)

Products Affected

- *acyclovir topical cream*
- *acyclovir topical ointment*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	acyclovir 5% cream, 12 yrs or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ADALIMUMAB

Products Affected

- ABRILADA(CF) PEN
- ABRILADA(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.4 ML, 40 MG/0.8 ML
- ADALIMUMAB-AATY SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- ADALIMUMAB-AATY SUBCUTANEOUS SYRINGE KIT 20 MG/0.2 ML, 40 MG/0.4 ML
- ADALIMUMAB-AATY(CF) AI CROHNS
- ADALIMUMAB-ADAZ SUBCUTANEOUS PEN INJECTOR 40 MG/0.4 ML, 80 MG/0.8 ML
- ADALIMUMAB-ADAZ SUBCUTANEOUS SYRINGE 10 MG/0.1 ML, 20 MG/0.2 ML, 40 MG/0.4 ML
- ADALIMUMAB-ADBM (PREFERRED NDCS STARTING WITH 00597) SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.4 ML, 40 MG/0.8 ML
- ADALIMUMAB-ADBM (PREFERRED NDCS STARTING WITH 00597) SUBCUTANEOUS SYRINGE KIT 10 MG/0.2 ML, 20 MG/0.4 ML, 40 MG/0.4 ML, 40 MG/0.8 ML
- ADALIMUMAB-RYVK SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML
- ADALIMUMAB-RYVK SUBCUTANEOUS SYRINGE KIT
- AMJEVITA (PREFERRED NDCS STARTING WITH 55513) SUBCUTANEOUS AUTO-INJECTOR 40 MG/0.4 ML, 40 MG/0.8 ML, 80 MG/0.8 ML
- AMJEVITA (PREFERRED NDCS STARTING WITH 55513) SUBCUTANEOUS SYRINGE 10 MG/0.2 ML, 20 MG/0.2 ML, 20 MG/0.4 ML, 40 MG/0.4 ML, 40 MG/0.8 ML
- CYLTEZO(CF) PEN
- CYLTEZO(CF) PEN CROHN'S-UC-HS SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.8 ML
- CYLTEZO(CF) PEN PSORIASIS-UV SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.8 ML
- CYLTEZO(CF) SUBCUTANEOUS SYRINGE KIT 10 MG/0.2 ML, 20 MG/0.4 ML, 40 MG/0.4 ML, 40 MG/0.8 ML
- HADLIMA
- HADLIMA PUSHTOUCH
- HADLIMA(CF)
- HADLIMA(CF) PUSHTOUCH
- HULIO(CF) PEN SUBCUTANEOUS PEN INJECTOR KIT
- HULIO(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.4 ML, 40 MG/0.8 ML
- HYRIMOZ PEN CROHN'S-UC STARTER (PREFERRED NDCS STARTING WITH 61314)
- HYRIMOZ PEN PSORIASIS STARTER (PREFERRED NDCS STARTING WITH 61314)
- HYRIMOZ(CF) (PREFERRED NDCS STARTING WITH 61314) SUBCUTANEOUS SYRINGE 10 MG/0.1 ML, 20 MG/0.2 ML, 40 MG/0.4 ML
- HYRIMOZ(CF) PEDI CROHN STARTER (PREFERRED NDCS STARTING WITH 61314) SUBCUTANEOUS SYRINGE 80 MG/0.8 ML, 80 MG/0.8 ML- 40 MG/0.4 ML
- HYRIMOZ(CF) PEN (PREFERRED NDCS STARTING WITH 61314)
- IDACIO(CF)
- IDACIO(CF) PEN CROHN-UC STARTER
- IDACIO(CF) PEN PSORIASIS STARTER
- IDACIO(CF) PEN SUBCUTANEOUS PEN INJECTOR KIT

- SIMLANDI(CF) AUTOINJECTOR SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- SIMLANDI(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.2 ML, 40 MG/0.4 ML, 80 MG/0.8 ML
- YUFLYMA(CF) AI CROHN'S-UC-HS
- YUFLYMA(CF) AUTOINJECTOR SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- YUFLYMA(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.2 ML, 40 MG/0.4 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
Required Medical Information	Diagnosis
Age Restrictions	Initial therapy only: CD-6 years and older, UC-5 years and older, AS/PsA/RA/PP/ Pyoderma gangrenosum/ sarcoidosis/ scleritis/ sterile corneal ulceration/ non-radiographic axial spondyloarthritis-18 years and older, JIA/UV/Behcet's disease-2 years and older, HS-12 years and older
Prescriber Restrictions	Initial therapy only for all dx, prescribed by or in consultation with one of the following specialists-RA/JIA/JRA/Ankylosing spondylitis/nr-axSpA, rheumatologist. PsA, rheumatologist or dermatologist. PP, dermatologist. UC/ CD, gastroenterologist. HS/pyoderma gangrenosum - dermatologist.UV/scleritis/sterile corneal ulceration-ophthalmologist. Behcet's- rheum, dermatologist, ophthalmologist, gastro, neuro. Sarcoidosis, pulm, ophthalmologist, dermatologist.
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: CROHN'S DISEASE (CD) [one of A, B, C, or D]: A) tried or currently taking corticosteroid (CS) or CS is contraindicated, B) tried one other conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX], certolizumab, infliximab, ustekinumab, vedolizumab), C) had ileocolonic resection, or D) enterocutaneous (perianal or abdominal) or rectovaginal fistulas. JUVENILE IDIOPATHIC ARTHRITIS (JIA)/JRA (one of A, B, C, D, or E): A) tried one other systemic therapy (e.g., MTX, sulfasalazine, leflunomide, NSAID), B) tried a biologic (e.g., etanercept, abatacept, infliximab, anakinra, tocilizumab), C) will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide, D) patient has absolute contraindication to MTX, sulfasalazine, or leflunomide, or E) patient has aggressive disease. HIDRADENITIS SUPPURATIVA (HS): tried one other therapy (e.g., intralesional or oral CS, systemic antibiotics,

PA Criteria	Criteria Details
	<p>isotretinoin). PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., MTX, cyclosporine (CSA), acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of a biologic will also count) or B) contraindication to MTX. RHEUMATOID ARTHRITIS (RA): tried one conventional synthetic DMARD for at least 3 months (Note: a 3-month trial of a biologic will also count). ULCERATIVE COLITIS (A or B): A) tried a systemic therapy (e.g., 6-MP, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a CS) or B) has pouchitis and tried therapy with an antibiotic, probiotic, CS enema, or mesalamine (Rowasa) enema. BEHCET'S DISEASE (A or B): A) tried one conventional therapy (e.g., systemic CS, azathioprine, MTX, CSA, chlorambucil, cyclophosphamide, interferon alfa), or B) has ophthalmic manifestations. SARCOIDOSIS (A and B): A) tried one CS, and B) tried one immunosuppressant (e.g. MTX, mycophenolate mofetil, chlorambucil, thalidomide, infliximab, chloroquine). SCLERITIS/STERILE CORNEAL ULCERATION: tried one other therapy (e.g. CS, CSA). NON RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation defined as either (A or B): A) C-reactive protein elevated beyond upper limit of normal, or B) sacroiliitis on MRI. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. ALL INDICATIONS, INITIAL AND CONTINUATION in addition to the above criteria: patients requesting a non-preferred adalimumab product must try two of the following preferred adalimumab products first: Hadlima, Simlandi.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Behcet's disease, pyoderma gangrenosum, sarcoidosis, scleritis/sterile corneal ulceration, non-radiographic axial spondyloarthritis.
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ADBRY

Products Affected

- ADBRY

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy (examples: Dupixent, Cinqair, Ebglyss, Fasenra, Nemluvio, Nucala, Tezspire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical] (examples: Cibinqo, Leqselvi, Rinvoq/LQ, Opzelura)
Required Medical Information	Diagnosis
Age Restrictions	AD-12 years of age and older (initial therapy)
Prescriber Restrictions	Atopic Dermatitis-prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
Coverage Duration	Initial-Atopic Dermatitis-4 months, Continuation-1 year
Other Criteria	Atopic Dermatitis, initial-patient has atopic dermatitis involvement estimated to be greater than or equal to 10 percent of the body surface area and patient meets a and b: a. Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid AND b. Inadequate efficacy was demonstrated with the previously tried topical corticosteroid therapy. Continuation- Approve if the patient has been receiving Adbry for at least 4 months and patient has responded to therapy. Note: A patient who has received less than 4 months of therapy or who is restarting therapy with Adbry should be considered under initial therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ADEMPAS

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Phosphodiesterase Inhibitors Used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PAH and CTEPH- must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

AIMOVIG

Products Affected

- AIMOVIG AUTOINJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with another cGRP inhibitor for migraine headache prevention
Required Medical Information	Diagnosis, number of migraine headaches per month
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) If pt is currently taking Aimovig, the pt has had significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Aimovig was initiated.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

AJOVY

Products Affected

- AJOVY AUTOINJECTOR
- AJOVY SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with another cGRP inhibitor for migraine headache prevention
Required Medical Information	Diagnosis, number of migraine headaches per month, prior therapies tried
Age Restrictions	Pending CMS Review
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AKEEGA

Products Affected

- AKEEGA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Prostate cancer- Approve if the patient meets the following (A, B, C, and D): A)Patient has metastatic castration-resistant prostate cancer, AND B)Patient has a BReast CAncer (BRCA) mutation, AND C)The medication is used in combination with prednisone, AND D)Patient meets one of the following (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog, Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), and Orgovyx (relugolix tablets).OR ii. Patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALECENSA

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Pediatric diffuse high grade glioma- less than or equal to 21 years old, All others- 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Non-small cell lung cancer-approve if the patient has both (A and B): A) either (i or ii): i) medication is used as adjuvant treatment following tumor resection (note: for tumors greater than or equal to 4 cm or node positive) or ii) advanced or metastatic disease and B) anaplastic lymphoma kinase (ALK)-positive disease as detected by an approved test. Anaplastic large cell lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease and (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory Myofibroblastic Tumor- pt has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) pt has advanced, recurrent or metastatic disease, or (ii) tumor is inoperable. Large B-Cell Lymphoma- pt has ALK-positive disease AND pt has relapsed or refractory disease. Pediatric diffuse high grade glioma- approve if (A and B): A) ALK-positive disease, and B) either (i or ii): i) medication is used as adjuvant treatment AND tumor is not diffuse midline glioma, H3 K27-altered or pontine location, or ii) medication is used for recurrent or progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Anaplastic large cell lymphoma, Erdheim Chester disease, Inflammatory Myofibroblastic Tumor, Large B-Cell Lymphoma, Pediatric Diffuse High Grade Glioma
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALOSETRON

Products Affected

- *alosetron*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALPHA 1 PROTEINASE INHIBITORS

Products Affected

- ARALAST NP INTRAVENOUS RECON SOLN 1,000 MG
- GLASSIA
- PROLASTIN-C INTRAVENOUS SOLUTION
- ZEMAIRA INTRAVENOUS RECON SOLN 1,000 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Alpha1-Antitrypsin Deficiency with Emphysema (or Chronic Obstructive Pulmonary Disease)-approve if the patient has a baseline (pretreatment) AAT serum concentration of less than 80 mg/dL or 11 micromol/L.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALUNBRIG

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	ALK status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has ALK positive disease and has advanced, recurrent or metastatic disease or the tumor is inoperable. NSCLC, must be ALK-positive, as detected by an approved test, have advanced or metastatic disease and patients new to therapy must have a trial of Alecensa or Lorbrina prior to approval of Alunbrig. Peripheral T-Cell Lymphoma- approve if patient has ALK-positive anaplastic large cell lymphoma (ALCL).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Erdheim-Chester disease, Inflammatory myofibroblastic tumor (IMT), Peripheral T-Cell Lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ALVAIZ

Products Affected

- ALVAIZ

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Aplastic anemia/Thrombo w/Hep C-18 years and older, Immune thrombocytopenia-6 years and older
Prescriber Restrictions	Immune Thrombo/AA-presc or consult heme(initial).Thrombo/Hep C-prescr or consult gastro, hepatologist, physician specializing in infectious disease. MDS-presc or consult heme/onc(initial).Post-trans-presc or consult heme/onc/stem cell transplant specialist physician (initial)
Coverage Duration	Immune thrombo/MDS init-3 mo,cont 1yr, AA-init-4 mo,cont-1 yr,Thrombo/Hep C-1 yr, transplant-6 mo.
Other Criteria	Thrombocytopenia in patients with immune thrombocytopenia, initial - approve if the patient has a platelet count less than 30 x 10 ⁹ /L (less than 30,000/mcL) or less than 50 x 10 ⁹ /L (less than 50,000/mcL) and the patient is at an increased risk for bleeding AND has tried ONE other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Nplate, Tavalisse, Doptelet, rituximab) or has undergone a splenectomy. Immune thrombocytopenia, cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Treatment of thrombocytopenia in patients with Chronic Hepatitis C - approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND if the patient has low platelet counts at baseline (pretreatment) Note: An example of a low platelet count is less than 75 x 10 ⁹ /L (less than 75,000/mcL). Aplastic anemia, initial - approve if the patient has low platelet counts at baseline (pretreatment) AND patient tried one immunosuppressant therapy OR patient will be using Alvaiz in combination with standard immunosuppressive therapy. Aplastic anemia, cont-approve if the patient demonstrates a beneficial clinical response. Note: An example of a low platelet count is less than 30 x 10 ⁹ /L (less than 30,000/mcL). Thrombocytopenia in a patient with Myelodysplastic

PA Criteria	Criteria Details
	<p>syndrome (MDS)-initial, approve if patient has low- to intermediate-risk MDS AND the patient has a platelet count less than 30 x 10⁹/L (less than 30,000/mcL) or less than 50 x 10⁹/L (less than 50,000/mcL) and is at an increased risk for bleeding. Thrombocytopenia in a pt with MDS, Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Thrombocytopenia in post allogeneic transplantation, initial-approve if the patient has poor graft function and has a platelet count less than 50 x 10⁹/L (less than 50,000/mcL). Cont-approve if the patient demonstrates a beneficial clinical response. In addition, for new starts and all covered diagnoses, patients must have a trial of Promacta prior to approval of Alvaiz.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Thrombocytopenia in Myelodysplastic Syndrome (MDS), Thrombocytopenia in a patient post -allogeneic transplantation
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ALYFTREK

Products Affected

- ALYFTREK ORAL TABLET 10-50-125 MG, 4-20-50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Patients with unknown cystic fibrosis transmembrane conductance regulator gene mutation. Combination therapy with other cystic fibrosis transmembrane conductance regulator modulators.
Required Medical Information	Diagnosis
Age Restrictions	6 years and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	<p>CYSTIC FIBROSIS - All of (A, B and C): A) Patient has at least one mutation in the cystic fibrosis conductance regulator gene that is considered to be a pathogenic or likely pathogenic variant, AND B) Patient meets at least ONE of the following (i, ii, or iii): i. Positive cystic fibrosis newborn screening test, OR ii. Family history of cystic fibrosis, OR iii. Clinical presentation consistent with signs and symptoms of cystic fibrosis, Note: Examples of clinical presentation of cystic fibrosis include but are not limited to meconium ileus, sino-pulmonary symptoms (e.g., persistent cough, wheezing, pulmonary function tests consistent with obstructive airway disease, excess sputum production), bronchiectasis, sinusitis, failure to thrive, pancreatic insufficiency, AND C) Patient has evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by at least ONE of the following (i, ii, or iii): i. Elevated sweat chloride test, OR ii. Two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations, OR iii. Abnormal nasal potential difference.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

ANDEMBRY

Products Affected

- ANDEMBRY AUTOINJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ANTIBIOTICS (IV)

Products Affected

- *amikacin injection solution 500 mg/2 ml*
- *ampicillin sodium injection recon soln 1 gram, 10 gram*
- *ampicillin-sulbactam injection*
- **AVYCAZ**
- *azithromycin intravenous*
- *aztreonam*
- **BAXDELA INTRAVENOUS**
- **BICILLIN C-R**
- **BICILLIN L-A**
- *cefoxitin*
- *ceftazidime*
- *cefuroxime sodium injection recon soln 750 mg*
- *cefuroxime sodium intravenous recon soln 1.5 gram*
- *ciprofloxacin in 5 % dextrose intravenous piggyback 200 mg/100 ml*
- *clindamycin in 5 % dextrose*
- *clindamycin phosphate injection*
- *colistin (colistimethate na)*
- *doxy-100*
- *doxycycline hyclate intravenous*
- *ertapenem*
- *gentamicin in nacl (iso-osm) intravenous piggyback 100 mg/100 ml, 60 mg/50 ml, 80 mg/100 ml, 80 mg/50 ml*
- *gentamicin injection*
- *imipenem-cilastatin*
- *levofloxacin in d5w intravenous piggyback 500 mg/100 ml, 750 mg/150 ml*
- *linezolid in dextrose 5%*
- *meropenem intravenous recon soln 1 gram, 500 mg*
- *metronidazole in nacl (iso-os)*
- *moxifloxacin-sod.chloride(iso)*
- *nafcillin injection*
- **NUZYRA INTRAVENOUS**
- *oxacillin*
- *oxacillin in dextrose(iso-osm) intravenous piggyback 2 gram/50 ml*
- **PENICILLIN G POT IN DEXTROSE INTRAVENOUS PIGGYBACK 2 MILLION UNIT/50 ML, 3 MILLION UNIT/50 ML**
- *penicillin g potassium injection recon soln 20 million unit*
- *penicillin g sodium*
- *polymyxin b sulfate*
- **SIVEXTRO INTRAVENOUS**
- **STREPTOMYCIN**
- *tazicef injection*
- **TEFLARO**
- *tigecycline*
- *tobramycin sulfate injection solution*
- **VABOMERE**
- **ZEMDRI**
- **ZERBAXA**
- **ZEVTERA**

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A

PA Criteria	Criteria Details
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ANTIFUNGALS (IV)

Products Affected

- *fluconazole in nacl (iso-osm) intravenous piggyback 200 mg/100 ml, 400 mg/200 ml*
- *voriconazole*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

APOKYN

Products Affected

- APOKYN
- *apomorphine*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a serotonin 5-HT ₃ Antagonist
Required Medical Information	Diagnosis, other therapies
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's disease (PD)-approve if the patient meets the following criteria: 1. patient is experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, 2. Patient is currently receiving carbidopa/levodopa, 3. patient has previously tried one other treatment for off episodes (e.g., entacapone, rasagiline, pramipexole, ropinirole, tolcapone, selegiline, Ongentys (opicapone capsules), or Xadago (safinamide tablets) and had significant intolerance or inadequate efficacy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ARANESP

Products Affected

- ARANESP (IN POLYSORBATE) INJECTION SOLUTION 100 MCG/ML, 200 MCG/ML, 25 MCG/ML, 40 MCG/ML, 60 MCG/ML
- ARANESP (IN POLYSORBATE) INJECTION SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Anemia w/CRF not on dialysis. A hemoglobin (Hb) of less than 10.0 g/dL for adults and less than or equal to 11 g/dL for children required for start, Hb has to be less than or equal 11.5 g/dL adults or less than or equal to 12 g/dL in children if previously receiving epoetin alfa (EA), Mircera or Aranesp. Anemia in a patient with cancer due to cancer chemotherapy, patients must be currently receiving myelosuppressive chemotherapy which is considered non-curative treatment, Hb is 10.0 g/dL or less to start or less than or equal to 12.0 g/dL if previously on EA or Aranesp. MDS, approve tx if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. If the pt has previously been receiving Aranesp or EA, approve only if Hb is 12.0 g/dL or less. All conds, deny if Hb exceeds 12.0 g/dL.
Age Restrictions	MDS anemia = 18 years of age and older.
Prescriber Restrictions	MDS anemia, prescribed by or in consultation with, a hematologist or oncologist.
Coverage Duration	Anemia w/myelosupp=6 mos, Anemia CKD-1 year, MDS-1 year, Other=6 mos.
Other Criteria	For all covered uses, the patient is required to try Procrit or Retacrit first line. For anemia associated with CRF in patients on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anemia due to myelodysplastic syndrome (MDS)
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

ARCALYST

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent biologic therapy
Required Medical Information	N/A
Age Restrictions	Initial tx CAPS/Pericarditis-Greater than or equal to 12 years of age.
Prescriber Restrictions	Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA initial-rheum, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis-cardiologist or rheum
Coverage Duration	CAPS-3 mos initial, 1 yr cont. DIRA-6 mos initial, 1 yr cont. Pericard-3 mos initial, 1 yr cont
Other Criteria	INITIAL THERAPY: DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA) [all of A, B, and C]: A) weighs at least 10 kg, B) genetic test has confirmed bi-allelic pathogenic variants in the IL1RN gene, and C) had clinical benefit with anakinra subcutaneous injection. PERICARDITIS: pericarditis is recurrent. CONTINUATION THERAPY: ALL INDICATIONS: patient had a positive response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ARIKAYCE

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous medication history (as described in Other Criteria field)
Age Restrictions	MAC-18 years and older (initial therapy)
Prescriber Restrictions	MAC initial-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections.
Coverage Duration	1 year
Other Criteria	<p>INITIAL THERAPY: MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE (all of A, B, and C): A) positive sputum culture for MAC [Note: any positive sputum culture taken after completion of a background multidrug regimen (throughout, see Example 1 below) fulfills this criterion], B) MAC isolate is susceptible to amikacin, and C) Arikayce will be used in combination with a background multidrug regimen.</p> <p>CONTINUATION THERAPY: MAC LUNG DISEASE (A and B): A) Arikayce prescribed in combination with a background multidrug regimen and B) patient meets one of the following (a or b): a) patient has not achieved negative sputum cultures for MAC or b) patient has achieved negative sputum cultures for MAC for less than 12 months. Example 1: background multidrug regimen example - a macrolide (azithromycin or clarithromycin), ethambutol, and a rifamycin (rifampin or rifabutin).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

ATTRUBY

Products Affected

- ATTRUBY

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other medications indicated for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis or transthyretin-mediated amyloidosis-cardiomyopathy (e.g., Amvuttra [vutrisiran subcutaneous injection], Onpattro [patisiran intravenous infusion], Tegsedi [inotersen subcutaneous injection], Wainua [eplontersen subcutaneous injection], or a tafamidis product).
Required Medical Information	Diagnosis
Age Restrictions	18 years and 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-Mediated Amyloidosis (ATTR-CM) Note: Variant Transthyretin Amyloidosis is also known as Hereditary Transthyretin Amyloidosis - (all of A, B and C): A. Diagnosis was confirmed by ONE of the following (i, ii, or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy), OR ii. A tissue biopsy with confirmatory transthyretin (TTR) amyloid typing by mass spectrometry, immunoelectron microscopy or immunohistochemistry, OR iii. Genetic testing which identified a transthyretin (TTR) pathogenic variant, Note: Examples of TTR variants include Val122Ile variant and Thr60Ala variant. If the patient has wild-type amyloidosis, this is not a TTR pathogenic variant., AND B. Diagnostic cardiac imaging has demonstrated cardiac involvement, Note: Examples of cardiac imaging include echocardiogram and cardiac magnetic imaging. Examples of cardiac involvement on imaging include increased thickness of the ventricular wall or interventricular septum., AND C. Patient has heart failure, but does not have New York Heart Association class IV disease. In addition to above criteria, patients are required to try Vyndamax or Vyndaqel prior to approval of Attruby.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AUBAGIO

Products Affected

- *teriflunomide*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of teriflunomide with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Relapsing form of MS, to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

AUGTYRO

Products Affected

- AUGTYRO ORAL CAPSULE 160 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	NSCLC - 18 years and older, Solid tumors - 12 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer-approve if the patient has locally advanced or metastatic disease, patient has ROS1-positive non-small cell lung cancer and the mutation was detected by an approved test. Solid tumors - approve if tumor is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion AND tumor is locally advanced or metastatic or surgical resection will likely result in severe morbidity AND disease has progressed following treatment or there are no satisfactory alternative therapies.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

AUSTEDO

Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR
- AUSTEDO XR TITRATION KT(WK1-4) ORAL TABLET, EXT REL 24HR DOSE PACK 12-18-24-30 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	TD - Prescribed by or in consultation with a neurologist or psychiatrist. Chorea HD - prescribed by or in consultation with a neurologist.
Coverage Duration	1 year
Other Criteria	Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing. Tardive dyskinesia-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

AVMAPKI-FAKZYNJA

Products Affected

- AVMAPKI-FAKZYNJA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER- ALL of the following (A, B and C): A) Patient has recurrent low-grade serous cancer, AND B) The cancer has a KRAS mutation, AND C) Patient has tried at least one systemic therapy. Note: Examples of systemic therapy include one or more of the following medications: paclitaxel, carboplatin, bevacizumab, letrozole, anastrozole, or exemestane.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Fallopian Tube or Primary Peritoneal Cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AVONEX

Products Affected

- AVONEX INTRAMUSCULAR PEN INJECTOR KIT
- AVONEX INTRAMUSCULAR SYRINGE KIT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of other disease-modifying agent used for multiple sclerosis
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

AYVAKIT

Products Affected

- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	GIST-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation or if the patient has tried two of the following: Gleevec (imatinib), Sutent (sunitinib), Sprycel (dasatinib), Stivarga (regorafenib) or Qinlock (ripretinib). Myeloid/Lymphoid Neoplasms with eosinophilia-approve if the tumor is positive for PDGFRA D842V mutation. Systemic mastocytosis-Approve if the patient has a platelet count greater than or equal to 50,000/mcL and patient has either indolent systemic mastocytosis or one of the following subtypes of advanced systemic mastocytosis-aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm or mast cell leukemia.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid neoplasms with Eosinophilia
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BAFIERTAM

Products Affected

- BAFIERTAM

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Diagnosis
Age Restrictions	N/A
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	Initial treatment - approve if the patient has tried TWO of the following: generic dimethyl fumarate, Vumerity, generic fingolimod or generic teriflunomide. Note: Prior use of brand Tecfidera, Gilenya, Aubagio with inadequate efficacy or significant intolerance (according to the prescriber) also counts. Cont tx - approve if the patient has been established on Bafiertam.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BALVERSA

Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy, other chemotherapy or checkpoint inhibitor therapy.</p> <p>Pancreatic adenocarcinoma- approve if (A, B, C and D): A) patient has a fibroblast growth factor receptor (FGFR) genetic alterations, and B) locally advanced, recurrent or metastatic disease, and C) medication is used for subsequent therapy and D) medication is used as a single agent. NSCLC- approve if patient has metastatic disease and FGFR alterations.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pancreatic adenocarcinoma, non-small cell lung cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BENLYSTA

Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics or Lupkynis
Required Medical Information	Diagnosis
Age Restrictions	Pending CMS Review
Prescriber Restrictions	SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont)
Coverage Duration	SLE-Initial-4 months, cont-1 year. Lupus Nephritis-6 mo initial, 1 year cont
Other Criteria	Lupus Nephritis Initial-approve if the patient has a diagnosis of lupus nephritis confirmed on biopsy (For example, World Health Organization class III, IV, or V lupus nephritis), AND the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid). Cont-approve if the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid) AND the patient has responded to Benlysta subcutaneous or intravenous. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA [anti-dsDNA] antibody AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity. Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to

PA Criteria	Criteria Details
	be intolerant due to a significant toxicity AND The patient has responded to Benlysta subcutaneous or intravenous.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

BESREMI

Products Affected

- BESREMI

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other interferon products
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Pending CMS Review
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

BETASERON/EXTAVIA

Products Affected

- BETASERON SUBCUTANEOUS KIT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year
Other Criteria	For patients requesting Betaseron-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

BEXAROTENE (ORAL)

Products Affected

- *bexarotene*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried (as described in Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

BEXAROTENE (TOPICAL)

Products Affected

- *bexarotene*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	Cutaneous T-Cell lymphoma-approve if pt has cutaneous manifestations/lesions. Adult T-Cell Leukemia/Lymphoma- approve if the patient has smoldering symptomatic subtype and this medication is used as first-line therapy. Primary cutaneous B-Cell lymphoma-approve if used as skin-directed therapy for either (a or b): a) primary cutaneous marginal zone lymphoma or b) follicle center lymphoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Adult T-Cell Leukemia/Lymphoma, Primary Cutaneous B-Cell Lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

BIMZELX

Products Affected

- BIMZELX AUTOINJECTOR
SUBCUTANEOUS AUTO-INJECTOR
160 MG/ML, 320 MG/2 ML
- BIMZELX SUBCUTANEOUS
SYRINGE 160 MG/ML, 320 MG/2 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	HS/PP: Prescribed by or in consultation with a dermatologist (initial therapy only). AS/NrAxS: Prescribed by or in consultation with a rheumatologist (initial therapy only). PsA: Prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy only).
Coverage Duration	Approve through end of plan year
Other Criteria	<p>Plaque psoriasis, initial therapy-approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi SC, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya. [A trial of a non-preferred adalimumab or non-preferred ustekinumab also counts.]</p> <p>Ankylosing Spondylitis, initial therapy-approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Rinvoq, Xeljanz/XR, Cosentyx. [A trial of a Non-Preferred adalimumab product, Cimzia, Taltz, an infliximab product (e.g. Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.]</p> <p>Non-radiographic axial spondyloarthritis, initial therapy-Approve if the patient has tried Rinvoq or Cosentyx. [A trial of an adalimumab product, Enbrel, Cimzia, Taltz, an infliximab product (e.g. Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.]</p> <p>Psoriatic arthritis, initial therapy-approve if the patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Cosentyx, Tremfya, a preferred ustekinumab product, Otezla, Rinvoq, Skyrizi or Xeljanz/XR. [A trial of a Non-Preferred adalimumab product, non-preferred ustekinumab, Cimzia, Taltz, an infliximab product (e.g. Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.]</p> <p>Hidradenitis Suppurativa: approve if the patient has tried ONE of</p>

PA Criteria	Criteria Details
	the following drugs in the past: a preferred adalimumab product or Cosentyx SC. A trial of a non-preferred adalimumab also counts. All indications, continuation-approve if the patient has had a response. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred ustekinumab products include Selarsdi, Yesintek.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BOSENTAN/AMBRISENTAN

Products Affected

- *ambrisentan*
- *bosentan oral tablet*
- TRACLEER ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) WHO Group 1, results of right heart cath
Age Restrictions	N/A
Prescriber Restrictions	For treatment of pulmonary arterial hypertension, ambrisentan or bosentan must be prescribed by or in consultation with a cardiologist or a pulmonologist. CTEPH-prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	Authorization will be for 1 year.
Other Criteria	CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving bosentan for CTEPH. Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. For all covered diagnoses, if the request is for brand name Tracleer tablets for suspension-the patient is required to have tried generic bosentan tablets AND cannot use the generic product due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction. Patients who cannot swallow or have difficulty swallowing tablets are not required to try generic bosentan tablets.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chronic thromboembolic pulmonary hypertension (CTEPH) (bosentan)
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

BOSULIF

Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	ALL - 15 years and older. Myeloid/lymphoid neoplasms w eosinophilia- 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	CML-approve if the patient has Ph-positive or BCR::ABL1-positive CML. For Ph-positive ALL-approve if pt has tried at least one other tyrosine kinase inhibitor for Ph+ ALL. Myeloid/lymphoid neoplasms with eosinophilia - approve if tumor has an ABL1 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia, myeloid/lymphoid neoplasms with eosinophilia
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BRAFTOVI

Products Affected

- BRAFTOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation. Colon or Rectal cancer- approve if the patient meets the following (A and B): A) The patient has BRAF V600E mutation-positive disease AND B) meets (i or ii): i) will be used as first-line systemic therapy for metastatic disease in combination with Erbitux (cetuximab intravenous infusion) and mFOLFOX6 (5-FU, leucovorin, and oxaliplatin) or ii) patient has previously received a chemotherapy regimen for colon or rectal cancer and this is prescribed in combination with Erbitux or Vectibix (panitumumab intravenous infusion). NSCLC- approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Mektovi (binimetinib tablets). Appendiceal adenocarcinoma-approve if (A, B and C): A) BRAF V600E mutation-positive, and B) used as subsequent therapy for advanced or metastatic disease, and C) used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Appendiceal adenocarcinoma
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

BRUKINSA

Products Affected

- BRUKINSA ORAL CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Follicular Lymphoma - approve if pt tried at least two other systemic regimens and will use this in combination with Gazyva (obinutuzumab intravenous infusion). CLL/SLL - approve. Mantle Cell Lymphoma-approve if patient meets one of (A, B, C or D): A) tried at least one systemic regimen, or B) is not a candidate for a systemic regimen, or C) will use this medication in combination with rituximab, or D) patient has TP53 mutation and this medication is used as induction therapy in combination with Venclexta (venetoclax tablets) and Gazyva (obinutuzumab intravenous infusion). Marginal zone lymphoma-approve if the patient has tried at least one systemic regimen. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma-approve. Hairy Cell Leukemia - approve if pt has received therapy for relapsed or refractory disease AND pt has progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Hairy Cell Leukemia
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

C1 ESTERASE INHIBITORS

Products Affected

- BERINERT INTRAVENOUS KIT
- CINRYZE
- HAEGARDA
- RUCONEST

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	prescribed by or in consultation with an allergist/immunologist or a physician 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], Prophylaxis (Cinryze and Haegarda only), Initial Therapy: approve if the patient has HAE type I or type II confirmed by low levels of functional C1-INH protein (less than 50 percent of normal) at baseline and lower than normal serum C4 levels at baseline. Patient is currently taking Cinryze or Haegarda for prophylaxis - approve if the patient meets the following criteria (i and ii): i) patient has a diagnosis of HAE type I or II, and ii) according to the prescriber, the patient has had a favorable clinical response since initiating prophylactic therapy compared with baseline. HAE Due to C1-INH Deficiency [Type I or Type II], Treatment of Acute Attacks (Berinert and Ruconest only), Initial Therapy: approve if the patient has HAE type I or type II confirmed by low levels of functional C1-INH protein (less than 50 percent of normal) at baseline and lower than normal serum C4 levels at baseline. Patient who has treated previous acute HAE attacks with Berinert or Ruconest: approve if the patient has a diagnosis of HAE Type I or Type II and according to the prescriber, the patient has had a favorable clinical response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

CABLIVI

Products Affected

- CABLIVI INJECTION KIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, concurrent medications
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	Approve for 12 months
Other Criteria	aTTP-approve if the requested medication was initiated in the inpatient setting in combination with plasma exchange therapy AND patient is currently receiving at least one immunosuppressive therapy AND if the patient has previously received Cablivi, he/she has not had more than two recurrences of aTTP while on Cablivi
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CABOMETYX

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, histology, RET gene rearrangement status for NSCLC
Age Restrictions	Neuroendocrine tumor/Thyroid carcinoma-12 years and older, other dx (except bone cancer)-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). Bone cancer-approve if the patient has Ewing sarcoma or osteosarcoma and has tried at least one previous systemic regimen. Thyroid carcinoma-approve if the patient has differentiated thyroid carcinoma, patient is refractory to radioactive iodine therapy and the patient has tried Lenvima or sorafenib. Endometrial carcinoma-approve if the patient has tried one systemic regimen. GIST-approve if the patient has tried two of the following-imatinib, Ayvakit, sunitinib, dasatinib, Stivarga or Qinlock. NSCLC-approve if the patient has RET rearrangement positive tumor and has progressed on one of the first-line therapies, Gavreto (pralsetinib capsules) or Retevmo (selpercatinib capsules or tablets). Neuroendocrine tumors- approve if (A, B, C and D): A) pt has locally advanced, unresectable, or metastatic disease, and B) patient has well-differentiated neuroendocrine tumors, and C) patient has pancreatic or extra-pancreatic neuroendocrine tumors and D) the medication will be used as subsequent therapy. Adrenal gland tumor- approve if pt has locoregional unresectable or metastatic adrenocortical carcinoma. Pheochromocytoma/paraganglioma- approve if pt has locally unresectable disease.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Non-Small Cell Lung Cancer, Gastrointestinal stromal tumors (GIST), Bone cancer, Endometrial carcinoma, Adrenal gland tumor, Pheochromocytoma/paraganglioma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CALQUENCE

Products Affected

- CALQUENCE (ACALABRUTINIB MAL)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	CLL and SLL-approve. Mantle Cell Lymphoma- approve if the patient meets (A or B): A) has tried at least one systemic regimen or is not a candidate for a systemic regimen (e.g., rituximab, dexamethasone, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, bortezomib, or lenalidomide) or B) this medication is used in combination with rituximab. Marginal Zone Lymphoma-approve if patient has tried at least one systemic regimen (e.g., bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, lenalidomide, or chlorambucil). Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen (e.g., Brukinsa [zanubrutinib capsules], Imbruvica [ibrutinib tablets and capsules], rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, fludarabine, or cladribine)
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Marginal zone lymphoma.
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

CAMZYOS

Products Affected

- CAMZYOS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by a cardiologist (initial and continuation)
Coverage Duration	Initial-8 months, continuation- 1 year
Other Criteria	<p>Obstructive hypertrophic cardiomyopathy, initial-Approve if the pt meets the following criteria (i, ii and iii): i.Pt meets both of the following (a and b): a)Pt has at least 1 symptom associated w/obstructive hypertrophic cardiomyopathy (Note: examples include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise), AND b)Pt has New York Heart Association Class II or III symptoms of heart failure (Note:Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest), AND ii.Pt has left ventricular hypertrophy and meets 1 of the following (a or b): a)Pt has maximal left ventricular wall thickness greater than or equal to 15 mm, OR b)Pt has familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness greater than or equal to 13 mm, AND iii.Pt has a peak left ventricular outflow tract gradient greater than or equal to 50 mmHg (at rest or after provocation [Valsalva maneuver or post exercise]). Cont-Approve if pt meets ALL of the following criteria (i, ii, iii and iv): i.Pt has been established on therapy for at least 8 months (Note: pt who has received less than 8 months of therapy or who is restarting therapy is reviewed under initial therapy), AND ii.Pt meets both of the following (a and b): a)Currently or prior to starting therapy, pt has or has experienced at least 1 symptom associated with obstructive hypertrophic cardiomyopathy, AND</p>

PA Criteria	Criteria Details
	<p>b)Currently or prior to starting therapy, pt is in or was in New York Heart Association Class II or III heart failure, AND iii.Pt has a current left ventricular ejection fraction of greater than or equal to 50 percent, AND iv.Pt meets at least 1 of the following (a or b): a)Pt experienced a beneficial clinical response when assessed by at least 1 objective measure (Note:Examples include improved peak oxygen consumption/mixed venous oxygen tension, decreases in left ventricular outflow tract gradient, reductions in N-terminal pro-B-type natriuretic peptide levels, decreased high-sensitivity cardiac troponin I levels, reduced ventricular mass index, and/or a reduction in maximum left atrial volume index), OR b)Pt experienced stabilization or improvement in at least 1 symptom related to obstructive hypertrophic cardiomyopathy (Note:Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, ability to perform physical exercise, and/or favorable changes in the Kansas City Cardiomyopathy Questionnaire-23 (KCCQ-23) Clinical Summary Score (CSS) or Hypertrophic Cardiomyopathy Symptom Questionnaire (HCMSQ) Shortness of Breath domain scores.)</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CAPRELSA

Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	MTC - approve. DTC - approve if refractory to radioactive iodine therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma.
Part B Prerequisite	No
Prerequisite Therapy Required	No

CARGLUMIC ACID

Products Affected

- *carglumic acid*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	NAGS-Pt meets criteria no genetic test-3 mo. Pt had genetic test-12 mo, other-approve 7 days
Other Criteria	N-Acetylglutamate synthase deficiency with hyperammonemia-Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency or if the patient has hyperammonemia. Propionic Acidemia or Methylmalonic Acidemia with Hyperammonemia, Acute Treatment-approve if the patient's plasma ammonia level is greater then or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (generic carglumic acid)
Part B Prerequisite	No
Prerequisite Therapy Required	No

CAYSTON

Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist, infectious diseases specialist or a physician who specializes in the treatment of cystic fibrosis.
Coverage Duration	1 year
Other Criteria	Approve if the patient has <i>Pseudomonas aeruginosa</i> in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CHEMET

Products Affected

- CHEMET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Blood lead level
Age Restrictions	Approve in patients between the age of 12 months and 18 years
Prescriber Restrictions	Prescribed by or in consultation with a professional experienced in the use of chelation therapy (eg, a medical toxicologist or a poison control center specialist)
Coverage Duration	Approve for 2 months
Other Criteria	Approve if Chemet is being used to treat acute lead poisoning (not as prophylaxis) and prior to starting Chemet therapy the patient's blood lead level was greater than 45 mcg/dL.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CIBINQO

Products Affected

- CIBINQO

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule drug. Concurrent use with other Janus Kinase Inhibitors. Concurrent use with a biologic immunomodulator. Concurrent use with other potent immunosuppressants.
Required Medical Information	Diagnosis
Age Restrictions	AD-12 years of age and older (initial therapy)
Prescriber Restrictions	Atopic Dermatitis-prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
Coverage Duration	Pending CMS Review
Other Criteria	Atopic Dermatitis, initial-approve if the patient has had a trial of Rinvoq, unless the patient is less than 40 kg. Continuation-Approve if the patient has been receiving Cibinqo for at least 90 days AND patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Cibinqo) in at least one of the following: estimated body surface area affected, erythema, induration/papulation/edema, excoriations, lichenification, and/or a decreased requirement for other topical or systemic therapies for atopic dermatitis AND compared with baseline (prior to receiving Cibinqo), patient experienced an improvement in at least one symptom, such as decreased itching. Note: A patient who has received less than 3 months of therapy or who is restarting therapy with Cibinqo should be considered under initial therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

CIMZIA

Products Affected

- CIMZIA POWDER FOR RECONST
- CIMZIA SUBCUTANEOUS SYRINGE KIT 400 MG/2 ML (200 MG/ML X 2)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried
Age Restrictions	18 years and older for AS, nr-axSpA, PsA, RA, CD and PP (initial therapy). 2 years and older for JIA (initial therapy).
Prescriber Restrictions	All dx initial therapy only. RA, AS, JIA, prescribed by or in consultation with a rheumatologist. Crohn's disease, prescribed by or in consultation with a gastroenterologist. PsA prescribed by or in consultation with a rheumatologist or dermatologist. PP, prescribed by or in consultation with a dermatologist. nr-axSpA-prescribed by or in consultation with a rheumatologist
Coverage Duration	Approve through end of plan year
Other Criteria	AS initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Xeljanz/XR, Cosentyx. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also count. PsA initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Cosentyx, Tremfya, a preferred ustekinumab product, Otezla, Rinvoq, Skyrizi or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab/ustekinumab product will also count. RA initial tx, approve if the patient has tried two of the following drugs in the past: Enbrel, a preferred adalimumab product, Rinvoq or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also count. CD initial tx, approve if patient has previously tried ONE of the following drugs in the past: a preferred adalimumab product, a preferred infliximab product, a preferred ustekinumab product, Skyrizi, Rinvoq, or Tremfya. Note: if the patient

PA Criteria	Criteria Details
	<p>does not meet this requirement, a previous trial of another non-preferred adalimumab/infliximab/ustekinumab product will also count. Plaque Psoriasis (PP), initial tx-approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Skyrizi, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya. A trial of a non-preferred adalimumab/ustekinumab also counts. JIA initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, Rinvoq/LQ, Xeljanz, a preferred adalimumab product. Note pt does not meet this requirement, a trial with a non-preferred adalimumab, Simponi Aria, tocilizumab, Kevzara, or infliximab will also count. Cont tx, AS/PsA/RA/CD/PP/JIA - approve if the pt had a response as determined by the prescriber. Non-radiographic axial spondylitis (nr-axSpA), initial tx-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroilitis reported on MRI. nr-axSpA continuation tx-approve if the patient has had a response as determined by the prescriber. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand name product), Zymfentra. Preferred ustekinumab products include Selarsdi, Yesintek.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CINACALCET

Products Affected

- *cinacalcet*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Hypercalcemia d/t parathyroid CA-prescr/consult w/onco or endo. Hypercalcemia w/primary hyperparathyroidism-prescr/consult w/nephro or endo. Hyperparathyroidism in post-renal transplant-prescr/consult w/transplant physician/nephro/endo.
Coverage Duration	12 months
Other Criteria	Hypercalcemia due to parathyroid carcinoma-approve. Hypercalcemia in patients with primary hyperparathyroidism-approve if the patient has failed or is unable to undergo a parathyroidectomy due to a contraindication. Secondary Hyperparathyroidism in patients with chronic kidney disease on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundles payment benefit). Hyperparathyroidism in Post-Renal Transplant Patients-approve if the baseline (prior to starting cinacalcet therapy) calcium and intact parathyroid hormone (iPTH) levels are above the normal range, as defined by the laboratory reference values.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	hyperparathyroidism in post-renal transplant patients
Part B Prerequisite	No
Prerequisite Therapy Required	No

CLOBAZAM

Products Affected

- *clobazam oral suspension*
- *clobazam oral tablet*
- SYMPAZAN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other medications tried
Age Restrictions	2 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Lennox-Gastaut Syndrome, initial therapy-patient has tried and/or is concomitantly receiving one of the following: lamotrigine, topiramate, rufinamide, felbamate, Fintepla, Epidiolex or valproic acid. Treatment refractory seizures/epilepsy, initial therapy-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs (e.g., valproic acid, lamotrigine, topiramate, clonazepam, levetiracetam, zonisamide, felbamate). Continuation-prescriber confirms patient is responding to therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Dravet Syndrome and treatment-refractory seizures/epilepsy
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

COMETRIQ

Products Affected

- COMETRIQ ORAL CAPSULE 100 MG/DAY(80 MG X1-20 MG X3), 60 MG/DAY(80 MG X1-20 MG X1), 140 MG/DAY (20 MG X 3/DAY)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	MTC - approve. Non-Small Cell Lung Cancer-approve if patient meets (A, B and C): A) recurrent, advanced, or metastatic disease, B) has RET gene rearrangement-positive tumor, and C) has progressed on one of the first-line therapies, Gavreto (pralsetinib capsules) or Retevmo (selpercatinib capsules or tablets). Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy and patient has tried tried Lenvima (lenvatinib capsules) or sorafenib tablets.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

COPIKTRA

Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma - approve if the patient has tried at least one Bruton tyrosine kinase inhibitor (examples: ibrutinib, zanubrutinib, acalabrutinib, pirtobrutinib) and at least one Venclexta (venetoclax)- based regimen. T-cell lymphoma- For peripheral T-cell lymphoma, approve. For breast implant-associated anaplastic large cell lymphoma, or hepatosplenic T-cell lymphoma, approve if the patient has relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	T-cell Lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

COSENTYX

Products Affected

- COSENTYX (2 SYRINGES)
- COSENTYX PEN (2 PENS)
- COSENTYX SUBCUTANEOUS SYRINGE 75 MG/0.5 ML
- COSENTYX UNOREADY PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis and previous medications use
Age Restrictions	PP-6 yr and older.AS/Spondy/HS initial - 18 years of age and older. PsA-2 years and older. Enthesitis-4 years and older
Prescriber Restrictions	PP initial-presc/consult derm. PsA initial - prescribed by or in consultation with a dermatologist or rheumatologist. AS/spondylo/enthesitis initial- by or in consultation with rheumatologist. HS initial - by or in consult w/ dermatologist
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: HIDRADENITIS SUPPURATIVA (HS): tried at least one other therapy (e.g. systemic antibiotics, isotretinoin). NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation and meets a or b: a) C-reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI. PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of at least one biologic that is not Cosentyx or a Cosentyx biosimilar also counts) or B) contraindication to MTX. CONTINUATION THERAPY: ALL INDICATIONS: patient has experienced benefit from the medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

COTELLIC

Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf AND patient has BRAF V600 mutation positive disease. CNS Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) circumscribed ganglioglioma/neuroglioma/glioneuronal tumor OR ii. Recurrent or progressive disease for one of the following conditions (a, b or c): a) high grade glioma, b) circumscribed glioma OR c) Glioblastoma, OR iii. Melanoma with brain metastases AND medication with be taken in combination with Zelboraf (vemurafenib tablets). Histiocytic Neoplasm-approve if the patient meets one of the following (i, ii, or iii): i. Patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR ii. Patient has Erdheim Chester disease OR iii. Patient has Rosai-Dorfman disease.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Cancer

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

CRENESSITY

Products Affected

- CRENESSITY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	4 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, urologist, or a physician who specializes in the treatment of adrenal hyperplasia (initial)
Coverage Duration	Pending CMS Review
Other Criteria	INITIAL-CLASSIC CONGENITAL ADRENAL HYPERPLASIA (CAH)-Patient meets BOTH of the following (a and b): a) The medication will be taken in combination with a systemic glucocorticoid, Note: Examples of glucocorticoids include hydrocortisone, prednisone, prednisolone, or dexamethasone, AND b) Patients has a diagnosis of 21-hydroxylase deficiency CAH confirmed by ONE of the following (1, 2, 3, or 4): 1. Elevated 17-hydroxyprogesterone level, OR 2. Confirmed cytochrome (CYP)21A2 genotype, OR 3. Positive newborn screening with confirmatory second-tier testing, OR 4. Diagnostic results after cosyntropin stimulation. CONTINUATION, CAH-patient is continuing to derive benefit.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CRESEMBA (ORAL)

Products Affected

- CRESEMBA ORAL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Candidiasis of the esophagus - HIV infection, sepsis
Part B Prerequisite	No
Prerequisite Therapy Required	No

CRINONE GEL

Products Affected

- CRINONE VAGINAL GEL 8 %

PA Criteria	Criteria Details
Exclusion Criteria	Use in patients to supplement or replace progesterone in the management of infertility.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Secondary amenorrhea, 12 months.Support of an established pregnancy, 9 months.
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Support of an established pregnancy
Part B Prerequisite	No
Prerequisite Therapy Required	No

CYSTEAMINE (OPHTHALMIC)

Products Affected

- CYSTADROPS
- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases
Coverage Duration	1 year
Other Criteria	Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

CYSTEAMINE (ORAL)

Products Affected

- CYSTAGON
- PROCYSBI ORAL GRANULES DEL RELEASE IN PACKET

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Cystagon and Procysbi
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	Procysbi only: greater than 1 year of age
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	1 year
Other Criteria	Cystinosis, nephropathic-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming biallelic pathogenic or likely pathogenic variants in the CTNS gene OR white blood cell cystine concentration above the upper limit of the normal reference range for the reporting laboratory.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DALFAMPRIDINE

Products Affected

- *dalfampridine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	MS. If prescribed by, or in consultation with, a neurologist or MS specialist (initial and continuation).
Coverage Duration	Pending CMS Review
Other Criteria	Initial-approve if the patient is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has impaired ambulation as evaluated by an objective measure (e.g., timed 25 foot walk and multiple sclerosis walking scale-12). Continuation-approve if the patient is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has responded to or is benefiting from therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DAURISMO

Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medications that will be used in combination, comorbidities
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML - approve if Daurismo will be used in combination with cytarabine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DEFERASIROX

Products Affected

- *deferasirox*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Serum ferritin level
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve if the patient is benefiting from therapy as confirmed by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DEFERIPRONE

Products Affected

- *deferiprone*
- FERRIPROX (2 TIMES A DAY)
- FERRIPROX ORAL SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Serum ferritin level
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias-Initial therapy - approve. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DESOXYN

Products Affected

- *methamphetamine*

PA Criteria	Criteria Details
Exclusion Criteria	Weight loss.
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIABETIC SUPPLY - ALCOHOL PADS

Products Affected

- *alcohol pads*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIABETIC SUPPLY - GAUZE PADS

Products Affected

- GAUZE PADS 2 X 2

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIABETIC SUPPLY - NEEDLES

Products Affected

- NOVO PEN NEEDLE
- EMBECTA PEN NEEDLE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body AND either (i or ii): (i) the patient is either requesting a preferred needle, or has tried one of the following preferred needles: Novofine, Novofine Plus, Novotwist, Novofine Autocover, BD Insulin Pen Needle UF Mini, BD Nano Pen Needle, BD Ultra-Fine Pen Needle, BD Autosshield Duo Pen Needle, or Embecta needles or (ii) the prescriber states the patient requires a needle of the requested length and/or gauge which is not available in any of the preferred products.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DIABETIC SUPPLY - SYRINGES

Products Affected

- EMBECTA INSULIN SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body AND either (i or ii): (i) the patient is either requesting a preferred syringe, or has tried one of the following preferred syringes: BD Eclipse, BD Insulin Syringe, BD Safetyglide, BD Safetyglide Syringe, BD Luer-Lok Syringe, Embecta syringes or (ii) the prescriber states the patient requires a needle of the requested length and/or gauge which is not available in any of the preferred products.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DIACOMIT

Products Affected

- DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of diagnosis.
Age Restrictions	6 months and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome-Initial therapy-approve if the patient is concomitantly receiving clobazam or is unable to take clobazam due to adverse events. Dravet Syndrome-Continuation-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DICLOFENAC (TOPICAL)

Products Affected

- DICLOFENAC EPOLAMINE
- FLECTOR
- LICART

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 mos.
Other Criteria	Pending CMS Review
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DIMETHYL FUMARATE

Products Affected

- *dimethyl fumarate oral capsule, delayed release(dr/ec) 120 mg, 120 mg (14)- 240 mg (46), 240 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DOPTELET

Products Affected

- DOPTELET (10 TAB PACK)
- DOPTELET (15 TAB PACK)
- DOPTELET (30 TAB PACK)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Chronic ITP-prescribed by or after consultation with a hematologist (initial therapy)
Coverage Duration	Thrombo w/chronic liver disease-5 days, chronic ITP-initial-3 months, cont-1 year
Other Criteria	THROMBOCYTOPENIA WITH CHRONIC LIVER DISEASE (A and B): A) current platelet count less than 50 x 10 ⁹ /L and B) scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. CHRONIC ITP, INITIAL THERAPY (A and B): A): (i or ii): i) platelet count less than 30,000 microliters or ii) platelet count less than 50,000 microliters and patient is at an increased risk of bleeding, and B) tried one other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, eltrombopag tablets and oral suspension, romiplostim subcutaneous injection, fostamatinib tablets, rituximab) or had a splenectomy. CHRONIC ITP, CONTINUATION THERAPY: patient had beneficial clinical response and remains at risk for bleeding complications.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DRONABINOL

Products Affected

- *dronabinol*

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

DROXIDOPA

Products Affected

- *droxidopa*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Medication history (as described in Other Criteria field)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a neurologist
Coverage Duration	12 months
Other Criteria	NOH, approve if the patient meets ALL of the following criteria: a) Patient has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND b) Patient has tried midodrine
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DUAL OREXIN RECEPTOR ANTAGONIST

Products Affected

- BELSOMRA
- DAYVIGO
- QUVIVIQ

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Treatment of insomnia, characterized by difficulties with sleep onset and /or sleep maintenance-approve. In addition to above, patients requesting Dayvigo or Quviviq must have a trial Belsomra first.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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
Exclusion Criteria	Concurrent use with another Monoclonal Antibody (examples: Adbry, Cinqair, Ebglyss, Fasentra, Nemluvio, Nucala, Tezspire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical].
Required Medical Information	Diagnosis. CONTINUATION CRITERIA: AD: responding positively to therapy. ASTHMA: responding positively to therapy and concurrent use with ICS. COPD (all of A, B and C): A) received Dupixent for at least 6 months and B) continues LABA and LAMA, and C) beneficial response (e.g. reduced symptoms, exacerbations, hospitalizations, ED/urgent care visits, improved lung function). CRSwNP (all of A, B, and C): A) received Dupixent for at least 6 months, B) responding positively to therapy, and C) concurrent use with intranasal CS. EoE (A and B): A) received Dupixent for at least 6 months and B) reduction in intraepithelial eosinophil count, decreased dysphagia/pain upon swallowing, or reduced frequency/severity of food impaction. PRURIGO NODULARIS (A and B): A) received Dupixent for at least 6 months and B) reduction in nodular lesion count, pruritis, or nodular lesion size. CSU (A and B): A) received at least 6 months of Dupixent and B) experienced a beneficial clinical response, defined by decreased itch severity, decreased number of hives or decreased size of hives.
Age Restrictions	Initial therapy only: AD-6 months and older, asthma-6 years of age and older, Esophagitis-1 yr and older, Chronic Rhinosinusitis/CSU- 12 and older, Prurigo nodularis/COPD-18 and older
Prescriber Restrictions	Initial therapy only: Atopic Dermatitis/prurigo nodularis/CSU-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist. Esophagitis-presc/consult-allergist or gastro. COPD-prescribed by or in consultation with an allergist, immunologist, or pulmonologist
Coverage Duration	Pending CMS Review

PA Criteria	Criteria Details
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EBGLYSS

Products Affected

- EBGLYSS PEN
- EBGLYSS SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy. Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical].
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
Coverage Duration	Initial-4 months, Continuation-1 year
Other Criteria	INITIAL, ATOPIC DERMATITIS- All of (A, B, and C): A. 12 to 17 years of age must weigh greater than or equal to 40 kg, and B. Atopic dermatitis involvement estimated to be greater than or equal to 10 percent of the body surface area, and C. Tried TWO of Dupixent, Nemluvio or Adbry. CONTINUATION, ATOPIC DERMATITIS-patient has received at least 4 months of therapy with Ebglyss and has responded to therapy. Note: A patient who has received less than 4 months of therapy or who is restarting therapy with Ebglyss should be considered under initial therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EGRIFTA

Products Affected

- EGRIFTA SV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician specializing in the treatment of human immunodeficiency virus (HIV) infection (initial therapy)
Coverage Duration	Pending CMS Review
Other Criteria	Lipodystrophy in HIV-infected patients-Initial-approve if Egrifta is being prescribed for the reduction of excess abdominal fat and the patient meets one of the following-If male, waist circumference is greater than or equal to 95 cm (37.4 in) and waist-to-hip ratio is greater than or equal to 0.94 OR If female, waist circumference is greater than or equal to 94 cm (37 in) and waist-to-hip ratio is greater than or equal to 0.88 AND the patient has been stable on anti-retroviral regimen for at least 8 weeks. Continuation-approve if the patient has responded to Egrifta therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ELYXYB

Products Affected

- ELYXYB

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Migraine, acute treatment-approve if the patient has tried at least one triptan therapy or has a contraindication to triptans.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EMFLAZA

Products Affected

- *deflazacort*
- *jaythari*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty
Age Restrictions	2 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders (initial and continuation therapy)
Coverage Duration	1 year
Other Criteria	Initial therapy-approve if the patient's diagnosis is confirmed by genetic testing with a confirmed pathogenic variant in the dystrophin gene. Continuation-approve if the patient has responded to or continues to have improvement or benefit from therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

EMGALITY

Products Affected

- EMGALITY PEN MG/ML, 300 MG/3 ML (100 MG/ML X 3)
- EMGALITY SYRINGE
- SUBCUTANEOUS SYRINGE 120

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with another cGRP inhibitor for migraine headache prevention
Required Medical Information	Diagnosis, number of migraine or cluster headaches per month
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Cluster headache tx-6 months, migraine prevention-1 year
Other Criteria	Migraine headache prevention-Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) If pt is currently taking Emgality, pt has had significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Emgality was initiated. Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

EMPAVELI

Products Affected

- EMPAVELI

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ENBREL

Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION
- ENBREL SUBCUTANEOUS SYRINGE
- ENBREL SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	Initial therapy: AS/RA- 18 years and older, JIA/PsA/Behcet's-2 years and older, GVHD-6 years and older, PP-4 years and older
Prescriber Restrictions	Initial only-RA/AS/JIA/JRA,prescribed by or in consult w/ rheumatologist. PsA, prescribed by or in consultation w/ rheumatologist or dermatologist.PP, prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center.Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist.
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA)/JUVENILE IDIOPATHIC ARTHRITIS (JIA)/JRA/ANKYLOSING SPONDYLITIS: approve if the patient has tried one preferred adalimumab product (a trial of a non-preferred adalimumab also counts). PLAQUE PSORIASIS (PP)/PSORIATIC ARTHRITIS: approve if the patient has tried one preferred adalimumab product (a non-preferred adalimumab also counts), unless the patient is less than 18 years of age. GRAFT VERSUS HOST DISEASE (GVHD): approve. BEHCET'S: tried at least one conventional therapy (e.g., systemic corticosteroid, immunosuppressant, interferon alfa, mycophenolate), adalimumab, or infliximab. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. Please Note: preferred adalimumab products include Hadlima, Simlandi.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Graft versus host disease (GVHD), Behcet's disease
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ENDARI

Products Affected

- ENDARI
- *glutamine (sickle cell)*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty
Age Restrictions	Greater than or equal to 5 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, a physician who specializes in sickle cell disease (e.g., a hematologist)
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ENTYVIO PEN

Products Affected

- ENTYVIO PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs) used for an inflammatory condition.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist (initial)
Coverage Duration	Approve through end of plan year
Other Criteria	<p>Ulcerative Colitis, initial therapy with Entyvio SC: approve if the patient meets (A and B): (A) the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months of initiating therapy with Entyvio subcutaneous, (B) patient meets (i or ii): (i): the patient has had a trial of TWO of the following: a preferred ustekinumab product, Skyrizi, Tremfya, Rinvoq, a preferred infliximab product, or a preferred adalimumab product. Trials of a Non-Preferred infliximab product, Simponi SC, a non-preferred ustekinumab or a Non-Preferred adalimumab product will also count. OR (ii) the patient has already started on Entyvio IV or is currently undergoing induction therapy with Entyvio IV. Ulcerative colitis, continuation of therapy with Entyvio SC: approve if the patient has had a response to therapy. Crohn's Disease, initial therapy with Entyvio SC: approve if the patient meets (A and B): (A) the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months of initiating therapy with Entyvio subcutaneous, (B) patient meets (i or ii): (i): the patient has had a trial of TWO of the following: a preferred adalimumab product, a preferred infliximab, a preferred ustekinumab product, Skyrizi, Tremfya or Rinvoq. Trials of a Non-Preferred infliximab product, a non-preferred ustekinumab or a Non-Preferred adalimumab product will also count. OR (ii) the patient has already started on Entyvio IV or is currently</p>

PA Criteria	Criteria Details
	undergoing induction therapy with Entyvio IV. Crohn's disease, continuation of therapy with Entyvio SC: approve if the patient has had a response to therapy. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand name product), Zymfentra. Preferred ustekinumab products include Selarsdi, Yesintek.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EPCLUSA

Products Affected

- EPCLUSA ORAL PELLETS IN PACKET 150-37.5 MG, 200-50 MG
- EPCLUSA ORAL TABLET 200-50 MG, 400-100 MG

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin.
Required Medical Information	Diagnosis
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	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. And, patients with genotype 1, 2, 3, 4, 5, or 6 must try TWO of the following: velpatasvir/sofosbuvir, Mavyret, Vosevi, unless velpatasvir/sofosbuvir, Mavyret and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Genotype unknown/undetermined must have a trial of velpatasvir/sofosbuvir AND Mavyret prior to approval of Epclusa unless velpatasvir/sofosbuvir and Mavyret are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EPIDIOLEX

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	Patients 1 year and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial therapy)
Coverage Duration	1 year
Other Criteria	Dravet Syndrome (initial therapy)-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs or if the patient has tried or is concomitantly receiving one of Diacomit or clobazam or Fintepla. Lennox Gastaut Syndrome (initial therapy)-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs. Tuberous Sclerosis Complex (initial therapy)-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs. Refractory epilepsy (initial therapy)-approve if patient tried or is concomitantly receiving at least two other antiseizure drugs. Continuation of therapy for all indications-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Refractory epilepsy
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EPOETIN ALFA

Products Affected

- EPOGEN INJECTION SOLUTION 2,000 UNIT/ML, 20,000 UNIT/2 ML, 20,000 UNIT/ML, 3,000 UNIT/ML, 4,000 UNIT/ML
- PROCRIT INJECTION SOLUTION 10,000 UNIT/ML, 2,000 UNIT/ML, 20,000 UNIT/ML, 3,000 UNIT/ML, 4,000 UNIT/ML, 40,000 UNIT/ML
- RETACRIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	MDS anemia = 18 years of age and older
Prescriber Restrictions	MDS anemia, myelofibrosis-prescribed by or in consultation with, a hematologist or oncologist.
Coverage Duration	Chemo-6m, Transfus-1m, CKD-1 yr, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr
Other Criteria	Anemia in a pt with Chronic Kidney Disease (CKD) not on dialysis- for initial therapy, approve if hemoglobin (Hb) is less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children, or for continuation of therapy in a pt currently on an erythropoiesis-stimulating agent (ESA) approve if Hb is less than or equal to 12 g/dL. Anemia in a pt with cancer due to chemotherapy- approve if pt is currently receiving myelosuppressive chemo as a non-curative treatment and (for initial therapy) Hb is less than 10.0 g/dL or (if currently on ESA) Hb is less than or equal to 12.0 g/dL. Anemia in HIV with zidovudine- for initial therapy, approve if Hb is less than 10.0 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA, approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Approve if Hb is less than or equal to 13, AND surgery is elective, nonvascular and non-cardiac AND pt is unwilling or unable to donate autologous blood prior to surgery. MDS- for initial therapy, approve if Hb is less than 10 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA approve if Hb is 12.0 g/dL or less. Myelofibrosis- for Initial therapy approve if patient has a Hb less than 10

PA Criteria	Criteria Details
	or serum erythropoietin less than or equal to 500 mU/mL, or for continuation of therapy in pt currently on ESA hemoglobin is less than or equal to 12g/dL. For all covered uses, if the request is for Epogen, then the patient is required to try Procrit and Retacrit. Anemia in patients with chronic renal failure on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anemia due to myelodysplastic syndrome (MDS), myelofibrosis
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ERIVEDGE

Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Basal cell carcinoma, locally advanced-patients new to therapy-approve if (A or B): A) pt has recurrent BCC following surgery or radiation therapy OR B) pt is not a candidate for surgery and is not a candidate for radiation therapy. Basal cell carcinoma, locally advanced-patients currently on therapy-approve. Central nervous system cancer (this includes brain and spinal cord tumors)-approve if the patient has medulloblastoma, the patient has tried at least one chemotherapy agent and according to the prescriber, the patient has a mutation of the sonic hedgehog pathway. Basal cell carcinoma, metastatic (this includes primary or recurrent nodal metastases and distant metastases)-approve. Diffuse Basal Cell Carcinoma Formation, including basal cell nevus syndrome (Gorlin syndrome) or other genetic forms of multiple basal cell carcinoma - approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central nervous System Cancer, diffuse basal cell carcinoma formation
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ERLEADA

Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Prostate cancer-non-metastatic, castration resistant and prostate cancer-metastatic, castration sensitive-approve if the requested medication will be used in combination with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ERLOTINIB

Products Affected

- *erlotinib oral tablet 100 mg, 150 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Advanced or Metastatic NSCLC, approve if the patient has EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note-Examples of EGFR mutation-positive non-small cell lung cancer include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. RCC, approve if the patient meets (A, B, and C): A) has stage IV or relapsed non-clear cell histology RCC and B) has advanced papillary disease including hereditary leiomyomatosis and renal cell carcinoma (HLRCC)-associated renal cell carcinoma and C) erlotinib will be used in combination with bevacizumab. Bone cancer-approve if the patient has chordoma and has tried at least one previous therapy. Pancreatic cancer-approve if the medication is used in combination with gemcitabine and if the patient has locally advanced, metastatic or recurrent disease. Vulvar cancer-approve if the patient has advanced, recurrent or metastatic disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Renal Cell Carcinoma, vulvar cancer and Bone Cancer-Chordoma.
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

EVEKEO

Products Affected

- *amphetamine sulfate*

PA Criteria	Criteria Details
Exclusion Criteria	Weight loss.
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

EVENTITY

Products Affected

- EVENTITY SUBCUTANEOUS SYRINGE
210MG/2.34ML (105MG/1.17MLX2)

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis (e.g., oral or IV bisphosphonates, Prolia, Forteo, Tymlos, calcitonin nasal spray) except calcium and Vitamin D
Required Medical Information	Diagnosis, medications that have been tried in the past, other medications that will be used in combination
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months of therapy per course of treatment.
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EVEROLIMUS

Products Affected

- *everolimus (antineoplastic) oral tablet*
- *everolimus (antineoplastic) oral tablet for suspension 2 mg, 3 mg, 5 mg*
- *torpenz*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer-HER2 status, hormone receptor (HR) status.
Age Restrictions	Pending CMS Review
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Breast Cancer-approve if pt meets ALL the following (A, B, C, D, E, and F):A)pt has recurrent or metastatic,HR+ disease AND B)pt has HER2-negative breast cancer AND C)pt has tried at least 1 prior endocrine therapy AND D)pt meets 1 of the following conditions (i or ii):i.pt is a postmenopausal woman or man OR ii.pt is pre/perimenopausal woman AND is receiving ovarian suppression/ablation with a GnRH agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND E)pt meets 1 of the following conditions (i or ii): i.Everolimus will be used in combo with exemestane and pt meets 1 of the following:pt is male and is receiving a GnRH analog or pt is a woman or ii. Everolimus will be used in combo with fulvestrant or tamoxifen AND F)pt has not had disease progression while on Everolimus. RCC, relapsed or Stage IV disease-approve if using for non-clear cell disease or if using for clear cell disease, pt has tried 1 prior systemic therapy (e.g., Inlyta, Votrient, Sutent, Cabometyx, Nexavar).TSC Associated SEGA-approve if pt requires therapeutic intervention but cannot be curatively resected. Thymomas and Thymic Carcinomas-approve if pt has tried chemotherapy or cannot tolerate chemotherapy.TSC associated renal angiomyolipoma -approve. WM/LPL - pt has tried at least one systemic regimen. Thyroid Carcinoma, differentiated-approve if pt is refractory to radioactive iodine therapy. Endometrial Carcinoma-approve if everolimus will be used in combo with letrozole. GIST-approve if pt has tried 2 of the following drugs: Sutent,</p>

PA Criteria	Criteria Details
	<p>Sprycel, Stivarga, Ayvakit, Qinlock or imatinib AND there is confirmation that everolimus will be used in combo with 1 of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST. TSC-associated partial-onset seizures-approve. NET tumors of the pancreas, GI Tract, Lung and Thymus (carcinoid tumors)-approve. Soft tissue sarcoma-approve if pt has perivascular epitheloid cell tumors (PE Coma) or recurrent angiomyolipoma/lymphangioliomyomatosis. Classic hodgkin lymphoma-approve if pt has relapsed or refractory disease AND not a candidate for high-dose therapy and autologous stem cell rescue. Histiocytic neoplasm-approve if pt has Erdheim-Chester disease or, Rosai-Dorfman disease or Langerhans cell histiocytosis. Patient must also have PIK3CA mutation. Meningioma-(A, B and C): A) approve if pt has recurrent or progressive disease AND B) pt has surgically inaccessible disease and radiation therapy is not possible AND C) medication will be used in combination with a somatostatin analogue or bevacizumab. Uterine Sarcoma-approve if the patient has advanced, recurrent, metastatic, or inoperable disease, AND has a perivascular epithelioid cell tumor (PEComa), AND has tried at least one systemic regimen. Note: Examples of systemic regimen include doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	<p>neuroendocrine tumors of the thymus (Carcinoid tumors). Soft tissue sarcoma, classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Thymomas and Thymic carcinomas, Differentiated Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST), men with breast cancer, Pre-peri-menopausal women with breast cancer, Histiocytic Neoplasm, uterine sarcoma, meningioma</p>
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EYSUVIS

Products Affected

- EYSUVIS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

FABHALTA

Products Affected

- FABHALTA

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with another complement inhibitor
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial/continuation)
Prescriber Restrictions	PNH: Prescribed by or in consultation with a hematologist (initial/continuation), IgAN/C3G: prescribed by or in consultation with a nephrologist (initial/continuation)
Coverage Duration	Initial-PNH/C3G: 6 months, IgAN: 9 months. continuation- all dx: 1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Pending CMS Review

FASENRA

Products Affected

- FASENRA PEN
- FASENRA SUBCUTANEOUS SYRINGE 10 MG/0.5 ML, 30 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy.
Required Medical Information	Diagnosis
Age Restrictions	Asthma: 6 years of age and older, EGPA: 18 years and older
Prescriber Restrictions	Asthma: Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. EGPA: Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist
Coverage Duration	Asthma: 6 months initial, 12 months continuation. EGPA: 8 months initial, 12 months continuation.
Other Criteria	INITIAL THERAPY: ASTHMA (all of A, B, and C): A) blood eosinophil greater than or equal to 150 cells per microliter within previous 6 weeks prior to Fasenra or another monoclonal antibody, B) used an inhaled corticosteroid (ICS) in combination with at least one additional asthma controller/maintenance medication, and C) uncontrolled asthma prior to any asthma monoclonal antibody as defined by one of the following (a, b, c, d, or e): a) one or more exacerbations requiring a systemic CS in the past year, b) one or more exacerbations requiring hospital/urgent care/emergency department visit in the past year, c) FEV1 less than 80 percent predicted or less than 90 percent predicted for patients less than 18, d) FEV1/FVC less than 0.80, or e) worsened asthma with systemic CS taper. EGPA: (all of A, B, and C): A) active, non-severe disease, and B) currently on systemic CS for at least 4 weeks, and C) blood eosinophil greater than or equal to 150 cells per microliter within previous 4 weeks or prior to treatment with any monoclonal antibody that may alter eosinophil levels. CONTINUATION THERAPY: ASTHMA (A and B): A) patient has responded to therapy (e.g., decrease in any of the following: asthma exacerbations, asthma symptoms, hospitalizations, emergency department/urgent care visits, physician visits, requirement for oral corticosteroid therapy) and B) continues to receive therapy with an ICS.

PA Criteria	Criteria Details
	EGPA: patient has responded to therapy (e.g. reduced rate of relapse, CS dose reduction, reduced eosinophil levels).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FILSPARI

Products Affected

- FILSPARI

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with any renin-angiotensin-aldosterone antagonists (e.g., angiotensin converting enzyme inhibitors or angiotensin receptor blockers), endothelin receptor antagonists, or aliskiren
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist (initial/continuation)
Coverage Duration	1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Pending CMS Review

FILSUVEZ

Products Affected

- FILSUVEZ

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with Vyjuvek (beremagene geperpavec-svdt topical gel).
Required Medical Information	Diagnosis
Age Restrictions	6 months and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with dermatologist or wound care specialist (initial/continuation).
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

FINGOLIMOD

Products Affected

- *fingolimod*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of fingolimod with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	10 years and older
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

FINTEPLA

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
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-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex, Clobazam or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. Lennox-Gastaut Syndrome, initial-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Lennox-Gastaut Syndrome, continuation-approve if the patient is responding to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FIRMAGON

Products Affected

- FIRMAGON KIT W DILUENT SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Patients new to therapy, are required to try Eligard prior to approval of Firmagon.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FOTIVDA

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
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. Note: Examples of systemic regimens for renal cell carcinoma include axitinib tablets, axitinib + pembrolizumab injection, cabozantinib tablets, cabozantinib + nivolumab injection, sunitinib malate capsules, pazopanib tablets, sorafenib tablets, and lenvatinib capsules + everolimus.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FRUZAQLA

Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Colon cancer, rectal cancer, or appendiceal cancer-Approve if the patient meets the following (A, B and C): A.Patient has advanced or metastatic disease, AND B. Patient meets (i or ii): i. has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease, or ii. patient is ineligible for or progressed on checkpoint inhibitor therapy (examples: Keytruda [pembrolizumab intravenous infusion] and Opdivo [nivolumab intravenous infusion]) and meets ONE of the following (a or b): a. has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or b. is polymerase epsilon/delta (POLE/POLD1) mutation positive, AND C. Patient has previously been treated with the following (i, ii, and iii): i.Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, Note: Examples of fluoropyrimidine agents include 5-fluorouracil (5-FU) and capecitabine. AND ii.An anti-vascular endothelial growth factor (VEGF) agent, Note: Examples of anti-VEGF agents include bevacizumab. AND iii. If the tumor is RAS wild-type (KRAS wild-type and NRAS wild-type) [that is, the tumor or metastases are KRAS and NRAS mutation negative], the patient meets ONE of the following (a or b): a.According to the prescriber, anti-epidermal growth factor receptor (EGFR) therapy is NOT medically appropriate, OR b. The patient has received an anti-EGFR therapy. Note: Examples of anti-EGFR therapy</p>

PA Criteria	Criteria Details
	includes Erbitux (cetuximab intravenous infusion) and Vectibix (panitumumab intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Appendiceal cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FULPHILA

Products Affected

- FULPHILA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-30 days.
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) 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), 2) 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 according to the prescribing physician (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status or HIV infection patients with low CD4 counts), or 3) patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

FYLNETRA

Products Affected

- FYLNETRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) 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), 2) 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 according to the prescribing physician (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status or HIV infection patients with low CD4 counts, OR 3) patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. Patients are required to try Fulphila and Nyvepria and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or

PA Criteria	Criteria Details
	surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Fylnetra.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GALAFOLD

Products Affected

- GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Elfabrio (pegunigalsidase alfa intravenous infusion)
Required Medical Information	Diagnosis
Age Restrictions	16 years and older
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, nephrologist, or a physician who specializes in the treatment of Fabry disease
Coverage Duration	Pending CMS Review
Other Criteria	Approve if the patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

GATTEX

Products Affected

- GATTEX 30-VIAL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 year and older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	Initial-approve if the patient is currently receiving parenteral nutrition on 3 or more days per week or according to the prescriber, the patient is unable to receive adequate total parenteral nutrition required for caloric needs. Continuation-approve if the patient has experienced improvement.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GAVRETO

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	NSCLC-18 years and older. thyroid cancer-12 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NSCLC-approve if the patient has advanced, recurrent, or metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an Food and Drug Administration (FDA) approved test. Differentiated Thyroid Cancer- pt has unresectable, recurrent, or metastatic disease AND pt has RET fusion-positive or RET-mutation-positive disease AND disease requires treatment with systemic therapy AND the disease is radioactive iodine-refractory. Anaplastic thyroid cancer or Medullary Thyroid Cancer- pt has unresectable, recurrent, or metastatic disease AND pt has disease positive for RET pathogenic variant.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Medullary Thyroid Cancer, Anaplastic Thyroid Cancer
Part B Prerequisite	No
Prerequisite Therapy Required	No

GEFITINIB

Products Affected

- *gefitinib*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NSCLC-approve if the patient has advanced or metastatic disease and the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	NSCLC with EGFR L861Q, G719X, or S768I mutations.
Part B Prerequisite	No
Prerequisite Therapy Required	No

GILOTRIF

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For NSCLC - EGFR exon deletions or mutations or if NSCLC is squamous cell type
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	NSCLC EGFR pos - For the treatment of advanced or metastatic non small cell lung cancer (NSCLC)-approve if the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: examples of sensitizing EGFR mutation-positive NSCLC include the following mutations : exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. NSCLC metastatic squamous cell must have disease progression after treatment with platinum based chemotherapy. Head and neck cancer-approve if the patient has non-nasopharyngeal head and neck cancer and the patient has disease progression on or after platinum based chemotherapy. (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan)
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Head and neck cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GLATIRAMER

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

GLUCAGON-LIKE PEPTIDE-1 AGONISTS

Products Affected

- *exenatide subcutaneous pen injector 10 mcg/dose(250 mcg/ml) 2.4 ml, 5 mcg/dose (250 mcg/ml) 1.2 ml*
- *liraglutide*
- MOUNJARO
- OZEMPIC SUBCUTANEOUS PEN INJECTOR 0.25 MG OR 0.5 MG (2 MG/3 ML), 1 MG/DOSE (4 MG/3 ML), 2 MG/DOSE (8 MG/3 ML)
- RYBELSUS
- TRULICITY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

GOCOVRI

Products Affected

- GOCOVRI ORAL
CAPSULE,EXTENDED RELEASE
24HR 137 MG, 68.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Previous medications tried, concurrent medications
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial and continuation).
Coverage Duration	Pending CMS Review
Other Criteria	Initial therapy Parkinson's disease - approve if the following criteria are met: 1) patient is currently receiving levodopa-based therapy (e.g., carbidopa/levodopa) AND, 2) patient has tried immediate-release amantadine (capsules, tablets, or oral solution) and derived benefit from the immediate-release formulation but had intolerable adverse events or the patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber AND 3) patients is experiencing dyskinesia or off episodes. Cont. therapy - approve if 1) the patient is currently receiving levodopa-based therapy (e.g., carbidopa/levodopa) AND 2) patient has tried immediate-release amantadine (capsules, tablets, or oral solution) and derived benefit from the immediate-release formulation but had intolerable adverse events or the patient could not achieve a high enough dosage to gain adequate benefit, as determined by the prescriber, and 3) has had a response to therapy (e.g., decrease in dyskinesia, decrease in off episodes), as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GOMEKLI

Products Affected

- GOMEKLI ORAL CAPSULE 1 MG, 2 MG
- GOMEKLI ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NEUROFIBROMATOSIS TYPE 1- patient has or had symptomatic plexiform neurofibromas prior to starting Gomekli and the tumor is not amenable to complete resection.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

GONADOTROPIN-RELEASING HORMONE AGONISTS - CPP

Products Affected

- LUPRON DEPOT-PED (3 MONTH) INTRAMUSCULAR SYRINGE KIT 11.25 MG
- LUPRON DEPOT-PED INTRAMUSCULAR KIT 7.5 MG (PED)
- LUPRON DEPOT-PED INTRAMUSCULAR SYRINGE KIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Gender dysphoria- prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender persons
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	gender-dysphoric/gender-incongruent persons, persons undergoing gender reassignment (female-to-male or male-to-female)
Part B Prerequisite	No
Prerequisite Therapy Required	No

GONADOTROPIN-RELEASING HORMONE AGONISTS - ONCOLOGY

Products Affected

- ELIGARD
- ELIGARD (3 MONTH)
- ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)
- LEUPROLIDE ACETATE (3 MONTH)
- *leuprolide subcutaneous kit*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prostate cancer- prescribed by or in consultation with an oncologist or urologist. Head and neck-salivary gland tumors- prescribed by or in consultation with an oncologist.
Coverage Duration	1 year
Other Criteria	Prostate cancer - for patients new to therapy requesting a non-preferred product (i.e., Leuprolide Depot), approve if the pt has tried Eligard first. Head and neck cancer-salivary gland tumor- approve if pt has recurrent, unresectable, or metastatic disease AND androgen receptor-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Head and neck cancer- salivary gland tumors (Eligard only)
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GRALISE/HORIZANT/LYRICA CR

Products Affected

- *gabapentin oral tablet extended release 24 hr 300 mg, 600 mg*
- *pregabalin oral tablet extended release 24 hr 165 mg, 330 mg, 82.5 mg*
- HORIZANT ORAL TABLET
EXTENDED RELEASE 300 MG, 600
MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

GRANIX

Products Affected

- GRANIX SUBCUTANEOUS SOLUTION 300 MCG/ML
- GRANIX SUBCUTANEOUS SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer patient receiving chemo-Prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist or physician that specializes in transplantation. Myelodysplastic syndromes-prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	PBPC-1 month, MDS-3 months, All others-6 months
Other Criteria	Cancer patients receiving Myelosuppressive Chemotherapy-Must meet ONE of the following: 1) be receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), 2) receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (e.g., age greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status, HIV infection patients with low CD4 counts) 3) have had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment, OR 4) has received chemotherapy has febrile neutropenia and has at least one risk factor for poor clinical outcomes or for developing infection-associated complications according to the

PA Criteria	Criteria Details
	prescribing physician (e.g., sepsis syndrome, older than 65 years, severe neutropenia - ANC less than 100 cells/mm ³ , neutropenia expected to be more than 10 days in duration, pneumonia or other clinically documented infection, invasive fungal infection, hospitalization at the time of fever, or prior episode of febrile neutropenia). Patients are required to try Releuko and Nivestym and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Granix unless patient has initiated therapy with Granix and requires additional medication to complete the current cycle of chemotherapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing peripheral blood progenitor cell (PBPC) Collection and Therapy. Myelodysplastic syndromes.
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GROWTH HORMONES

Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK
- HUMATROPE INJECTION CARTRIDGE
- NORDITROPIN FLEXPRO
- NUTROPIN AQ NUSPIN
- OMNITROPE
- SEROSTIM SUBCUTANEOUS RECON SOLN 4 MG, 5 MG, 6 MG
- ZOMACTON

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	<p>HIV 1.wasting/cachexia due to malabsorption, opportunistic infx, depression and other causes which have been addressed prior to starting tx, 2.on antiretroviral or HAART for more than 30 days and will cont throughout Serostim tx, 3.not being used for alternations in body fat distribution (abdom girth, liopdystrophy, dorsocervical fat pad, excess abdm fat), AND 4. unintentional wt loss greater than 10 percent from baseline, wt less than 90 percent of lower limit of IBW, or BMI less than or equal to 20 kg/m2. GHD in Children/Adolescents. Pt meets one of the following-1-had 2 GH stim tests with the following-levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon and both are less than 10ng/mL OR had at least 1 GH test less than 10ng/mL and has at least one risk factor for GHD (e.g., ht for age curve deviated down across 2 major height percentiles [e.g., from above the 25 percentile to below the 10 percentile], growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels). 2.brain radiation or tumor resection and pt has 1 GH stim test less than 10ng/mL or has def in at least 1 other pituitary hormone (that is, ACTH, TSH, gonadotropin deficiency [LH and/or FSH] are counted as 1 def], or prolactin).3. congenital hypopituitarism and has one GH stim test less than 10ng/mL OR def in at least one other pituitary hormone and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk 4.pt has multiple pituitary deficiencies and pt has 3 or more pituitary hormone deficiencies or pt has had one GH test less than 10ng/mL 5.pt had a hypophysectomy. Cont-pt responding to therapy</p>
Age Restrictions	ISS 5 y/o or older, SGA 2 y/o or older, HIV wasting/cachexia 18 y/o or older
Prescriber Restrictions	GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, ISS (initial), Noonan (initial), Prader Willi

PA Criteria	Criteria Details
	(initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist.
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Short bowel syndrome (all products except Serostim)
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GROWTH HORMONES - LONG-ACTING

Products Affected

- NGENLA
- SOGROYA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist (all dx except hypophysectomy)
Coverage Duration	1 year
Other Criteria	<p>GHD child/adol,init-1 of(i,ii,iii,iv,or,v):i.Either(1or2):1-2 stim tests w/levodopa,insulin-induced hypoglyc, arginine, clonidine, or glucagon w/BOTH resp below 10ng/mL OR 2-BOTH (a and b):a-1 stim test below 10ng/mL AND b-at least 1 GHD risk factor ii.Brain radiation/tumor resection AND (1or2):1-1 stim test below 10ng/mL OR 2-1 other pit horm defc (ACTH,TSH,gonadotrop[LH, FSH are 1],prolactin), OR iii.congenital hypopit AND 1 of (1,2or3):1-1 stim test resp below 10ng/mL OR 2-1 other pit horm def OR 3-Imaging triad ectopic posterior pit and pit hypoplasia w/ abn pit stalk. iv.Mult pit horm defc and 1 of (1or2):1-3+ pit horm def: somatrop,ACTH,TSH,gonadotrop,prolact, OR 2-1 stim test below 10ng/mL lab norm. v.Hypophysectomy. GHD child/adol, cont-pt respond to tx. GHD Adult/TransitionAdol (Sogroya only)-ALL of (A,B,C,andD):A)endo certify not for anti-aging/athletic ability/body building,AND B)GHD that is 1 of:Child onset OR Adult onset from 1 of:GHD alone or mult horm def (hypopit) from pit dz, hypothalam dz, pit surgery, cranial radiation tx, tumor tx, TBI, or subarach hem, AND C)1 of (i,ii,or iii): i.Known perinatal insults OR congenital/genetic defects, OR ii.ALL of: 3+ pit horm def: ACTH, TSH, gonadotropin defc, prolactin, AND IGF-1 below lab norm, AND Other causes of low IGF-1 excluded, OR iii. 1 of (a or b):a-Adult-Neg resp to stim test (1,2,3,4,5,or6):Note: arginine test peak less/eq to 0.4mcg/L, meets neg resp stim test. 1-Insulin tol test (3 GH levels in atleast 60min [not incl time zero], w/adeq</p>

PA Criteria	Criteria Details
	<p>hypoglycemia) peak less/equal to 5mcg/L, OR 2-Glucagon stim test (GST) (3 GH levels in atleast 180min[not incl time 0]) peak less/eq to 3mcg/L AND BMI less than 25, OR 3-GST peak less/eq to 3mcg/L AND BMI gr/eq to 25 and less/eq to 30 w/ hi pretest prob of GHD, OR 4-GST peak less/eq to 1mcg/L AND BMI gr/eq to and less/eq to 30 w/low pretest prob of GHD, OR 5-GST peak less/eq to 1mcg/L AND BMI gr than 30, OR 6-Macrilan test (4 GH levels in atleast 90min[not incl time 0]) peak less than 2.8ng/mL AND BMI gr/eq to 40. OR b-Transition adol-BOTH of (1and2): Note: Macrilan peak less than 2.8ng/mL meets neg resp to stim. 1-Pt off GH tx for at least month before retest AND 2-1 of:(i,ii,iii,iv,v,or,vi): i-Insulin tol test peak less/eq to 5mcg/L, OR ii.GST peak less/eq to 3mcg/L AND BMI less than 25, OR iii. GST peak less/eq to 3mcg/L AND BMI gr/eq to 25 and less/eq to 30 w/hi pretest prob of GHD, OR iv-GST peak less/eq to 1mcg/L AND BMI gr/eq to 25 and less/eq to 30 w/ low pretest prob of GHD, OR v-GST peak less/eq to 1mcg/L AND BMI greater than 30, OR vi-If both insulin tol test AND GST contraind, arginine test can be used (3 GH levels in atleast 120min[not incl time 0]) peak less/eq to 0.4mcg/L. In addition for all dx (initial and cont)-try Omnitrope with inadequate efficacy or signif intol (Note: If not tried Omnitrope, trial of Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ, Saizen, or Zomacton w/ inadeq efficacy, signif intol can count).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

HARVONI

Products Affected

- HARVONI ORAL PELLETS IN PACKET 33.75-150 MG, 45-200 MG
- HARVONI ORAL TABLET 45-200 MG, 90-400 MG

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	Diagnosis
Age Restrictions	3 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
Coverage Duration	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. And, patients with genotype 1, 4, 5, or 6 must try TWO of the following: ledipasvir/sofosbuvir, Mavyret, Vosevi, unless ledipasvir/sofosbuvir, Mavyret and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

HERNEXEOS

Products Affected

- HERNEXEOS

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

HETLIOZ

Products Affected

- HETLIOZ LQ
- *tasimelteon*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Non-24-patient is totally blind with no perception of light
Age Restrictions	Non-24-18 years or older (initial and continuation), SMS-3 years and older
Prescriber Restrictions	prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders (initial and continuation)
Coverage Duration	6 mos initial, 12 mos cont
Other Criteria	Initial - patient is totally blind with no perception of light, dx of Non-24 is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy plus evaluation of sleep logs. Cont - Approve if patient is totally blind with no perception of light and pt has achieved adequate results with tasimelteon therapy according to the prescribing physician (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep). Nighttime sleep disturbances in Smith-Magenis SYndrome (SMS)-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

HIGH RISK MEDICATIONS - ANTIPARKINSON AGENTS

Products Affected

- *benztropine oral*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For all covered indications, approve if the prescriber confirms he/she has assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

HIGH RISK MEDICATIONS - BENZODIAZEPINES

Products Affected

- *clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg*
- *diazepam intensol*
- *diazepam oral solution 5 mg/5 ml (1 mg/ml)*
- *diazepam oral tablet*
- *lorazepam intensol*
- *lorazepam oral tablet 0.5 mg, 1 mg, 2 mg*
- LOREEV XR ORAL CAPSULE,EXTENDED RELEASE 24HR 1 MG, 1.5 MG, 2 MG, 3 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Procedure-related sedation = 1mo. All other conditions = 6 months.
Other Criteria	All medically accepted indications other than insomnia, approve if the physician has assessed risk versus benefit in using the High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy. Insomnia, may approve lorazepam or Loreev XR if the patient has had a trial with two of the following: ramelteon, doxepin 3mg or 6 mg, eszopiclone, zolpidem, or zaleplon and the physician has assessed risk versus benefit in using the HRM in this patient and has confirmed that he/she would still like initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

Products Affected

- *carbinoxamine maleate oral liquid*
- *carbinoxamine maleate oral tablet*
- *clemastine*
- *cyproheptadine*
- *hydroxyzine hcl oral solution 10 mg/5 ml*
- *hydroxyzine hcl oral tablet*
- *hydroxyzine pamoate*
- *promethazine oral*
- *promethazine rectal suppository 12.5 mg, 25 mg*
- *promethegan rectal suppository 25 mg, 50 mg*
- RYVENT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For promethazine, for the treatment of emesis, approve if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant). For hydroxyzine hydrochloride or hydroxyzine pamoate, for the treatment of anxiety, approve if the patient has tried at least two other FDA-approved products. Additionally for all covered indications, the prescriber must confirm that he/she has assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

HIGH RISK MEDICATIONS - PHENOBARBITAL

Products Affected

- *phenobarbital*

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for use in sedation/insomnia.
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	For the treatment of seizures, approve only if the patient is currently taking phenobarbital. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

HIGH RISK MEDICATIONS - SKELETAL MUSCLE RELAXANTS

Products Affected

- *carisoprodol*
- *chlorzoxazone*
- *cyclobenzaprine*
- *metaxalone oral tablet 400 mg, 800 mg*
- *methocarbamol oral*
- *orphenadrine citrate oral*
- *orphenadrine-asa-caffeine oral tablet 25-385-30 mg*
- *tanlor*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 6 months.
Other Criteria	For all covered indications, approve if the prescriber confirms he/she has assessed risk versus benefit in using this High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

HYFTOR

Products Affected

- HYFTOR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	6 years and older (Initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or a physician who specializes in the management of patients with tuberous sclerosis complex (initial and continuation)
Coverage Duration	Initial-3 months, continuation-1 year
Other Criteria	<p>Facial angiofibroma associated with tuberous sclerosis, initial- approve if the patient meets the following criteria (i. and ii.): i. Patient has a definitive diagnosis of tuberous sclerosis complex by meeting one of the following (a or b): a) There is identification of a pathogenic variant in the tuberous sclerosis complex 1 (TSC1) gene or tuberous sclerosis complex 2 (TSC2) gene by genetic testing, OR b) According to the prescriber, clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex by meeting either two major features or one major feature with two minor features (Note: Major feature criteria involve angiofibroma (three or more) or fibrous cephalic plaque, angiomyolipomas (two or more), cardiac rhabdomyoma, hypomelanotic macules (three or more, at least 5 mm in diameter), lymphangiomyomatosis, multiple cortical tubers and/or radial migration lines, multiple retinal hamartomas, Shagreen patch, subependymal giant cell astrocytoma, subependymal nodule (two or more), or ungula fibromas (two or more). Minor feature criteria involve confetti skin lesions, dental enamel pits (three or more), intraoral fibromas (two or more), multiple renal cysts, nonrenal hamartomas, retinal achromic patch, and sclerotic bone lesions), AND ii. Patient has three or more facial angiofibromas that are at least 2 mm in diameter with redness in each.</p> <p>Continuation-approve if the patient meets the following criteria (i. and ii.): i. Patient has a definitive diagnosis of tuberous sclerosis complex by</p>

PA Criteria	Criteria Details
	<p>meeting one of the following (a or b): a) There is identification of a pathogenic variant in the tuberous sclerosis complex 1 (TSC1) gene or tuberous sclerosis complex 2 (TSC2) gene by genetic testing, OR b) According to the prescriber, clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex by meeting either two major features or one major feature with two minor features (Note: Major feature criteria involve angiofibroma (three or more) or fibrous cephalic plaque, angiomyolipomas (two or more), cardiac rhabdomyoma, hypomelanotic macules (three or more, at least 5 mm in diameter), lymphangiomyomatosis, multiple cortical tubers and/or radial migration lines, multiple retinal hamartomas, Shagreen patch, subependymal giant cell astrocytoma, subependymal nodule (two or more), or ungula fibromas (two or more). Minor feature criteria involve confetti skin lesions, dental enamel pits (three or more), intraoral fibromas (two or more), multiple renal cysts, nonrenal hamartomas, retinal achromic patch, and sclerotic bone lesions), AND ii. Patient has responded to Hyftor as evidenced by a reduction in the size and/or redness of the facial angiofibromas.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

IBRANCE

Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Liposarcoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

IBTROZI

Products Affected

- IBTROZI

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

ICATIBANT

Products Affected

- *icatibant*
- *sajazir*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant-the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

ICLUSIG

Products Affected

- ICLUSIG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status
Age Restrictions	All indications except ALL - 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Acute lymphoblastic leukemia, Philadelphia chromosome positive or ABL-class translocation: approve if the patient meets (1, 2 or 3): 1) will use in combination with chemotherapy, or 2) ALL is T315I-positive, or 3) pt tried at least one other tyrosine kinase inhibitor (examples: imatinib or dasatinib). Chronic myeloid leukemia, Philadelphia chromosome positive or BCR::ABL1-positive-approve if patient meets (1, 2 or 3): 1) CML is T315I-positive, or 2) pt tried at least one other tyrosine kinase inhibitor (examples: imatinib, dasatinib, nilotinib), or 3) pt has accelerated-phase or blast-phase CML and no other tyrosine kinase inhibitor is indicated. GIST - approve if the patient tried all of the following therapies first to align with NCCN recommendations which include: Imatinib or Ayvakit (avapritinib tablets), AND Sunitinib or Sprycel (dasatinib tablets), AND Stivarga (regorafenib tablets), AND Qinlock (ripretinib tablets). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has ABL1 rearrangement or FGFR1 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

IDHIFA

Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	IDH2-mutation status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	AML - approve if the patient is IDH2-mutation status positive as detected by an approved test
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ILUMYA

Products Affected

- ILUMYA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist (initial therapy)
Coverage Duration	Approve through end of plan year
Other Criteria	Initial Therapy - Approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Skyrizi, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya. [A trial of a non-preferred adalimumab or a non-preferred ustekinumab also counts.] Continuation Therapy - Patient must have responded, as determined by the prescriber. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred ustekinumab products include Selarsdi, Yesintek.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IMATINIB

Products Affected

- *imatinib oral tablet 100 mg, 400 mg*
- IMKELDI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restrictions	ASM, DFSP, HES, MDS/MPD/Myeloid/Lymphoid Neoplasms/Kaposi Sarcoma/Cutaneous Melanoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For ALL-approve for Ph-positive or ABL-class translocation ALL. CML-approve for Ph-positive or BCR::ABL1-mutation positive CML. Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease. Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT)-patient has tried Turalio or Romvimza or according to the prescriber, the patient cannot take Turalio or Romvimza. Myelodysplastic/myeloproliferative disease-approve if the condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements.Graft versus host disease, chronic-approve if the patient has tried at least one conventional systemic treatment (e.g., imbruvica). Cutaneous melanoma-approve if the patient has an activating KIT mutation, metastatic or unresectable melanoma, and has tried at least one systemic regimen. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement or an FIP1L1-PDGFR A or PDGFRB rearrangement. Approve Imkeldi if the patient has had a trial of imatinib tablets (brand or generic) dispersed in a glass of water or apple juice (per product labeling).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chordoma, desmoid tumors (aggressive fibromatosis), metastatic or unresectable cutaneous melanoma with activating kit mutation, Kaposi's

PA Criteria	Criteria Details
	Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia, GVHD, chronic.
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IMBRUVICA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	GVHD-1 year and older, other-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	CLL- Approve. GVHD-Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], imatinib, low-dose methotrexate, sirolimus, mycophenolate mofetil, Jakafi [ruxolitinib tablets]).B-cell lymphoma-approve if the patient has tried at least one systemic regimen (e.g., cisplatin, cytarabine, rituximab, oxaliplatin, gemcitabine, ifosfamide, carboplatin, etoposide, or rituximab). Central nervous system Lymphoma (primary)- approve if the patient is not a candidate for or is intolerant to high-dose methotrexate OR has tried at least one therapy (e.g., methotrexate, rituximab, vincristine, procarbazine, cytarabine, thiotepa, carmustine, intrathecal methotrexate, cytarabine, or rituximab). Hairy Cell Leukemia - approve if the patient has tried at least two systemic regimens (cladribine, Nipent [pentostatin injection], rituximab, or Pegasys [peginterferon alfa-2a subcutaneous injection]).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

IMPAVIDO

Products Affected

- IMPAVIDO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious diseases specialist
Coverage Duration	1 month
Other Criteria	Ameba related infections: approve if the patient is being treated for an infection due to one of the following: Acanthameoba, Balamuthia mandrillaris, or Naegleria fowleri. Note: Examples of ameba related infections are Acanthamoeba keratitis, granulomatous amebic encephalitis (GAE), and primary amebic meningoencephalitis (PAM).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ameba related infections
Part B Prerequisite	No
Prerequisite Therapy Required	No

INBRIJA

Products Affected

- INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE

PA Criteria	Criteria Details
Exclusion Criteria	Asthma, COPD, other chronic underlying lung disease
Required Medical Information	Diagnosis, medications that will be used in combination
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Approve if the patient is currently taking carbidopa-levodopa and is experiencing off episodes.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

INGREZZA

Products Affected

- INGREZZA
- INGREZZA INITIATION PK(TARDIV)
- INGREZZA SPRINKLE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	TD - Prescribed by or in consultation with a neurologist or psychiatrist. Chorea HD - prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Chorea associated with Huntington's Disease- approve if diagnosis is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- AVEED
- DEPO-TESTOSTERONE
INTRAMUSCULAR OIL 100 MG/ML
- *testosterone cypionate*
- *testosterone enanthate*
- XYOSTED

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, lab results
Age Restrictions	Delayed puberty or induction of puberty in males-14 years and older, 12 years and older (testosterone cypionate)
Prescriber Restrictions	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.
Coverage Duration	Delayed puberty or induction of puberty in males-6 months, all others-12 months
Other Criteria	Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. Delayed puberty or induction of puberty in males - Approve testosterone enanthate or testosterone cypionate. Breast cancer in females-approve testosterone enanthate. Male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Female is defined as an individual with the biological traits of a woman,

PA Criteria	Criteria Details
	regardless of the individual's gender identity or gender expression. Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-approve.Note: For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).
Part B Prerequisite	No
Prerequisite Therapy Required	No

INLYTA

Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Advanced Renal cell carcinoma-approve. Differentiated thyroid cancer, approve if patient is refractory to radioactive iodine therapy. Soft tissue sarcoma-approve if the patient has alveolar soft part sarcoma and the medication will be used in combination with Keytruda (pembrolizumab).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma, Soft tissue sarcoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

INPEFA

Products Affected

- INPEFA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Heart Failure, to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit-approve. Type 2 Diabetes, to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit-approve if the patient has chronic kidney disease AND has one or more cardiovascular risk factor(s).Note: Patients with heart failure should be reviewed under criteria for Heart Failure.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

INQOVI

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myelodysplastic Syndrome With Myeloproliferative Neoplasm Overlap Syndrome
Part B Prerequisite	No
Prerequisite Therapy Required	No

INREBIC

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has higher-risk disease. Myeloid/Lymphoid Neoplasms with Eosinophilia-approve if the tumor has a JAK2 rearrangement. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid Neoplasms with Eosinophilia, accelerated or blast phase myeloproliferative neoplasm
Part B Prerequisite	No
Prerequisite Therapy Required	No

IQIRVO

Products Affected

- IQIRVO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial)
Coverage Duration	6 months initial, 1 year cont.
Other Criteria	<p>INITIAL THERAPY: PRIMARY BILIARY CHOLANGITIS-All of (i and ii): i. Diagnosis of primary biliary cholangitis as defined by TWO of the following (a, b, or c): a) Alkaline phosphatase is elevated above the upper limit of normal, OR b) Positive anti-mitochondrial antibodies or other primary biliary cholangitis-specific auto-antibodies, including sp100 or gp210, if anti-mitochondrial antibodies are negative, OR c) Histologic evidence of primary biliary cholangitis from a liver biopsy, AND ii.Has been receiving ursodiol therapy for greater than or equal to 1 year and had an inadequate response or is unable to tolerate, Note: Examples: ursodiol generic tablets and capsules, Urso 250, Urso Forte, Actigall.</p> <p>CONTINUATION THERAPY: has demonstrated a response to therapy. Note: Examples of a response to therapy are improved biochemical markers of primary biliary cholangitis (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT]).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Pending CMS Review

ISTURISA

Products Affected

- ISTURISA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
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	1 year
Other Criteria	Approve if (A, B, or C): A) the patient is not a candidate for surgery or surgery has not been curative, or B) patient is awaiting surgery for endogenous Cushing's syndrome, or C) patient is awaiting therapeutic response after radiotherapy for endogenous Cushing's syndrome.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ITOVEBI

Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>BREAST CANCER (all of A, B, C, D, E and F): A. Patient meets ONE of the following (i or ii): i. Patient is a postmenopausal female, OR ii. Patient meets BOTH of the following (a and b): a. Patient is a pre/perimenopausal female or a male, AND b. Patient is receiving a gonadotropin-releasing hormone (GnRH) agonist OR had surgical bilateral oophorectomy or ovarian irradiation (female) or orchiectomy (male), Note: Examples of a GnRH agonist include leuprolide acetate, leuprolide acetate intramuscular injection, triptorelin pamoate intramuscular injection, goserelin acetate subcutaneous injection. AND B. Patient has locally advanced or metastatic hormone receptor (HR)-positive disease, AND C. Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D. Patient has PIK3CA-mutated breast cancer as detected by an approved test, AND E. Patient meets (i or ii): i) has disease progression while on adjuvant endocrine therapy or ii) had disease recurrence within 12 months after completing adjuvant endocrine therapy, Note: Examples of endocrine therapy include tamoxifen, anastrozole, letrozole, exemestane, toremifene. AND F. The medication will be used in combination with palbociclib capsules/tablets and fulvestrant injection.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IVERMECTIN (ORAL)

Products Affected

- *ivermectin oral tablet 3 mg, 6 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	30 days
Other Criteria	Pediculosis-approve if the patient has infection caused by pediculus humanus capitis (head lice), pediculus humanus corporis (body lice), or has pediculosis pubis caused by phthirus pubis (pubic lice). Scabies-approve if the patient has classic scabies, treatment resistant scabies, is unable to tolerate topical treatment, has crusted scabies or is using ivermectin tablets for prevention and/or control of scabies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ascariasis, Enterobiasis (pinworm infection), Hookworm-related cutaneous larva migrans, Mansonella ozzardi infection, Mansonella streptocerca infection, Pediculosis, Scabies. Trichuriasis, Wucheria bancrofti infection
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IVIG

Products Affected

- BIVIGAM
- GAMMAGARD LIQUID
- GAMMAGARD S-D (IGA < 1 MCG/ML)
- GAMMAKED INJECTION SOLUTION
1 GRAM/10 ML (10 %)
- GAMMAPLEX
- GAMMAPLEX (WITH SORBITOL)
- GAMUNEX-C INJECTION SOLUTION
1 GRAM/10 ML (10 %)
- OCTAGAM
- PANZYGA
- PRIVIGEN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Part B versus D determination per CMS guidance to establish if drug used for PID in pt's home.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

IWILFIN

Products Affected

- IWILFIN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Neuroblastoma-Approve if the patient meets the following (A, B and C): A) Patient has high-risk disease, AND B) The medication is being used to reduce the risk of relapse, AND C) Patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy. Note: Examples of anti-GD2 immunotherapy includes Unituxin (dinutuximab intravenous infusion).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JAKAFI

Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	ALL-1 to 21 years of age, GVHD-12 and older, MF/PV/accelerated or blast phase MPN/CMML-2/essential thrombo/myeloid/lymphoid neoplasm/T-cell Lymphoma-18 and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For polycythemia vera patients must have tried hydroxyurea or peginterferon alfa-2a or Besremi (ropeginterferon alfa-2b-njft subcutaneous injection). ALL-approve if the mutation/pathway is Janus associated kinase (JAK)-related. GVHD, chronic-approve if the patient has tried one conventional systemic treatment for graft versus host disease (for example: prednisone, ibrutinib capsules/tablets). GVHD, acute-approve if the patient has tried one systemic corticosteroid. Atypical chronic myeloid leukemia-approve if the patient has a CSF3R mutation or a janus associated kinase 2 (JAK2) mutation. Chronic monomyelocytic leukemia-2 (CMML-2)-approve if the patient is also receiving a hypomethylating agent. Essential thrombocythemia-approve if the patient has tried hydroxyurea, peginterferon alfa-2a or anagrelide. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the tumor has a janus associated kinase 2 (JAK2) rearrangement. T-Cell Lymphoma - approve if pt has (A or B): A) peripheral T-cell lymphoma or B) meets (i and ii): i) pt has T-cell prolymphocytic leukemia, T-cell large granular lymphocytic leukemia, hepatosplenic T-cell lymphoma, or breast implant-associated anaplastic large cell lymphoma and ii) pt has tried at least one systemic regimen. Accelerated or blast phase myeloproliferative neoplasm-approve if pt has at least one disease-related symptom (examples: fatigue, fever, night sweats,

PA Criteria	Criteria Details
	weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms, T-Cell lymphoma, accelerated or blast phase myeloproliferative neoplasm
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JAYPIRCA

Products Affected

- JAYPIRCA ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Mantle cell lymphoma-approve if the patient has tried at least one systemic chemotherapy regimen or patient is not a candidate for a systemic regimen (i.e., an elderly patient who is frail), AND the patient has tried one Bruton tyrosine kinase inhibitor (BTK) for mantle cell lymphoma. Note: Examples of a systemic regimen contain one or more of the following products: rituximab, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, methotrexate, bendamustine, Velcade (bortezomib intravenous or subcutaneous injection), lenalidomide, gemcitabine, and Venclexta (venetoclax tablets). Note: Examples of BTK inhibitors indicated for mantle cell lymphoma include Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib capsules), and Imbruvica (ibrutinib capsules, tablets, and oral suspension). CLL/SLL-patient meets (A or B): A) patient has resistance or intolerance to Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules) or B) patient has relapsed or refractory disease and has tried a Bruton tyrosine kinase (BTK) inhibitor and Venclexta (venetoclax tablet)-based regimen. Examples of BTK inhibitor include: Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules). Richter's Transformation to DLBCL- pt has tried at least one chemotherapy regimen or is not a candidate for a chemotherapy regimen. Marginal Zone</p>

PA Criteria	Criteria Details
	Lymphoma - approve if pt has tried at least one Bruton tyrosine kinase inhibitor.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Richter's Transformation to Diffuse Large B-Cell Lymphoma, Marginal Zone Lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JUXTAPID

Products Affected

- JUXTAPID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	<p>HYPERLIPIDEMIA WITH HoFH (all of A, B, and C): A) meets (a or b): a) phenotypic confirmation of HoFH, or b) meets (i and ii): i) untreated LDL-C greater than 400 mg/dL or treated LDL-C greater than or equal to 300 mg/dL, and ii) clinical manifestations of HoFH before 10 years of age or at least one parent with untreated LDL-C or total cholesterol consistent with FH, AND B) meets (a or b): a) tried a PCSK9 inhibitor for at least 8 weeks and LDL-C remains 70 mg/dL or higher, or b) has two LDL-receptor negative alleles, AND C) meets (a or b): a) tried one high-intensity statin and ezetimibe and LDL-C remains 70 mg/dL or higher or b) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JYNARQUE

Products Affected

- *tolvaptan (polycystic kidney dis)*

PA Criteria	Criteria Details
Exclusion Criteria	Patient is currently receiving Samsca (tolvaptan tablets) . Patients with Stage 5 CKD
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 (initial and continuation)
Other Criteria	Approve if the patient has rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) (e.g., reduced or declining renal function, high or increasing total kidney volume [height adjusted]),according to the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

KALYDECO

Products Affected

- KALYDECO

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other CF Transmembrane Regulator Modulators
Required Medical Information	N/A
Age Restrictions	1 month of age and older
Prescriber Restrictions	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF - must meet A, B, and C: A) pt must have one mutation in the cystic fibrosis transmembrane conductance regulator gene that is considered to be pathogenic or likely pathogenic B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

KERENDIA

Products Affected

- KERENDIA

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with spironolactone or eplerenone
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

KESIMPTA

Products Affected

- KESIMPTA PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	18 years and older
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 1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

KEVEYIS

Products Affected

- *ormalvi*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of condition, prior medications tried and results, potassium levels
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial 2 months, cont 12 months.
Other Criteria	HypoPP and Related Variants initial must meet all - 1. HypoPP has been confirmed by one of the following - serum potassium concentration of less than 3.5 mEq/L during a paralytic attack, family history of the condition, or a genetically confirmed skeletal muscle calcium or sodium channel mutation, 2. had improvements in paralysis attack symptoms with potassium intake, and 3. tried oral acetazolamide therapy, and 4. according to the prescribing physician, acetazolamide therapy did not worsen the paralytic attack frequency or severity in the patient, and 5. the prescribing physician has excluded other reasons for acquired hypokalemia (e.g., renal, adrenal, thyroid dysfunction, renal tubular acidosis, diuretic and laxative abuse). HyperPP and Related Variants initial must meet all - 1. HyperPP has been confirmed by one of the following - an increase from baseline in serum potassium concentration of greater than or equal to 1.5 mEq/L during a paralytic attack, serum potassium concentration during a paralytic attack of greater than 5.0 mEq/L, a family history of the condition, or genetically confirmed skeletal muscle sodium channel mutation, 2. prescribing physician has excluded other reasons for acquired hyperkalemia (e.g., drug abuse, renal and adrenal dysfunction), 3. tried oral acetazolamide therapy, 4. according to the prescribing physician, acetazolamide therapy did not worsen the paralytic attack frequency or severity in the patient. Cont tx HypoPP and HyperPP - patient has

PA Criteria	Criteria Details
	responded to dichlorphenamide (e.g., decrease in the frequency or severity of paralytic attacks) as determined by the prescribing physician.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

KEVZARA

Products Affected

- KEVZARA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	RA/polymyalgia rheumatica-18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist (initial therapy).
Coverage Duration	Approve through end of plan year
Other Criteria	<p>RA initial - approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, a preferred tocilizumab product, Rinvoq or Xeljanz/XR (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: Cimzia, an infliximab product, golimumab SC/IV, Orencia or another non-preferred adalimumab or non-preferred tocilizumab product. OR , B) patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx - pt must have had a response as determined by the prescriber. PJIA initial - approve if the patient has tried TWO of the following drugs in the past: Enbrel, Rinvoq, Xeljanz, a preferred tocilizumab product, or a preferred adalimumab product. (Note: if the patient does not meet this requirement, a previous trial with Orencia, infliximab, a non-preferred adalimumab, or a non-preferred tocilizumab product also counts toward meeting the try two requirement.) Cont tx - pt must have had a response to therapy. Polymyalgia rheumatica, initial-approve if the patient has tried one systemic corticosteroid. Cont tx-pt must have had a response to therapy. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred tocilizumab products include Actemra, Tyenne.</p>
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

KINERET

Products Affected

- KINERET

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	RA/AOSD-18 years and older, SJIA-2 years and older
Prescriber Restrictions	Initial therapy only-RA, SJIA and Still's disease, prescribed by or in consultation with a rheumatologist. CAPS (Neonatal-Onset Multisystem Inflammatory Disease or Chronic Infantile Neurological Cutaneous and Articular [CINCA] syndrome), prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA-rheum, geneticist, dermatologist, or physician specializing in the treatment of autoinflammatory disorder.
Coverage Duration	Approve through end of plan year
Other Criteria	RA initial. Approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Rinvoq, Xeljanz/XR, or a preferred tocilizumab product. [Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: a non-preferred tocilizumab product, Orencia, Cimzia, infliximab, Kevzara, golimumab IV/SC or another non-preferred adalimumab product.] DIRA initial-approve if genetic testing has confirmed bi-allelic pathogenic variants in the IL1RN gene. Adult Onset Still's Disease, approve. SJIA-initial-approve. cont tx - approve if the patient had responded to therapy as determined by the prescriber. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred tocilizumab products include Actemra, Tyenne.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Adult onset Still's disease (SD). Systemic Juvenile Idiopathic Arthritis (SJIA)

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

KISQALI

Products Affected

- KISQALI ORAL TABLET 200 MG/DAY (200 MG X 1), 400 MG/DAY (200 MG X 2), 600 MG/DAY (200 MG X 3)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast cancer - approve for hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative early (stage II or III), recurrent, or metastatic breast cancer [for early breast cancer must be adjuvant treatment and high risk of recurrence] when the pt meets ONE of the following (1, 2, 3 or 4): 1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole 2. meets (a, b and c): a) pt is premenopausal or perimenopausal and b) is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND c) Kisqali will be used in combination with anastrozole, exemestane, or letrozole 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Kisqali with be used in combination with anastrozole, exemestane or letrozole. 4. Patient meets (a and b): a) is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and b) Kisqali will be used in combination with fulvestrant. Endometrial cancer - approve if pt meets all of (A, B and C): A) pt has recurrent or metastatic disease, and B) has

PA Criteria	Criteria Details
	estrogen receptor (ER)-positive tumors, and C) if request is for Kisqali, Kisqali will be used in combination with letrozole.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Endometrial cancer
Part B Prerequisite	No
Prerequisite Therapy Required	No

KORLYM

Products Affected

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Pending CMS Review
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 syndrome
Coverage Duration	1 year
Other Criteria	Endogenous Cushing's Syndrome-Approve if mifepristone is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance AND pt meets (i, ii or iii): i) patient is not a candidate for surgery or surgery has not been curative, or (ii) patient is awaiting surgery for endogenous Cushing's Syndrome or (iii) patient is awaiting therapeutic response after radiotherapy for endogenous Cushing's Syndrome.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

KOSELUGO

Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Neurofibromatosis Type 1-approve if prior to starting Koselugo, the patient has symptomatic, inoperable plexiform neurofibromas and if the patient is 2 to 18 years old OR if the patient is 19 years or older if the patient started on therapy with Koselugo prior to becoming 19. Circumscribed Glioma-approve if the patient has recurrent, refractory or progressive disease AND the tumor is BRAF fusion positive OR BRAF V600E activating mutation positive OR patient has neurofibromatosis type 1 mutated glioma AND this medication will be used as a single agent AND the patient is 3-21 years of age OR is greater 21 and has been previously started on therapy with Koselugo prior to becoming 21 years of age. Langerhans Cell Histiocytosis- approve if the patient meets the following criteria (A and B): A) Patient meets one of the following (i, ii, iii, iv, or v): i. Patient meets both of the following (a and b): a) Patient has multisystem Langerhans cell histiocytosis, AND b) Patient has symptomatic disease or impending organ dysfunction, OR ii. Patient has single system lung Langerhans cell histiocytosis, OR iii. Patient meets (a and b): a) Patient has single system bone disease, AND b) Patient has not responded to treatment with a bisphosphonate, OR iv. Patient has central nervous system disease, OR v. patient has relapsed or refractory disease, AND B) The medication is used as a single agent.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Circumscribed Glioma, Langerhans Cell Histiocytosis
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

KRAZATI

Products Affected

- KRAZATI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Non-Small Cell Lung Cancer (NSCLC)-approve if (A and B): A) the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an approved test AND B) patient meets either (i or ii): i) has been previously treated with at least one systemic regimen [Examples of systemic regimens include those containing one or more of the following products: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Alimta (pemetrexed intravenous infusion), Yervoy (ipilimumab intravenous infusion), Abraxane (albumin-bound paclitaxel intravenous infusion), bevacizumab, cisplatin, carboplatin, docetaxel, gemcitabine, paclitaxel, vinorelbine.] or ii) patient has brain metastases. Colon or Rectal Cancer- approve if pt has unresectable, advanced, or metastatic disease AND pt has KRAS G12C mutation-positive disease AND medication is prescribed as part of a combination regimen or the patient is unable to tolerate combination therapy AND pt has has previously received a chemotherapy regimen for colon or rectal cancer. Ampullary adenocarcinoma-approve if (A, B and C): A) metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy. Biliary tract cancer- approve if (A, B and C): A) unresectable or metastatic disease, B) KRAS G12C mutation-positive disease, and C) previously treated with at least one systemic regimen. Pancreatic adenocarcinoma- approve if (A and B): A) KRAS G12C mutation-positive</p>

PA Criteria	Criteria Details
	disease, and B) either (i or ii): (i) locally advanced or metastatic disease and previously treated with at least one systemic regimen, or (ii) recurrent disease after resection. Small bowel adenocarcinoma- approve if (A, B and C): A) advanced or metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ampullary adenocarcinoma, biliary tract cancer, pancreatic adenocarcinoma, small bowel adenocarcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LAPATINIB

Products Affected

- *lapatinib*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which lapatinib is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bone cancer-chordoma, colon or rectal cancer, breast cancer in pre/perimenopausal women and men
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LAZCLUZE

Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NON-SMALL CELL LUNG CANCER-ALL of the following (A, B, C, and D): A. Locally advanced or metastatic disease, AND B. Epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test, AND C. Used in combination with Rybrevant, AND D. Used as first-line treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

LEDIPASVIR/SOFOSBUVIR

Products Affected

- LEDIPASVIR-SOFOSBUVIR

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	Diagnosis
Age Restrictions	3 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No
Prerequisite Therapy Required	No

LENALIDOMIDE

Products Affected

- *lenalidomide*
- REVLIMID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (except Kaposi Sarcoma, Castleman Disease, Primary CNS Lymphoma)
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Follicular lymphoma-approve if (A, B or C): A) the patient is using lenalidomide in combination with rituximab or B) using in combination with Gazyva (obinutuzumab intravenous infusion), or C) pt has tried at least one prior therapy. MCL-approve -if the patient is using lenalidomide in combination with rituximab or has tried at least one other regimen. MZL-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one other regimen. Multiple myeloma-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]), OR 4) meets (i, ii and iii): i) pt has myelodysplastic syndrome/myeloproliferative neoplasm overlap neoplasm, and ii) has SF3B1 mutation, and iii) pt has thrombocytosis . B-cell-lymphoma (other) [examples: diffuse large B-cell lymphoma, high grade B-cell lymphoma, post-transplant lymphoproliferative disorders, HIV-related B-cell lymphoma]-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia with presence of del(5q) and will use this in combination with prednisone. Primary CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease, or is not a candidate for high-dose MTX,</p>

PA Criteria	Criteria Details
	<p>or had intolerance to high-dose MTX. Hodgkin lymphoma, classic-approve if (A and B): A) pt has relapsed or refractory disease, and B) pt is not a candidate for high-dose therapy and autologous stem cell rescue.</p> <p>Castleman disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. Systemic light chain amyloidosis-approve if lenalidomide is used in combination with dexamethasone. Histiocytic neoplasms-approve if (A or B): A) the patient has Langerhans cell histiocytosis with either (i or ii): i) single-system multifocal skin disease or ii) relapsed or refractory disease, or B) pt has Rosai-Dorfman disease. T-Cell lymphoma- approve if (A, B or C): A) pt has peripheral T-cell lymphoma, or B) pt has T-cell leukemia/lymphoma and has tried at least one other regimen, or C) pt has hepatosplenic T-cell lymphoma and has tried at least two other regimens. Chronic lymphocytic leukemia/Small lymphocytic leukemia- approve if (A, B and C): A) relapsed or refractory disease, and B) tried at least one Bruton-tyrosine kinase inhibitor, and C) tried at least one B-cell lymphoma (BCL)2 inhibitor. POEMS Syndrome- approve if used in combination with dexamethasone.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Systemic Amyloidosis Light Chain, B-Cell Lymphoma (other), Myelofibrosis, Castleman Disease, Hodgkin lymphoma (Classic), T-Cell Lymphoma, Primary Central nervous system Lymphoma, Kaposi sarcoma, histiocytic neoplasms, Chronic Lymphocytic Leukemia, Small Lymphocytic Leukemia, POEMS syndrome.
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LENVIMA

Products Affected

- LENVIMA ORAL CAPSULE 10 MG/DAY (10 MG X 1), 12 MG/DAY (4 MG X 3), 14 MG/DAY(10 MG X 1-4 MG X 1), 18 MG/DAY (10 MG X 1-4 MG X2), 20 MG/DAY (10 MG X 2), 24 MG/DAY(10 MG X 2-4 MG X 1), 4 MG, 8 MG/DAY (4 MG X 2)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>DTC - must be refractory to radioactive iodine treatment for approval. RCC - approve if the pt meets ALL of the following criteria: 1) pt has advanced disease AND if the patient meets i or ii-i. Lenvima is is being used in combination with Keytruda OR ii. Lenvima is used in combination with Afinitor/Afinitor Disperz and the patient meets a or b-a. Patient has clear cell histology and patient has tried one antiangiogenic therapy or b. patient has non-clear cell histology. MTC-approve if the patient has tried at least one systemic therapy. Endometrial Carcinoma-Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has advanced endometrial carcinoma that is mismatch repair proficient (pMMR) or not microsatellite instability-high (MSI-H) AND B) The medication is used in combination with Keytruda (pembrolizumab for intravenous injection) AND C)the disease has progressed on at least one prior systemic therapy AND D) The patient is not a candidate for curative surgery or radiation. HCC-approve if the patient has unresectable or metastatic disease. Thymic carcinoma-approve if the patient has tried at least one chemotherapy regimen. Melanoma - approve if the patient has unresectable or metastatic melanoma AND the medication will be used in combination with Keytruda (pembrolizumab intravenous injection) AND the patient has disease progression on anti-programmed death receptor-1 (PD-1)/programmed</p>

PA Criteria	Criteria Details
	death-ligand 1 (PD-L1)-based therapy. Anaplastic thyroid carcinoma-approve if the medication is used in combination with Keytruda (pembrolizumab intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Melanoma, Anaplastic thyroid carcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LEQSELVI

Products Affected

- LEQSELVI

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

LEUKINE

Products Affected

- LEUKINE INJECTION RECON SOLN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	AML if prescribed by or in consultation with an oncologist or hematologist, PBPC/BMT - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation, Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome. Neuroblastoma-prescribed by or in consultation with an oncologist.
Coverage Duration	Radiation Syndrome/BMT - 1 mo, AML/Neuroblastoma-6 months, PBPC-14 days
Other Criteria	Neuroblastoma-approve if the patient is receiving Leukine in a regimen that recommends administration in combination with a granulocyte-macrophage colony stimulating factor (examples: dinutuximab or naxitamab).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Neuroblastoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIDOCAINE PATCH

Products Affected

- *lidocaine topical adhesive patch, medicated 5 %*
- *lidocan iii*
- *tridacaine ii*
- ZTLIDO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Diabetic neuropathic pain, chronic back pain
Part B Prerequisite	No
Prerequisite Therapy Required	No

LITFULO

Products Affected

- LITFULO

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with an oral or topical Janus Kinase Inhibitor (JAKi), a biologic immunomodulator or other potent immunosuppressants (e.g., cyclosporine, azathioprine)
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist (initial therapy)
Coverage Duration	Initial-6 months, Continuation-1 year
Other Criteria	Alopecia areata, initial therapy: approve if the patient has a current episode of alopecia areata lasting for greater than or equal to 6 months and the patient has greater than or equal to 50 percent scalp hair loss. Alopecia areata, continuation of therapy: approve if the patient has been established on Litfulo for at least 6 months (less than 6 months or a restart, review under initial therapy), and the patient experienced a beneficial clinical response defined as improvement from baseline (prior to initiating Litfulo) in extent and density of scalp hair loss, and the patient continues to require systemic therapy for treatment of alopecia areata.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIVMARLI

Products Affected

- LIVMARLI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Alagille Syndrome- 3 months and older (initial therapy), PFIC-12 months and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastroenterologist, or a physician who specializes in Alagille syndrome or PFIC, respectively (initial and continuation)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	Alagille Syndrome, initial-approve if the patient meets (i, ii, iii and iv): i. Patient has moderate-to-severe pruritus, according to prescriber AND ii. Diagnosis of Alagille syndrome was confirmed by genetic testing demonstrating a JAG1 or NOTCH2 deletion or mutation AND iii. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory AND iv. pt does not have cirrhosis, portal hypertension or history of a hepatic decompensation event. Alagille Syndrome, continuation-approve if the patient has had a response to therapy. PFIC, initial-approve if the patient meets (i, ii, iii and iv): i. Patient has moderate-to-severe pruritus, according to prescriber AND ii. Diagnosis of PFIC was confirmed by genetic testing demonstrating a gene mutation affiliated with PFIC (including ATP8B1 gene, ABCB11 gene, ABCB4 gene, TJP2 gene, NR1H4 gene, and MYO5B gene) AND iii. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory AND iv. pt does not have cirrhosis, portal hypertension or history of a hepatic decompensation event. PFIC, continuation- approve if the patient has had a response to therapy.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIVTENCITY

Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with ganciclovir or valganciclovir
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center. (initial therapy)
Coverage Duration	2 months
Other Criteria	Cytomegalovirus Infection, Treatment, initial therapy-approve if the patient meets the following criteria (A, B, and C): A) Patient weighs greater than or equal to 35 kg, AND B) Patient is post-transplant, AND Note: This includes patients who are post hematopoietic stem cell transplant or solid organ transplant. C) Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of the following: cidofovir, foscarnet, ganciclovir, or valganciclovir or patient has a significant intolerance to ganciclovir or valganciclovir. Cytomegalovirus Infection, Treatment, continuation of therapy - approve if patient has responded as demonstrated by cytomegalovirus polymerase chain DNA laboratory results within 4 weeks demonstrating improvement in cytomegalovirus levels.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

LODOCO

Products Affected

- LODOCO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Atherosclerotic Disease- approve if the patient meets ALL of the following criteria (A, B, C and D): (A) the pt has had one of the following: previous myocardial infarction or a history of an acute coronary syndrome, angina (stable or unstable), past history of stroke or transient ischemic attack, coronary artery disease, peripheral arterial disease, or the patient has undergone a coronary or other arterial revascularization procedure in the past, (B) Lodoco is being added onto other background regimens of other atherosclerotic disease medications [ex: aspirin, antiplatelet agents, anticoagulants, lipid-lowering agents, beta blockers, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers], (C) pt does not have severe hepatic impairment, (D) pt has a creatinine clearance greater than or equal to 15 mL/min.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LONG ACTING OPIOIDS

Products Affected

- BELBUCA
- *buprenorphine transdermal patch*
- CONZIP
- *hydrocodone bitartrate, oral only, er 12hr*
- *hydrocodone bitartrate, oral only,ext.rel.24 hr*
- *hydromorphone oral tablet extended release 24 hr*
- *methadone oral solution 10 mg/5 ml, 5 mg/5 ml*
- *methadone oral tablet 10 mg, 5 mg*
- *morphine oral capsule, er multiphase 24 hr*
- *morphine oral capsule,extend.release pellets*
- *morphine oral tablet extended release*
- NUCYNTA ER
- OXYCONTIN ORAL TABLET,ORAL ONLY,EXT.REL.12 HR 10 MG, 15 MG, 20 MG, 30 MG, 40 MG, 60 MG, 80 MG
- *oxymorphone oral tablet extended release 12 hr*
- TRAMADOL ORAL CAPSULE,ER BIPHASE 24 HR 17-83
- TRAMADOL ORAL CAPSULE,ER BIPHASE 24 HR 25-75 100 MG, 200 MG
- *tramadol oral tablet extended release 24 hr*
- XTAMPZA ER

PA Criteria	Criteria Details
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	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment (with no cancer or sickle cell diagnosis, not in long term care facility and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic

PA Criteria	Criteria Details
	<p>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 (ie, FDA labeled use) prior to reviewing for quantity exception. IN ADDITION to the above criteria, if the request is for Oxycontin, patient must meet (A or B): A) patient has tried TWO of: hydrocodone extended-release caps/tabs, hydromorphone extended-release tabs, morphine sulfate extended-release caps/tabs, oxycodone extended-release tabs, oxymorphone extended-release tabs or B) patient is intolerant or allergic to morphine or has renal insufficiency and has tried ONE of: hydrocodone extended-release caps/tabs, oxycodone extended-release tabs.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LONSURF

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Colon, rectal or appendiceal cancer- approve if patients meets (A, B, and C): A) advanced or metastatic disease, B) meets (i or ii): i) has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease or ii) is ineligible for or progressed on checkpoint inhibitor therapy and meets ONE of the following (a or b): a) has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease, or b) is polymerase epsilon/delta (POLE/POLD1) mutation positive, and C) has previously been treated with ALL of the following per labeling (i, ii and iii): i) fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, ii) an anti-vascular endothelial growth factor (VEGF) agent (ex: bevacizumab), and iii) if the tumor is wild-type RAS (KRAS wild-type and NRAS wild-type), patient has received anti-EGFR therapy (ex: Erbitux or Vectibix) or EGFR therapy is not medically appropriate. Gastric or Gastroesophageal Junction Adenocarcinoma, approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Appendiceal cancer
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

LORBRENA

Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Pediatric Diffuse High-Grade Glioma- less than 18 years old, All others- 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Erdheim Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has ALK-positive disease and (i or ii): i) advanced, recurrent, or metastatic disease or ii) tumor is inoperable. NSCLC - Approve if the patient has ALK-positive advanced or metastatic NSCLC, as detected by an approved test. NSCLC-ROS1 Rearrangement-Positive, advanced or metastatic NSCLC-approve if the patient has tried at least one of crizotinib, entrectinib or ceritinib. Large B-Cell Lymphoma- approve if ALK-positive disease and disease is relapsed or refractory. Pediatric Diffuse High-Grade Glioma- approve if ALK-positive disease and (i or ii): i) used as adjuvant therapy, or ii) used for recurrent or progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer (NSCLC)-ROS1 Rearrangement-Positive, Erdheim Chester Disease, Inflammatory Myofibroblastic Tumor (IMT), Large B-Cell Lymphoma, Pediatric Diffuse High-Grade Glioma
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

LUCEMYRA

Products Affected

- *lofexidine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 14 days
Other Criteria	Opioid withdrawal symptoms-patient is using requested medication to facilitate abrupt opioid discontinuation
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

LUMAKRAS

Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 240 MG, 320 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test AND has been previously treated with at least one systemic regimen. Ampullary adenocarcinoma - approve if pt has KRAS G12C-mutated disease as determined by an approved test AND this is used as subsequent therapy. Colon or rectal cancer - approve if pt meets all (A, B, C and D): A) advanced or metastatic disease, and B) KRAS G12C mutation-positive disease, and C) used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion) or patient is unable to tolerate combination therapy, and D) previously received a chemotherapy regimen for colon or rectal cancer. Pancreatic Adenocarcinoma- approve if patient has KRAS G12C-mutated disease, as determined by an approved test AND either (i or ii): (i) patient has locally advanced or metastatic disease and has been previously treated with at least one systemic regimen OR (ii) patient has recurrent disease after resection. Small bowel adenocarcinoma- approve if pt meets all of (A, B and C): A) has advanced or metastatic disease, and B) has KRAS G12C mutation-positive disease, and C) medication will be used as subsequent therapy.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma, Small Bowel Adenocarcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LUMRYZ

Products Affected

- LUMRYZ
- LUMRYZ STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of sodium oxybate, Xywav, Wakix, Sunosi
Required Medical Information	Diagnosis
Age Restrictions	7 years and older
Prescriber Restrictions	Prescribed by a sleep specialist physician or a neurologist
Coverage Duration	1 year
Other Criteria	For Excessive daytime sleepiness (EDS) in patients with narcolepsy - narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT) and the patient has tried sodium oxybate. Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LUPKYNIS

Products Affected

- LUPKYNIS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with biologics or with cyclophosphamide
Required Medical Information	Diagnosis, lab results (as specified in the Other Criteria field)
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or rheumatologist (initial and continuation)
Coverage Duration	Initial therapy-6 months, continuation-1 year
Other Criteria	Lupus Nephritis, Initial therapy- Approve if the patient meets all of the following criteria (A, B, and C): A) the medication is being used concurrently with an immunosuppressive regimen B) Patient has an estimated glomerular filtration rate (eGFR) greater than 45 mL/min/m ² C) the diagnosis of lupus nephritis has been confirmed on biopsy. Note: For example, World Health Organization class III, IV, or V lupus nephritis. Lupus Nephritis, Continuation therapy- Approve if the medication is being used concurrently with an immunosuppressive regimen and the patient has responded to therapy with the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

LUPRON DEPOT

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Premenstrual disorders - 18 years and older
Prescriber Restrictions	Prostate cancer-prescribed by/consultation with oncologist or urologist. Other cancer diagnosis- prescribed by/consultation with an oncologist. Gender dysphoria/reassignment- prescribed by/consultation with endocrinologist or physician who specializes in treatment of transgender patients
Coverage Duration	uterine leiomyomata - 3 months, abnormal uterine bleeding - 6 months, all others - 12 months
Other Criteria	Endometriosis-approve if the pt has tried one of the following, unless contraindicated: a contraceptive, an oral progesterone or depo-medroxyprogesterone injection. An exception can be made if the pt has previously tried a gonadotropin-releasing hormone [GnRH] agonist (e.g. Lupron Depot) or antagonist (e.g. Orilissa). Head and neck cancer-salivary gland tumor- approve if pt has recurrent, unresectable, or metastatic disease AND androgen receptor-positive disease. Premenstrual disorders including PMS and PMDD- approve if pt has severe refractory premenstrual symptoms AND pt has tried an SSRI or combined oral contraceptive. Prostate cancer - for patients new to therapy requesting Lupron 7.5 mg, 22.5 mg, 30 mg or 45 mg, patients are required to try Eligard prior to approval.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	abnormal uterine bleeding, breast cancer, gender dysphoria/gender reassignment, head and neck cancer-salivary gland tumors, ovarian cancer including fallopian tube and primary peritoneal cancers, premenstrual disorders including premenstrual syndrome and premenstrual dysphoric

PA Criteria	Criteria Details
	disorder, prophylaxis or treatment of uterine bleeding or menstrual suppression in pts with hematologic malignancy or undergoing cancer treatment or prior to bone marrow or stem cell transplant, uterine cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LYNPARZA

Products Affected

- LYNPARZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND The patient is in complete or partial response to at least one platinum-based chemotherapy regimen (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combination therapy-approve if the medication is used in combination with bevacizumab, the patient has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and the patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast cancer, adjuvant-approve if the patient has germline BRCA mutation-positive, HER2-negative breast cancer and the patient has tried neoadjuvant or adjuvant therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has recurrent or metastatic disease and has (i or ii): i) germline BRCA mutation-positive breast cancer or ii) germline PALB2 mutation-positive breast cancer. Pancreatic Cancer-maintenance therapy-approve if the 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 the patient has metastatic disease, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog</p>

PA Criteria	Criteria Details
	<p>or the pateint has had a bilateral orchiectomy, and the patient meets either (i or ii): i) the patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test and the patient has been previously treated with at least one androgen receptor directed therapy or ii) the patient has a BRCA mutation and the medication is used in combination with abiraterone plus one of prednisone or prednisolone. Uterine Leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried at least one systemic regimen.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Uterine Leiomyosarcoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LYTGOBI

Products Affected

- LYTGOBI ORAL TABLET 12 MG/DAY (4 MG X 3), 16 MG/DAY (4 MG X 4), 20 MG/DAY (4 MG X 5)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease, tumor has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements as detected by an approved test and if the patient has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include gemcitabine + cisplatin, 5-fluorouracil + oxaliplatin or cisplatin, capecitabine + cisplatin or oxaliplatin, gemcitabine + Abraxane (albumin-bound paclitaxel) or capecitabine or oxaliplatin, and gemcitabine + cisplatin + Abraxane.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MAVENCLAD

Products Affected

- MAVENCLAD (10 TABLET PACK)
- MAVENCLAD (4 TABLET PACK)
- MAVENCLAD (5 TABLET PACK)
- MAVENCLAD (6 TABLET PACK)
- MAVENCLAD (7 TABLET PACK)
- MAVENCLAD (8 TABLET PACK)
- MAVENCLAD (9 TABLET PACK)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis
Required Medical Information	Diagnosis, other medications that will be used in combination
Age Restrictions	N/A
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	Initial treatment-approve if the patient has tried one S1P drug (generic fingolimod or Zeposia) AND one fumarate product (generic dimethyl fumarate or Vumerity) prior to approval of Mavenclad. Regarding fumarate products-Prior use of brand Tecfidera or Bafiertam also counts as a fumarate product. Regarding S1P products-Prior use of brand Gilenya or a Non-preferred S1P (e.g., Ponvory, Mayzent) also counts as a trial of a S1P. Patients with underlying cardiovascular disease or risk (for example, patients with heart failure, myocardial infarction, stroke, transient ischemic attack, unstable angina, cardiac arrhythmias, atrioventricular block, bradyarrhythmias) are not required to try an S1P product. If the patient has experienced inadequate efficacy or significant intolerance to one of Kesimpta (ofatumumab subcutaneous injection), a natalizumab intravenous (IV) product (Tysabri, biosimilar), Briumvi (ublituximab-xiij IV infusion), Lemtrada (alemtuzumab IV infusion), or Ocrevus (ocrelizumab IV infusion) a trial of a S1P and fumarate product is not required. Cont tx-approve if the patient has received Mavenclad in the past.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MAVYRET

Products Affected

- MAVYRET ORAL PELLETS IN PACKET
- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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 consistent with current AASLD/IDSA guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No
Prerequisite Therapy Required	No

MAYZENT

Products Affected

- MAYZENT ORAL TABLET 0.25 MG, 1 MG, 2 MG
- MAYZENT STARTER(FOR 1MG MAINT)
- MAYZENT STARTER(FOR 2MG MAINT)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis
Required Medical Information	Diagnosis
Age Restrictions	N/A
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	Initial treatment-Active secondary progressive MS - approve. If the patient does not have active secondary progressive MS, approve if the patient has tried one S1P drug (generic fingolimod or Zeposia) AND one fumarate product (generic dimethyl fumarate or Vumerity). Regarding fumarate products, Prior use of brand Tecfidera or Bafiertam with inadequate efficacy or significant intolerance (according to the prescriber) also counts. A patient who has previously tried a glatiramer product (Copaxone, Glatopa, generic) can bypass the fumarate requirement. Regarding S1P products-Prior use of brand Gilenya or a Non-Preferred S1P (i.e., Ponvory) also counts. Cont tx-approve if the patient has been established on Mayzent or if the patient has active secondary progressive MS.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

MEGESTROL

Products Affected

- *megestrol oral suspension 400 mg/10 ml (40 mg/ml), 625 mg/5 ml (125 mg/ml)*
- *megestrol oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for weight gain for cosmetic reasons.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEKINIST

Products Affected

- MEKINIST ORAL RECON SOLN
- MEKINIST ORAL TABLET 0.5 MG, 2 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 year and older (low grade glioma/solid tumors)
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Melanoma (not including uveal melanoma)-must be used in patients with BRAF V600 mutation, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. Uveal melanoma - approve if metastatic or unresectable disease. For NSCLC - approve if (A, B and C): A) recurrent, advanced or metastatic disease and B) pt has BRAF V600 Mutation and C) pt will use in combination with Tafenlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafenlar AND the patient has BRAF V600-positive disease. Ovarian/fallopian tube/primary peritoneal cancer-approve if the patient has recurrent disease and the medication is used for (a or b): a) low-grade serous carcinoma or b) the patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafenlar. Low grade glioma-patient has BRAF V600 mutation positive disease and the medication will be used in combination with Tafenlar. Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis or Erdheim Chester disease or Rosai-Dorfman disease. Solid Tumors [Note: Examples of solid tumors are: biliary tract cancer, brain metastases due to melanoma, high-grade gliomas, differentiated thyroid carcinoma, gastrointestinal stromal tumors, gastric cancer, esophageal and</p>

PA Criteria	Criteria Details
	<p>esophagogastric junction cancers, salivary gland tumors, pancreatic adenocarcinoma, neuroendocrine tumors, occult primary, and ampullary adenocarcinoma]-Approve if the patient meets the following (A and B): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafenlar (dabrafenib capsules). Hairy Cell Leukemia, approve if pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Tafenlar. Small bowel adenocarcinoma, approve if pt has BRAF V600E mutation-positive advanced or metastatic disease and this will be used with Tafenlar AND (i or ii): i) this will be used as initial therapy and pt has received previous FOLFOX/CAPEOX therapy in the adjuvant setting within the past 12 months or has a contraindication, or (ii) this will be used as second-line and subsequent therapy.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Histiocytic Neoplasm, Hairy Cell Leukemia
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MEKTOVI

Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status, concomitant medications
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi. Histiocytic neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following (i, ii, or iii): i. multisystem disease OR, ii. pulmonary disease or, iii. central nervous system lesions. NSCLC-approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Braftovi (encorafenib capsules).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Histiocytic Neoplasms
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEMANTINE

Products Affected

- *memantine oral capsule, sprinkle, er 24hr*
- *memantine oral solution*
- *memantine oral tablet*
- MEMANTINE ORAL TABLETS, DOSE PACK
- *memantine-donepezil*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Indication for which memantine is being prescribed.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with mild to moderate vascular dementia.
Part B Prerequisite	No
Prerequisite Therapy Required	No

MIGLUSTAT

Products Affected

- *miglustat*
- *yargesa*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other approved therapies for Gaucher Disease for example Cerezyme (imiglucerase intravenous infusion), Elelyso (taliglucerase alfa intravenous infusion), Vpriv (velaglucerase alfa intravenous infusion), and Cerdelga (eliglustat capsules).
Required Medical Information	Diagnosis
Age Restrictions	NPC - greater than or equal to 2 years of age
Prescriber Restrictions	Gaucher Disease- Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of Gaucher disease or related disorders. NPC-prescribed by or in consultation with a geneticist, endocrinologist, metabolic disorder subspecialist, or a physician who specializes in the treatment of NPC or related disorders.
Coverage Duration	1 year
Other Criteria	Gaucher Disease Type 1-approve if the diagnosis is established by one of the following (i or ii): i. Demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts, OR ii. Molecular genetic testing documenting biallelic pathogenic glucocerebrosidase (GBA) gene variants.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Niemann-Pick Disease Type C (NPC)
Part B Prerequisite	No
Prerequisite Therapy Required	No

MIRCERA

Products Affected

- MIRCERA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Hemoglobin level (initial level and after therapy if applicable), medication history for indication
Age Restrictions	Pending CMS Review
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Anemia in CKD for patients not on dialysis-initial therapy, Hb is less than 10.0 g/dL. For patients currently receiving Mircera, epoetin alfa injection or Aranesp (darbepoetin alfa injection), Hb is less than or equal to 12.0 g/dL AND, if pt is less than 18 years old, according to the prescriber the Hb level has been stabilized by treatment with an ESA. For all covered uses, the patient is required to try Procrit or Retacrit before Mircera.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MODAFINIL/ARMODAFINIL

Products Affected

- *armodafinil*
- *modafinil oral tablet 100 mg, 200 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	Excessive daytime sleepiness associated with narcolepsy-prescribed by or in consultation with a sleep specialist physician or neurologist
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Excessive daytime sleepiness (EDS) associated with myotonic dystrophy - modafinil only. Adjunctive/augmentation for treatment of depression in adults - modafinil only. Idiopathic hypersomnia - modafinil only.
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MODEYSO

Products Affected

- MODEYSO

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	Pending CMS Review
Off-Label Uses	Pending CMS Review
Part B Prerequisite	Pending CMS Review
Prerequisite Therapy Required	Pending CMS Review

MULPLETA

Products Affected

- MULPLETA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, platelet count, date of procedure
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	Approve if the patient has a current platelet count less than 50 x 10 ⁹ /L AND the patient is scheduled to undergo a procedure within 8 to 14 days after starting Mulpleta therapy. In addition, patients must have a trial of Doptelet prior to Mulpleta, unless the patient has already started a course of therapy with Mulpleta for the upcoming procedure.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MYALEPT

Products Affected

- MYALEPT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or a geneticist physician specialist. For congenital generalized lipodystrophy where genetic testing did not demonstrate the clinical diagnosis, must have a specialist with experience in treating patients with lipodystrophy.
Coverage Duration	Authorization will be for 1 year
Other Criteria	If the patient has congenital generalized lipodystrophy, patient must have had a genetic test demonstrating one gene mutation (i.e., AGPAT2, BSCL2, CAV1, or PTRF) confirming the diagnosis of congenital generalized lipodystrophy, OR the patient had a genetic test that did not demonstrate an AGPAT2, BSCL2, CAV1 or PTRF gene mutation and the clinical diagnosis of congenital generalized lipodystrophy has been made by a specialist with experience in treating patients with lipodystrophy. For both congenital or acquired generalized lipodystrophy, the patient must have experienced one or more manifestations of leptin deficiency.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

MYCAPSSA

Products Affected

- MYCAPSSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	1 year
Other Criteria	Acromegaly-approve if the patient has (or had) 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 if the patient has tried generic octreotide or generic lanreotide prior to approval of Mycapssa.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MYFEMBREE

Products Affected

- MYFEMBREE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results (as specified in the Other Criteria field)
Age Restrictions	18 years and 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	24 months of total therapy between Myfembree or Oriahnn
Other Criteria	Uterine Fibroids (Leiomyomas)-approve if the patient is premenopausal (before menopause) and is experiencing heavy menstrual bleeding associated with the uterine fibroids, the uterine fibroids have been confirmed by a pelvic ultrasound, including transvaginal ultrasonography or sonohysterography, hysteroscopy, or magnetic resonance imaging. Endometriosis-approve if the patient is premenopausal and patient has previously tried one of the following (i or ii): i. A contraceptive (e.g., combination oral contraceptives, levonorgestrel-releasing intrauterine systems, a depo-medroxyprogesterone injection), unless contraindicated OR ii. An oral progesterone (e.g., norethindrone tablets), unless contraindicated. Note: An exception to this requirement can be made if the patient has previously used a gonadotropin-releasing hormone agonist (e.g., Lupron Depot [leuprolide depot suspension]) or Orilissa (elagolix tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

NAYZILAM

Products Affected

- NAYZILAM

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other medications used at the same time
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiepileptic medication(s).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NEMLUVIO

Products Affected

- NEMLUVIO

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy
Required Medical Information	Diagnosis
Age Restrictions	AD: 12 years and older (initial therapy), PN: 18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
Coverage Duration	Initial-4 months, Continuation-1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NERLYNX

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Stage of cancer, HER2 status, previous or current medications tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Adjuvant tx-Approve for 1 year (total), advanced or metastatic disease-1 year
Other Criteria	Breast cancer, adjuvant therapy - approve if the patient meets all of the following criteria: patient will not be using this medication in combination with HER2 antagonists, patient has HER2-positive breast cancer AND patient has completed one year of adjuvant therapy with trastuzumab OR could not tolerate one year of therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has HER-2 positive breast cancer, Nerlynx will be used in combination with capecitabine and the patient has tried at least two prior anti-HER2 based regimens.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NEULASTA

Products Affected

- NEULASTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation. Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC/Radiation Syndrome-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) 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), 2) 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, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status or HIV infection patients with low CD4 count), or 3) patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. Patients are required to try Fulphila and Nyvepria and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a

PA Criteria	Criteria Details
	significant allergy or serious adverse reaction prior to approval of Neulasta unless patient has a diagnosis of radiation syndrome.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NEUPOGEN

Products Affected

- NEUPOGEN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer/AML, MDS, ALL-oncologist or a hematologist. Cancer patients receiving BMT and PBPC-prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. SCN- hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD)- hematologist, or MD specializing in HIV/AIDS. Radiation-prescribed by or in consult with physician who has expertise in treating acute radiation syndrome.
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 months.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT, Radiation-1 mo.
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)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), 2)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 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2mg/dL) or renal dysfunction (CrCl less than 50 mL/min), poor performance status, HIV infection patients with low CD4 counts), 3)patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy, has febrile neutropenia and has at least one risk

PA Criteria	Criteria Details
	<p>factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm³], neutropenia expected to be greater than 10 days in duration, pneumonia or other clinically documented infections, invasive fungal infection, hospitalization at the time of fever, prior episode of febrile neutropenia). For all diagnoses (except PBPC and radiation syndrome): Patients are required to try Releuko and Nivestym and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Neupogen unless patient has initiated therapy with Neupogen and requires additional medication to complete the current cycle of chemotherapy. For PBPC, patients are required to try Nivestym and cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Neupogen unless patient has initiated therapy with Neupogen and requires additional medication to complete the current cycle of chemotherapy.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Acute lymphocytic leukemia (ALL).
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NEXLETOL

Products Affected

- NEXLETOL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	<p>HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL, b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, AND B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and ezetimibe and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below). ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and ezetimibe and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD or HeFH) [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of</p>

PA Criteria	Criteria Details
	atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NEXLIZET

Products Affected

- NEXLIZET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	<p>HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL, b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, AND B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below).</p> <p>ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD or HeFH) [A or B]: A) tried one high-intensity statin for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of</p>

PA Criteria	Criteria Details
	atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NILOTINIB

Products Affected

- DANZITEN
- *nilotinib hcl oral capsule 150 mg, 200 mg, 50 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older, ALL - 15 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Acute lymphoblastic leukemia, philadelphia chromosome positive-approve. CML, philadelphia chromosome positive or BCR::ABL1-mutation positive chronic myeloid leukemia- approve. For GIST, approve if the patient has tried two of the following: imatinib, avapritinib, sunitinib, dasatinib, regorafenib or ripretinib. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement. Pigmented villonodular synovitis/tenosynovial giant cell tumor-approve if the patient has tried Turalio or Romvimza or cannot take Turalio or Romvimza, according to the prescriber. For melanoma, cutaneous - approve if the patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST), Pigmented villonodular synovitis/tenosynovial giant cell tumor, Myeloid/Lymphoid neoplasms with Eosinophilia, melanoma cutaneous.
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

NILUTAMIDE

Products Affected

- *nilutamide*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Prostate cancer-approve if nilutamide is used concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

NINLARO

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	MM - approve if (A, B, C or D): A) this medication will be used in combination with lenalidomide or cyclophosphamide and dexamethasone, OR B) pt had received at least ONE prior regimen for multiple myeloma OR C) this medication will be used following hematopoietic stem cell transplantation or D) the patient is not a candidate for bortezomib or Kyprolis (carfilzomib intravenous infusion) and is also not a transplant candidate. Systemic light chain amyloidosis-approve if the patient has tried at least one other regimen for this condition. Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma-approve if used in combination with a rituximab product and dexamethasone (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma, Multiple myeloma after previous treatment (either monotherapy or in combination other than lenalidomide/dexamethasone) or stem cell transplant
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

NITISINONE

Products Affected

- *nitisinone*
- NITYR
- ORFADIN ORAL SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of therapy with nitisinone products
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	1 year
Other Criteria	Hereditary Tyrosinemia, Type 1-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming biallelic pathogenic/likely pathogenic variants in the FAH gene OR elevated levels of succinylacetone in the serum or urine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

NIVESTYM

Products Affected

- NIVESTYM

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer/AML, MDS, ALL-oncologist or a hematologist. Cancer patients receiving BMT and PBPC-prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. Radiation-expertise in acute radiation. SCN-hematologist. HIV/AIDS neutropenia-infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT,Radiation-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)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), 2)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 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status, or HIV infection patients with low CD4 counts), 3)patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia

PA Criteria	Criteria Details
	[absolute neutrophil count less than 100 cells/mm ³], neutropenia expected to be greater than 10 days in duration, pneumonia or other clinically documented infections, invasive fungal infection, hospitalization at the time of fever, prior episode of febrile neutropenia).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Acute lymphocytic leukemia (ALL), Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome)
Part B Prerequisite	No
Prerequisite Therapy Required	No

NON-INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- JATENZO ORAL CAPSULE 158 MG, 198 MG, 237 MG
- testosterone transdermal gel in metered-dose pump 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
- TLANDO
- UNDECATREX
- VOGELXO TRANSDERMAL GEL IN METERED-DOSE PUMP

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]
Age Restrictions	N/A
Prescriber Restrictions	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-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	Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and

PA Criteria	Criteria Details
	<p>symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-approve. Note: For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).
Part B Prerequisite	No
Prerequisite Therapy Required	No

NOURIANZ

Products Affected

- NOURIANZ

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's disease, patients with off episodes-approve if the patient is experiencing off episodes and if the patient is currently taking carbidopa-levodopa.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NUBEQA

Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (See Note 1) or if the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration sensitive-approve if the medication will be used in combination with a GnRH analog (See Note 1) or if the patient had a bilateral orchiectomy. Note 1: examples of GnRH analogs are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUCALA

Products Affected

- NUCALA SUBCUTANEOUS AUTO-INJECTOR
- NUCALA SUBCUTANEOUS RECON SOLN
- NUCALA SUBCUTANEOUS SYRINGE 100 MG/ML, 40 MG/0.4 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy.
Required Medical Information	N/A
Age Restrictions	Asthma-6 years of age and older. EGPA/Polyps-18 years of age and older. HES-12 years and older.
Prescriber Restrictions	Asthma-Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. EGPA-prescribed by or in consultation with an allergist, immunologist, pulmonologist or rheumatologist. HES-prescribed by or in consultation with an allergist, immunologist, hematologist, pulmonologist or rheumatologist. Polyps-prescribed by or in consult with allergist, immunologist or Otolaryngologist.
Coverage Duration	Pending CMS Review
Other Criteria	Asthma initial - must have blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks (or prior to tx with Nucala or another monoclonal antibody therapy that may lower blood eosinophil levels) AND has received combo tx w/inhaled corticosteroid AND at least 1 additional asthma controller/maintenance med (Examples: LAMA, LABA, leukotriene receptor antagonist, monoclonal antibody) AND pt's asthma cont to be uncontrolled, or was uncontrolled prior to starting Nucala or another monoclonal antibody therapy for asthma as defined by 1 of following-pt experi 2 or more asthma exacer req tx w/systemic corticosteroids in prev yr, pt experienced 1 or more asthma exacer requiring hospitalization, urgent care visit or ED visit in the prev yr, pt has a FEV1 less than 80 percent predicted, Pt has FEV1/FVC less than 0.80, or Pt's asthma worsens upon taper of oral (systemic) corticosteroid therapy. Cont-pt responded to Nucala tx as determined by the prescribing physician AND Pt cont to receive tx with an inhaled corticosteroid. EGPA initial-approve if pt has active, non-severe disease, has/had a blood

PA Criteria	Criteria Details
	<p>eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks or prior to any monoclonal antibody that may lower blood eosinophil levels. Cont-pt responded to Nucala tx as determined by the prescribing physician.HES initial-pt has had hypereosinophilic synd for greater than or equal to 6 months AND has FIP1L1-PDGFRalpha-negative dis AND pt does NOT have identifiable non-hematologic secondary cause of hypereosinophilic synd AND prior to initiating tx with monoclonal antibody that may lower blood eosinophil levels, pt has/had a blood eosinophil level of greater than or equal to 1,000 cells per microliter. Cont-approve if the patient has responded to Nucala tx. Nasal polyps, initial-approve if pt meets ALL of the following criteria(A, B, C and D):A) pt has chronic rhinosinusitis w/nasal polyposis as evidenced by direct examination, endoscopy, or sinus CT scan AND B)pt experienced 2 or more of the following sympt for at least 6 months:nasal congest/obstruct/discharge, and/or reduction/loss of smell AND C)pt meets BOTH of the following (a and b): a)Pt has received tx with intranasal corticosteroid AND b)Pt will continue to receive tx with intranasal corticosteroid concomitantly with Nucala AND D)pt meets 1 of the following (a, b or c): a)Pt has received at least 1 course of tx with a systemic corticosteroid for 5 days or more within the previous 2 years, OR b)Pt has a contraindication to systemic corticosteroid tx, OR c)Pt had prior surgery for nasal polyps.Cont-approve if the pt has received at least 6 months of therapy, continues to receive tx with an intranasal corticosteroid and has responded to tx.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NUEDEXTA

Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUPLAZID

Products Affected

- NUPLAZID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

NURTEC

Products Affected

- NURTEC ODT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention if Nurtec ODT is being taking for the preventive treatment of episodic migraine.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Migraine, Acute treatment-approve if the patient has tried at least one triptan or has a contraindication to triptans. Preventive treatment of episodic migraine-approve if the patient has greater than or equal to 4 but less than 15 migraine headache days per month (prior to initiating a migraine preventive medication) and if the patient is currently taking Nurtec ODT, the patient has had a significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Nurtec ODT was initiated.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NYVEPRIA

Products Affected

- NYVEPRIA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) 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), 2) 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 according to the prescribing physician (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status or HIV infection patients with low CD4 counts), or 3) patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

OCALIVA

Products Affected

- OCALIVA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Prescriber specialty, lab values, prior medications used for diagnosis and length of trials
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial therapy)
Coverage Duration	6 months initial, 1 year continuation.
Other Criteria	Initial treatment of PBC-Patient must meet both 1 and 2-1. Patient has a diagnosis of PBC as defined by TWO of the following:a)Alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values b)Positive anti-mitochondrial antibodies (AMAs) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative c)Histologic evidence of primary biliary cholangitis (PBC) from a liver biopsy 2. Patient meets ONE of the following: a) Patient has been receiving ursodiol therapy for greater than or equal to 1 year and has had an inadequate response. b) Patient is unable to tolerate ursodiol therapy. Cont tx - approve if the patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT] levels)). Patients new to therapy and continuing therapy must not have cirrhosis or must have compensated cirrhosis without evidence of portal hypertension.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

OCTREOTIDE INJECTABLE

Products Affected

- *octreotide acetate injection solution*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Acromegaly-prescr/consult w/endocrinologist. NETs-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist, neurosurg/thymoma/thymic carcinoma-presc/consult with oncologist. Diarrhea assoc w chemo-presc/consult with oncologist/gastro.
Coverage Duration	Enterocutaneous fistula/diarrhea assoc w chemo - 3 months, all others - 1 year
Other Criteria	ACROMEGALY (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender. DIARRHEA ASSOC W CHEMO (A and B): A) grade 3 or 4 diarrhea [Examples: more than 6 bowel movements above baseline per day, colitis symptoms, interference with activities of daily living, hemodynamic instability, hospitalization, serious complications (eg, ischemic bowel, perforation, toxic mega-colon), or other colitis-related life-threatening conditions] and B) patient has tried at least one antimotility medication.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma, enterocutaneous fistulas, diarrhea associated with chemotherapy

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ODACTRA

Products Affected

- ODACTRA

PA Criteria	Criteria Details
Exclusion Criteria	The patient is NOT currently receiving SC or SL allergen immunotherapy
Required Medical Information	Diagnosis
Age Restrictions	Greater than or equal to 5 years of age
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	House Dust Mite (HDM)-Induced Allergic Rhinitis (AR)-approve if the diagnosis is confirmed by meeting ONE of the following conditions (i or ii): i. The patient has a positive skin test response to house dust mite allergen extracts OR ii. The patient has a positive in vitro test (i.e., a blood test for allergen-specific IgE antibodies) for house dust mite (HDM).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ODOMZO

Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	BCC - Must not have had disease progression while on Erivedge (vismodegib).
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Locally advanced BCC approve if the BCC has recurred following surgery/radiation therapy or if the patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician. Metastatic BCC - approve, if the disease is limited to nodal metastases. (Note-This includes primary or recurrent nodal metastases. A patient with distant metastasis does not meet this requirement.) Diffuse Basal Cell Carcinoma Formation, including basal cell nevus syndrome (Gorlin syndrome) or other genetic forms of multiple basal cell carcinoma - approve.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Metastatic BCC, diffuse basal cell carcinoma formation
Part B Prerequisite	No
Prerequisite Therapy Required	Pending CMS Review

OFEV

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	IPF-Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist.
Coverage Duration	1 year
Other Criteria	IDIOPATHIC PULMONARY FIBROSIS (IPF), INITIAL [A and B]: A) diagnosis confirmed by presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) or surgical lung biopsy and B) forced vital capacity (FVC) greater than or equal to 40 percent of the predicted value. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS, INITIAL (A and B): A) diagnosis confirmed by HRCT and B) FVC greater than or equal to 40 percent of the predicted value. CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE, INITIAL (all of A, B and C): A) FVC greater than or equal to 45 percent of the predicted value, B) fibrosing lung disease impacting more than 10 percent of lung volume on HRCT, and C) clinical signs of progression. ALL INDICATIONS, CONTINUATION: approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

OGSIVEO

Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Desmoid tumors (aggressive fibromatosis)-approve if the patient has progressing desmoid tumors, the desmoid tumors are not amenable to surgery or radiotherapy and if the patient requires systemic treatment. Note: Progressing desmoid tumors are defined as greater than or equal to 20 percent progression within 12 months
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

OHTUVAYRE

Products Affected

- OHTUVAYRE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) - trial of one preferred Long-Acting Muscarinic Antagonist (LAMA) product AND one preferred Long-Acting Beta-Agonist (LABA) product. (A trial of a non-preferred LAMA or LABA will also count. A combination LAMA/LABA product will count for both requirements. An inhaled corticosteroid [ICS]/LABA product will count towards trial of a LABA.) Preferred products: Bevespi Aerosphere (LAMA/LABA), Stiolto Respimat (LAMA/LABA), tiotropium bromide (LAMA), Spiriva Respimat (LAMA), Striverdi Respimat (LABA), fluticasone-salmeterol diskus (ICS/LABA), budesonide-formoterol (ICS/LABA), Breo Ellipta (ICS/LABA).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

OJEMDA

Products Affected

- OJEMDA ORAL SUSPENSION FOR RECONSTITUTION MG/WEEK (100 MG X 5), 600 MG/WEEK (100 MG X 6)
- OJEMDA ORAL TABLET 400 MG/WEEK (100 MG X 4), 500

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	6 months of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	PEDIATRIC LOW GRADE GLIOMA-patient has relapsed or refractory disease and the tumor is positive for one of the following: BRAF fusion, BRAF rearrangement or BRAF V600 mutation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

OJJAARA

Products Affected

- OJJAARA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Myelofibrosis-approve if the patient has (A, B or C): A) higher-risk disease, or B) lower-risk disease and has one disease-related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis), or C) myelofibrosis-associated anemia. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease- related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Accelerated or blast phase myeloproliferative neoplasm
Part B Prerequisite	No
Prerequisite Therapy Required	No

OLPRUVA

Products Affected

- OLPRUVA

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant therapy with another phenylbutyrate product
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	Pending CMS Review
Other Criteria	Urea cycle disorder (e.g., deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or argininosuccinic acid synthetase)-approve if the diagnosis was confirmed by genetic testing confirming a mutation resulting in a urea cycle disorder or if the patient has hyperammonemia diagnosed with an ammonia level above the upper limit of the normal reference range for the reporting laboratory. Patients are required to have a trial of generic sodium phenylbutyrate oral suspension or tablets prior to approval of Olpruva, unless the patient does not have a feeding tube.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

OLUMIANT

Products Affected

- OLUMIANT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic, biologic immunomodulators, topical Janus Kinase Inhibitors (JAKis), targeted synthetic DMARDs, or other potent immunosuppressants. Exclude for indication of COVID-19 treatment in hospitalized patients (ie, non-D use).
Required Medical Information	Diagnosis, previous medication use, concurrent medication
Age Restrictions	Alopecia areata-18 years and older (initial/cont).All other dx-18 years of age and older (initial therapy)
Prescriber Restrictions	RA-Prescribed by or in consultation with a rheumatologist (initial therapy). Alopecia Areata-prescribed by or in consultation with a dermatologist (initial/cont).
Coverage Duration	Approve through end of plan year
Other Criteria	Initial therapy, RA - approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Rinvoq or Xeljanz/XR. [Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: Cimzia, infliximab, Simponi golimumab IV/SC, Kevzara, Orencia, a tocilizumab product or a non-preferred adalimumab product.] Continuation therapy - approve if the patient has had a response, as determined by the prescriber. Alopecia areata-approve if the patient has a current episode of alopecia areata lasting for greater than or equal to 6 months and has greater than or equal to 50 percent scalp hair loss. Continuation-approve if the patient has experienced an improvement from baseline in extent and density of scalp hair loss and if the prescriber states the patient continues to require systemic therapy for the treatment of alopecia areata. Please Note: preferred adalimumab products include Hadlima, Simlandi.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

OMVOH SC

Products Affected

- OMVOH PEN SUBCUTANEOUS PEN INJECTOR 100 MG/ML, 300MG/3ML(100MG /ML-200 MG/2ML)
- OMVOH SUBCUTANEOUS SYRINGE 100 MG/ML, 300MG/3ML(100MG /ML-200 MG/2ML)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic disease-modifying antirheumatic drug (DMARD).
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist (initial therapy only)
Coverage Duration	Approve through end of plan year
Other Criteria	<p>Ulcerative colitis, initial - Approve if the patient meets i and ii: i. Patient will receive three induction doses with Omvoh intravenous within 3 months of initiating therapy with Omvoh subcutaneous, AND ii.the patient has had a trial of TWO of the following: a preferred ustekinumab product, Skyrizi, Tremfya, Rinvoq, a preferred infliximab product, or a preferred adalimumab product. Trial(s) of a Non-Preferred infliximab product, Simponi SC, Entyvio SC, a non-preferred ustekinumab product or a Non-Preferred adalimumab product will also count. Ulcerative colitis, continuation-approve if the patient has had a response.</p> <p>Crohn's disease, initial - Approve if the patient meets i and ii: i. Patient will receive three induction doses with Omvoh intravenous within 3 months of initiating therapy with Omvoh subcutaneous, AND ii.the patient has had a trial of TWO of the following: a preferred adalimumab product, a preferred infliximab product, a preferred ustekinumab product, Rinvoq, Skyrizi, Tremfya. Trials of a Non-Preferred infliximab product, a non-preferred adalimumab, or a non-preferred ustekinumab product will also count. Crohn's disease, continuation-approve if the patient has had a response.</p> <p>Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand</p>

PA Criteria	Criteria Details
	name product), Zymfentra. Preferred ustekinumab products include Selarsdi, Yesintek.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ONAPGO

Products Affected

- ONAPGO

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a serotonin 5-HT3 antagonist
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	PARKINSON'S DISEASE- All of the following (A, B, C and D): A. Diagnosed with advanced Parkinson's disease, AND B. Experiencing off episodes, Note: Examples of off episodes include muscle stiffness, slow movements, or difficulty starting movements. AND C. Tried an oral carbidopa/levodopa therapy and had significant intolerance or inadequate efficacy, AND D. Previously tried or is currently receiving ONE other treatment for off episodes Note: Examples of treatment for off episodes include entacapone, rasagiline, pramipexole, ropinirole, tolcapone, cabergoline, selegiline, opicapone capsules, or safinamide tablets.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ONGENTYS

Products Affected

- ONGENTYS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's Disease-Approve if the patient is currently receiving carbidopa/levodopa therapy and if the patient has tried an entacapone product and had significant intolerance or inadequate efficacy or if the patient is currently receiving Ongentys.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ONUREG

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML - Approve if the medication is used for post-remission maintenance therapy AND allogeneic hematopoietic stem cell transplant is not planned. Peripheral T-cell lymphoma - all of (A, B, and C): A) relapsed or refractory disease, and B) pt has one of the following (i, ii or iii): i) angioimmunoblastic T-cell lymphoma, or ii) nodal peripheral T-cell lymphoma with T-follicular helper (TFH) phenotype, or iii) follicular T-cell lymphoma, and C) medication is used as a single agent.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Peripheral T-cell lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	No

OPSUMIT

Products Affected

- OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	PAH WHO group, right heart catheterization
Age Restrictions	N/A
Prescriber Restrictions	PAH - must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1 patients are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

OPSYNVI

Products Affected

- OPSYNVI

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with guanylate cyclase stimulators
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation)
Coverage Duration	1 year
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1-approve if patient has had a right-heart catheterization to confirm the diagnosis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

OPZELURA

Products Affected

- OPZELURA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with other JAK inhibitors. Concurrent use with other potent immunosuppressants
Required Medical Information	Diagnosis, other medications tried
Age Restrictions	12 years and older
Prescriber Restrictions	AD-Prescribed by or in consultation with an allergist, immunologist or dermatologist. Vitiligo-prescribed by or in consultation with a dermatologist.
Coverage Duration	AD-8 weeks, vitiligo-6 months
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ORENCIA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	Initial-RA-18 years and older, JIA/PsA-2 years and older
Prescriber Restrictions	Initial therapy only-RA and JIA/JRA prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist.
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL: RHEUMATOID ARTHRITIS: approve if (A or B): A) patient has tried two of: Enbrel, a preferred adalimumab product, Rinvoq, Xeljanz/XR, or a preferred tocilizumab product, or B) patient has heart failure, a previously treated lymphoproliferative disorder, previous serious infection, or demyelinating disease. [Note: trials with the following also count: a non-preferred tocilizumab product, Cimzia, infliximab, golimumab IV/SC, Kevzara, or a non-preferred adalimumab product.] JIA: approve if patient has tried two of: Enbrel, a preferred adalimumab product, Rinvoq, Xeljanz, or a preferred tocilizumab product. [Note: trials with the following drugs also count: a non-preferred tocilizumab product, infliximab, or a non-preferred adalimumab product.] PSORIATIC ARTHRITIS: approve if patient has tried two of: Enbrel, a preferred adalimumab product, Cosentyx, Tremfya, a preferred ustekinumab product, Otezla, Rinvoq, Skyrizi, Xeljanz/XR. Note: A previous trial of a non-preferred adalimumab or a non-preferred ustekinumab product would also count. CONTINUATION, ALL INDICATIONS: approve if patient is responding to therapy. Please note: Preferred adalimumab products include Hadlima, Simlandi. Preferred ustekinumab products include Selarsdi, Yesintek. Preferred tocilizumab products include Actemra, Tyenne.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ORENITRAM

Products Affected

- ORENITRAM MONTH 1 TITRATION KT
- ORENITRAM MONTH 2 TITRATION KT
- ORENITRAM MONTH 3 TITRATION KT
- ORENITRAM ORAL TABLET EXTENDED RELEASE 0.125 MG, 0.25 MG, 1 MG, 2.5 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Inhaled or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension.
Required Medical Information	Diagnosis, results of right heart cath
Age Restrictions	N/A
Prescriber Restrictions	PAH must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). For initial Orenitram therapy, approve Orenitram if the patient has tried Uptravi or if the patient is receiving a strong cytochrome P450 2C8 inhibitor (e.g., gemfibrozil).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ORGOVYX

Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Prostate Cancer-approve
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORIAHNN

Products Affected

- ORIAHNN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, test results
Age Restrictions	18 years and 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	24 months of total therapy
Other Criteria	Heavy menstrual bleeding associated with uterine fibroids-approve if the patient is premenopausal and uterine fibroids have been confirmed by a pelvic ultrasound, hysteroscopy or magnetic resonance imaging.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORKAMBI

Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other CF Transmembrane Conductance Regulator Modulators
Required Medical Information	N/A
Age Restrictions	1 year of age and older
Prescriber Restrictions	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF - Approve if the pt mees A, B and C: A) pt has two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator gene, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORLADEYO

Products Affected

- ORLADEYO

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant Use with Other HAE Prophylactic Therapies (e.g., Cinryze, Haegarda, Takhzyro).
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders. (initial and continuation)
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Prophylaxis, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Continuation-According to the prescriber the patient has had a favorable clinical response since initiating Orladeyo prophylactic therapy compared with baseline.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORSERDU

Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast cancer in postmenopausal women or Men-approve if the patient meets the following criteria (A, B, C, D, and E): A) Patient has recurrent or metastatic disease, AND B) Patient has estrogen receptor positive (ER+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has estrogen receptor 1 gene (ESR1)-mutated disease, AND E) Patient has tried at least one endocrine therapy. Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

OTEZLA

Products Affected

- OTEZLA MG (51), 10 MG (4)-20 MG (4)-30 MG
- OTEZLA STARTER ORAL (47)
- TABLETS,DOSE PACK 10 MG (4)- 20

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARD).
Required Medical Information	Diagnosis, previous drugs tried
Age Restrictions	Pending CMS Review
Prescriber Restrictions	All dx, initial only-PsA - Prescribed by or in consultation with a dermatologist or rheumatologist. PP - prescribed by or in consultation with a dermatologist. Behcet's-prescribed by or in consultation with a dermatologist or rheumatologist
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: PLAQUE PSORIASIS (PP) [A, B or C]: A) tried at least one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial with a biologic also counts) or B) contraindication to MTX or C) patient has mild to moderate disease and the patient requires systemic therapy. PSORIATIC ARTHRITIS (PsA): approve. BEHCET'S-oral ulcers or other mucocutaneous involvement. CONTINUATION THERAPY (PP/PsA/Behcet's): received 4 months of therapy and had a response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

OXERVATE

Products Affected

- OXERVATE

PA Criteria	Criteria Details
Exclusion Criteria	Treatment duration greater than 16 weeks per affected eye(s)
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by an ophthalmologist or an optometrist.
Coverage Duration	Initial-8 weeks, continuation-approve for an additional 8 weeks
Other Criteria	Patients who have already received Oxervate-approve if the patient has previously received less than or equal to 8 weeks of treatment per affected eye(s) and the patient has a recurrence of neurotrophic keratitis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PALYNZIQ

Products Affected

- PALYNZIQ SUBCUTANEOUS
SYRINGE 10 MG/0.5 ML, 2.5 MG/0.5
ML, 20 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, phenylalanine concentrations
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	1 year (initial and continuation)
Other Criteria	Initial therapy - approve if the patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., prior treatment with Kuvan). Maintenance therapy - approve if the patient has experienced improvement while on Palynziq.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PANRETIN

Products Affected

- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist, oncologist, or infectious disease specialist
Coverage Duration	1 year
Other Criteria	Kaposi Sarcoma-approve if the patient is not receiving systemic therapy for Kaposi Sarcoma.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PEMAZYRE

Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Cholangiocarcinoma-approve if the patient has unresectable locally advanced, gross residual, or metastatic disease and the tumor has a fibroblast growth factor receptor 2 (FGFR2) gene fusion or other rearrangement, as detected by an approved test AND the patient has been previously treated with at least one systemic therapy regimen.</p> <p>Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia, and the cancer has fibroblast growth factor receptor 1 (FGFR1) rearrangement, as detected by an approved test.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PENICILLAMINE

Products Affected

- *penicillamine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Wilson's Disease-Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant physician
Coverage Duration	1 year
Other Criteria	Cystinuria-approve. Wilson's disease-approve if diagnosis is confirmed by ONE of the following (i or ii): i. Genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals), OR ii. Confirmation of at least two of the following (a, b, c, d): a) Presence of Kayser-Fleischer rings, b) Serum ceruloplasmin level less than 20 mg/dL, c) Liver biopsy findings consistent with Wilson's disease, d) 24-hour urinary copper greater than 40 mcg/24 hours.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PHENYL BUTYRATE

Products Affected

- PHEBURANE
- RAVICTI
- *sodium phenylbutyrate*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant therapy with more than one phenylbutyrate product
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	Pending CMS Review
Other Criteria	Urea cycle disorders-approve if genetic or enzymatic testing confirmed a urea cycle disorder or if the patient has hyperammonemia diagnosed with an ammonia level above the upper limit of the normal reference range for the reporting laboratory.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PHEOCHROMOCYTOMA

Products Affected

- *metyrosine*
- *phenoxybenzamine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior medication trials
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial therapy for phenoxybenzamine, initial and continuation therapy for metyrosine)
Coverage Duration	Authorization will be for 1 year
Other Criteria	If the requested drug is metyrosine for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin). If the requested drug is metyrosine for continuation therapy, approve if the patient is currently receiving metyrosine or has received metyrosine in the past.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PHOSPHODIESTERASE-5 INHIBITORS

Products Affected

- *alyq*
- *sildenafil (pulmonary arterial hypertension) oral suspension for reconstitution 10 mg/ml*
- *sildenafil (pulmonary arterial hypertension) oral tablet 20 mg*
- *tadalafil (pulmonary arterial hypertension) oral tablet 20 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use With Guanylate Cyclase Stimulators.
Required Medical Information	Diagnosis, right heart cath results
Age Restrictions	N/A
Prescriber Restrictions	For PAH, if prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Pulmonary arterial hypertension (PAH), are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Raynaud's Phenomenon-approve if the patient has tried one calcium channel blocker or if use of a calcium channel blocker is contraindicated. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets and suspension require confirmation that the indication is PAH or Raynaud's prior to reviewing for quantity exception.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Raynaud's Phenomenon
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PIQRAY

Products Affected

- PIQRAY ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X 1), 300 MG/DAY (150 MG X 1), 300 MG/DAY (150 MG X 2)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast Cancer. Approve if the patient meets the following criteria (A, B, C, D, E and F): A) The patient is a postmenopausal female, male or pre/perimenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene or fulvestrant) AND F) Piqray will be used in combination with fulvestrant injection.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

PIRFENIDONE

Products Affected

- *pirfenidone oral capsule*
- *pirfenidone oral tablet 267 mg, 801 mg*
- PIRFENIDONE ORAL TABLET 534 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	1 year
Other Criteria	IPF (initial therapy)- must have FVC greater than or equal to 40 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. IPF (continuation of therapy)-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PLEGRIDY

Products Affected

- PLEGRIDY SUBCUTANEOUS PEN INJECTOR 125 MCG/0.5 ML
- PLEGRIDY SUBCUTANEOUS SYRINGE 125 MCG/0.5 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of with other disease-modifying agents used for multiple sclerosis (MS).
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

POMALYST

Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Kaposi Sarcoma/MM/Systemic light chain amyloidosis-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Primary CNS Lymphoma-approve if the patient has relapsed or refractory disease or is not a candidate for high-dose MTX or had intolerance to high-dose MTX. Kaposi Sarcoma-Approve if the patient meets one of the following (i or ii): i. patient is Human Immunodeficiency Virus (HIV)-negative OR ii. patient meets both of the following (a and b): a) The patient is Human Immunodeficiency Virus (HIV)-positive AND b) The patient continues to receive highly active antiretroviral therapy (HAART). MM-approve if the patient has tried at least one other regimen. Systemic light chain amyloidosis- approve if this is used in combination with dexamethasone and pt tried at least one other regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Systemic Light Chain Amyloidosis, Primary Central Nervous System (CNS) Lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PONVORY

Products Affected

- PONVORY
- PONVORY 14-DAY STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Diagnosis
Age Restrictions	N/A
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	Patients new to therapy-approve if the patient has tried one fumarate-based product (generic dimethyl fumarate or Vumerity) AND one Preferred S1P receptor modulator (generic fingolimod or Zeposia). Note: Prior use of brand Tecfidera or Bafiertam with inadequate efficacy or significant intolerance (according to the prescriber) also counts as a fumarate product. Also, a patient who has previously tried a glatiramer product (Copaxone, Glatopa, generic) can bypass the fumarate requirement. Prior use of brand Gilenya or a Non-preferred S1P (i.e., Mayzent, Tascenso ODT) with inadequate efficacy or significant intolerance (according to the prescriber) also counts. Cont tx-approve if the patient has been established on Ponvory.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

POSACONAZOLE (ORAL)

Products Affected

- NOXAFIL ORAL SUSP, DELAYED RELEASE FOR RECON
- *posaconazole oral suspension*
- *posaconazole oral tablet, delayed release (dr/ec)*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Aspergillus/Candida prophylaxis, mucormycosis, esophageal candida-6 mo, all others-3 months
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	esophageal candidiasis - treatment, mucormycosis - maintenance, fusariosis, invasive - treatment fungal infections (systemic) in patients with human immunodeficiency virus (HIV) infections (e.g., histoplasmosis, coccidioidomycosis) - treatment.
Part B Prerequisite	No
Prerequisite Therapy Required	No

PRALUENT

Products Affected

- PRALUENT PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Leqvio or Repatha.
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	HeFH - 8 years and older. All other - 18 years of age and older.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	<p>HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL (or 155 mg/dL if less than 16 years old), b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below). ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD, HeFH, or HoFH) [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. HYPERLIPIDEMIA WITH HoFH (both A and B): A) meets (a or b): a) phenotypic confirmation of HoFH, or b) meets (i and ii): i) untreated LDL-C greater than 400 mg/dL or treated LDL-C greater than or equal to 300 mg/dL, and ii) clinical manifestations of HoFH before 10 years of age or at least one parent with untreated LDL-C or total cholesterol consistent with FH, AND B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 70 mg/dL or higher or b) statin intolerant. FOR ALL INDICATIONS: must</p>

PA Criteria	Criteria Details
	<p>try Repatha prior to approval of Praluent, unless the request is for the treatment of HeFH in a patient less than 10 years old and greater than or equal to 8 years old. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PRETOMANID

Products Affected

- PRETOMANID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, concomitant therapy
Age Restrictions	Patients 18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with an infectious diseases specialist
Coverage Duration	9 months
Other Criteria	Tuberculosis, Pulmonary Extensively Drug Resistant or Treatment-Intolerant or Nonresponsive Multidrug-Resistant-approve if prescribed in combination with Sirturo (bedaquiline tablets) and linezolid tablets or oral suspension.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PREVYMIS

Products Affected

- PREVYMIS ORAL PELLETS IN PACKET 120 MG, 20 MG
- PREVYMIS ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

PROMACTA

Products Affected

- *eltrombopag olamine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy. MDS-platelet counts.
Age Restrictions	N/A
Prescriber Restrictions	Immune Thrombocytopenia or Aplastic Anemia, prescribed by, or after consultation with, a hematologist (initial therapy). Hep C, prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease (initial therapy). MDS-presc or after consult with heme/onc (initial therapy). Post-transplant, prescribed by or in consult with a hematologist, oncologist or stem cell transplant specialist physician (initial)
Coverage Duration	ImmuneThrombo/MDS init3mo,cont1yr,AAinit4mo,cont1yr,Thrombo/HepC1yr,Transplant- init3mo,cont6mo
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Thrombocytopenia in Myelodysplastic Syndrome (MDS), Thrombocytopenia in a patient post-allogeneic transplantation
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PYRIMETHAMINE

Products Affected

- *pyrimethamine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Patient's immune status (Toxoplasma gondii Encephalitis, chronic maintenance and prophylaxis, primary)
Age Restrictions	N/A
Prescriber Restrictions	Toxoplasma gondii Encephalitis, Chronic Maintenance and Prophylaxis (Primary)-prescribed by or in consultation with an infectious diseases specialist. Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist.
Coverage Duration	12 months
Other Criteria	Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis
Part B Prerequisite	No
Prerequisite Therapy Required	No

PYRUKYND

Products Affected

- PYRUKYND ORAL TABLET 20 MG, 5 MG, 5 MG (4-WEEK PACK), 50 MG
- PYRUKYND ORAL TABLETS,DOSE PACK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a hematologist (initial and continuation)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	<p>Initial therapy-Approve if the patient has the presence of at least two variant/mutant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene and at least one of the variant/mutant alleles was a missense variant AND the patient has a current hemoglobin level less than or equal to 10g/dL or patient is currently receiving red blood cell transfusions regularly, defined as at least six transfusion within the last year.</p> <p>Continuation of therapy-Approve if the patient has the presence of at least two variant/mutant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene and at least one of the variant/mutant alleles was a missense variant AND the patient has experienced a benefit from therapy, defined as increase in or maintenance of hemoglobin levels, or improvement in or maintenance of hemolysis laboratory parameters, OR decrease in or maintenance of transfusion requirements.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

QINLOCK

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other therapies tried
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Gastrointestinal stromal tumor (GIST)-approve if the patient has tried imatinib or avapritinib tablets, AND the patient meets one of the following criteria (i, ii, or iii): i. Patient has tried sunitinib and regorafenib tablets, OR ii. Patient has tried dasatinib tablets, OR iii. Patient is intolerant of sunitinib. Melanoma, cutaneous-approve if the patient has metastatic or unresectable disease, AND the patient has an activating KIT mutation, AND the patient has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Melanoma, cutaneous
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

QULIPTA

Products Affected

- QULIPTA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Migraine headache prevention-approve if the patient meets (A and B): A) has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication, and B) if the pt is currently taking Qulipta, the pt has had significant clinical benefit. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Qulipta was initiated.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

RADICAVA ORS

Products Affected

- RADICAVA ORS STARTER KIT SUSP

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	ALSFRS-R score
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS (initial and continuation).
Coverage Duration	Initial, 6 months. Continuation, 6 months
Other Criteria	ALS, initial therapy - approve if the patient meets ALL of the following criteria: 1. According to the prescribing physician, the patient has a definite or probable diagnosis of ALS, based on the application of the El Escorial or the revised Airlie house diagnostic criteria AND 2. Patient has a score of two points or more on each item of the ALS Functional Rating Scale - Revised (ALSFRS-R) [ie, has retained most or all activities of daily living], AND 3. Patient has adequate respiratory function according to the prescriber, AND 4. Patient has received or is currently receiving riluzole tablets. Note-a trial of Tiglutik or Exservan would also count. ALS, continuation therapy - approve if, according to the prescribing physician, the patient continues to benefit from therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

REBIF

Products Affected

- REBIF (WITH ALBUMIN) MCG/0.5 ML, 8.8MCG/0.2ML-22
- REBIF REBIDOSE SUBCUTANEOUS MCG/0.5ML (6)
- PEN INJECTOR 22 MCG/0.5 ML, 44
- REBIF TITRATION PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or an MS specialist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Initial treatment-approve if the patient has tried TWO of the following: Avonex, Plegridy, Betaseron, or generic glatiramer. Cont tx-approve if the patient has been established on Rebif.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RECORLEV

Products Affected

- RECORLEV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of endogenous Cushing's syndrome.
Coverage Duration	1 year
Other Criteria	Endogenous Cushing's Syndrome-approve if the patient has hypercortisolemia, and the patient has tried ketoconazole tablets, and the patient meets (i, ii or iii): i) the patient is not a candidate for surgery or surgery has not been curative, or ii) patient is awaiting surgery for endogenous Cushing's Syndrome, or iii) patient is awaiting therapeutic response after radiotherapy for endogenous Cushing's Syndrome.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RELEUKO

Products Affected

- RELEUKO SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer/AML, MDS, ALL-oncologist or a hematologist. Cancer patients receiving BMT and PBPC-prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. SCN-hematologist. HIV/AIDS neutropenia-infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. Radiation syndrome-prescribed by or in consultation with expert in acute radiation.
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N, ALL,BMT,Radi-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), 2)patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status, or HIV infection patients with low CD4 counts), 3)patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy, has febrile neutropenia and has at

PA Criteria	Criteria Details
	least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm ³], neutropenia expected to be greater than 10 days in duration, pneumonia or other clinically documented infection, invasive fungal infection, hospitalization at the time of fever, prior episode of febrile neutropenia)
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	No

REPATHA

Products Affected

- REPATHA
- REPATHA SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Leqvio or Praluent.
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	ASCVD/Primary Hyperlipidemia - 18 yo and older, HoFH/HeFH - 10 yo and older.
Prescriber Restrictions	N/A
Coverage Duration	Approve for 1 year
Other Criteria	<p>HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL (or 155 mg/dL if less than 16 years old), b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below). ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD, HeFH, or HoFH) [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. HYPERLIPIDEMIA WITH HoFH (both A and B): A) meets (a or b): a) phenotypic confirmation of HoFH, or b) meets (i and ii): i) untreated LDL-C greater than 400 mg/dL or treated LDL-C greater than or equal to 300 mg/dL, and ii) clinical manifestations of HoFH before 10 years of age or at least one parent with untreated LDL-C or total cholesterol consistent with FH, AND B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 70</p>

PA Criteria	Criteria Details
	mg/dL or higher or b) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RETEVMO

Products Affected

- RETEVMO ORAL TABLET 120 MG, 160 MG, 40 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Medullary Thyroid Cancer/Thyroid Cancer/Solid tumors-2 years and older, all others 18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has recurrent, advanced or metastatic disease AND the tumor is RET fusion-positive. Thyroid cancer-approve if the patient has rearranged during transfection (RET) fusion positive or RET mutation positive disease or RET pathogenic variant AND the patient meets i or ii: i. patient has anaplastic thyroid cancer OR ii. the disease requires treatment with systemic therapy and patient has medullary thyroid cancer or the disease is radioactive iodine-refractory. Solid tumors-approve if the patient has recurrent, advanced or metastatic disease and the tumor is rearranged during transfection (RET) fusion-positive. Histiocytic neoplasm-approve if the patient has a rearranged during transfection (RET) fusion and has Langerhans cell histiocytosis or Erdheim Chester disease or Rosai-Dorfman disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anaplastic thyroid carcinoma, histiocytic neoplasm
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

REVC0VI

Products Affected

- REVC0VI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, lab values, genetic tests (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with, an immunologist, hematologist/oncologist, or physician that specializes in ADA-SCID or related disorders.
Coverage Duration	12 months
Other Criteria	ADA-SCID - approve if the patient had absent or very low (less than 1% of normal) ADA catalytic activity at baseline (i.e., prior to initiating enzyme replacement therapy) OR if the patient had molecular genetic testing confirming bi-allelic pathogenic variants in the ADA gene.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

REVUFORJ

Products Affected

- REVUFORJ ORAL TABLET 110 MG, 160 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	1 year and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	ACUTE LEUKEMIA-patient has relapsed or refractory disease and the disease is positive for a lysine methyltransferase 2A (KMT2A) gene translocation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZDIFFRA

Products Affected

- REZDIFFRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist (initial/continuation)
Coverage Duration	1 year
Other Criteria	<p>INITIAL THERAPY: METABOLIC-DYSFUNCTION ASSOCIATED STEATOHEPATITIS (MASH)/NON-ALCOHOLIC STEATOHEPATITIS (NASH) WITH MODERATE-ADVANCED LIVER FIBROSIS: All of (i, ii and iii): i) Diagnosed by (a or b): a) Liver biopsy performed within 3 years preceding treatment with Rezdiffra showing non-alcoholic fatty liver disease activity score of greater than or equal to 4 with a score of greater than or equal to 1 in ALL of the following: steatosis, ballooning and lobular inflammation, or b) One of the following within 6 months preceding treatment with Rezdiffra (1, 2 or 3): 1) Elastography (e.g. vibration-controlled transient elastography (e.g., FibroScan), transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, shear wave elastography) or 2) Computed tomography or 3) Magnetic resonance imaging, and ii) stage F2 or F3 fibrosis prior to Rezdiffra and iii) This will be used in combination with appropriate diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise). CONTINUATION THERAPY (on therapy less than 1 year or restarting, review as initial therapy):</p> <p>MASH/NASH: All of (i, ii and iii): i) completed greater than or equal to 1 year of therapy and has not had worsening of fibrosis or MASH/NASH, and ii) has not progressed to stage F4 (cirrhosis) and iii) This will be used in combination with appropriate diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise).</p>

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZLIDHIA

Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Acute myeloid leukemia-approve if the patient has relapsed or refractory disease and the patient has isocitrate dehydrogenase-1 (IDH1) mutation positive disease as detected by an approved test.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZUROCK

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial therapy)
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Graft-versus-host disease, initial-approve if the patient has chronic graft-versus-host disease and has tried at least two systemic medications (examples: Jakafi [ruxolitinib], Nektinvo [axatilimab-csfr], ibrutinib) for chronic graft-versus-host disease. Graft-versus-host disease, continuation-approve if patient has demonstrated a beneficial clinical response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RILUZOLE

Products Affected

- *riluzole*
- TIGLUTIK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

RINVOQ

Products Affected

- RINVOQ ORAL TABLET EXTENDED
RELEASE 24 HR 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic oral small molecule drug, Concurrent use with other potent immunosuppressants, or concurrent use with a biologic immunomodulator.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	PsA/JIA - 2 years and older (initial therapy), RA/UC/AS/CD/nraxSpA/GCA-18 years and older (initial therapy), AD-12 years and older (initial therapy)
Prescriber Restrictions	RA/AS/Non-Radiographic Spondy/JIA/GCA, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescr/consult with allergist, immunologist or dermatologist. UC/CD-prescribed by or in consultation with a gastroenterologist. (all apply to initial therapy only)
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA)/PSORIATIC ARTHRITIS (PsA)/ULCERATIVE COLITIS (UC)/ANKYLOSING SPONDYLITIS (AS)/CROHN'S DISEASE (CD)/ JUVENILE IDIOPATHIC ARTHRITIS (JIA): 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial. ATOPIC DERMATITIS (AD): 4-month trial of at least one systemic therapy (e.g., Dupixent [dupilumab subcutaneous injection], Ebglyss [lebrikizumab-lbkz subcutaneous injection], Nemludio (nemolizumab-ilto subcutaneous injection), and Adbry [tralokinumab-ldrm subcutaneous injection]. Azathioprine, cyclosporine, or mycophenolate mofetil also count.) or unable to tolerate a 4-month trial. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (A and B): A) objective signs of inflammation defined as having at least one of the following (a or b): a) C-reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI and B) 3-month trial of at least one TNFi or was unable to

PA Criteria	Criteria Details
	tolerate a 3-month trial. GIANT CELL ARTERITIS: tried one systemic corticosteroid. CONTINUATION THERAPY: ALL INDICATIONS: patient responded to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RINVOQ LQ

Products Affected

- RINVOQ LQ

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic DMARD, other potent immunosuppressants, other janus kinase inhibitors, or a biologic immunomodulator.
Required Medical Information	Diagnosis
Age Restrictions	PsA-2 years and older (initial therapy)
Prescriber Restrictions	JIA-prescribed by or in consultation with a rheumatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or a dermatologist (initial therapy)
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: JUVENILE IDIOPATHIC ARTHRITIS (JIA)/ PSORIATIC ARTHRITIS (PsA) - 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial. CONTINUATION THERAPY: ALL INDICATIONS - patient responded to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RIVFLOZA

Products Affected

- RIVFLOZA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of Rivfloza with Oxlumio (lumasiran subcutaneous injection)
Required Medical Information	Diagnosis
Age Restrictions	2 years of age and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or urologist (initial)
Coverage Duration	Initial-6 months, continuation 1 year
Other Criteria	<p>Primary Hyperoxaluria Type 1, initial therapy-Approve if the patient meets the following (i, ii, iii and iv): i. Patient has had a genetic test confirming the diagnosis of Primary Hyperoxaluria Type 1 via identification of biallelic pathogenic variants in the alanine:glyoxylate aminotransferase gene (AGXT), AND ii. Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 ml/min per 1.73 m², AND iii. Patient meets ONE of the following (1 or 2): 1) patient is 2 to less than 12 years of age and meets (a or b): a) urinary oxalate excretion greater than or equal to 0.5 mmol/24 hours/1.73 meters² with the absence of secondary sources of oxalate, or b) urinary oxalate:creatinine ratio above 2 times the 95th percentile for age, or 2) patient is greater than or equal to 12 years of age and meets (a, b, or c): a) Patient has a urinary oxalate excretion greater than or equal to 0.5 mmol/24 hours/1.73 meters² with the absence of secondary sources of oxalate, OR b) Patient has a urinary oxalate:creatinine ratio above the age-specific upper limit of normal, OR c) Patient has a plasma oxalate level greater than or equal to 20 micromol/L, AND iv. Patient has not previously received a liver transplant for Primary Hyperoxaluria Type 1. Primary Hyperoxaluria Type 1, continuation-Approve if the patient is continuing to derive benefit from Rivfloza and has not previously received a liver transplant for primary hyperoxaluria type 1. Note: Examples of response to Rivfloza therapy are reduced urinary oxalate excretion, decreased urinary oxalate:creatinine ratio, or reduced plasma oxalate levels</p>

PA Criteria	Criteria Details
	from baseline (i.e., prior to Rivfloza therapy) or improved or stabilized clinical signs/symptoms of Primary Hyperoxaluria Type 1 (e.g., nephrocalcinosis, formation of renal stones, renal impairment).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ROFLUMILAST (ORAL)

Products Affected

- *roflumilast*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD), medications tried.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial therapy - 6 months, Continuation of therapy - 1 year
Other Criteria	<p>INITIAL THERAPY, COPD: all of (A, B, C and D): A) patient has forced expiratory volume in 1 second (FEV1) less than 50 percent predicted, and B) history of two or more moderate COPD exacerbations or one or more severe COPD exacerbations [Note: A moderate exacerbation is an exacerbation that required treatment with a short-acting bronchodilator and a systemic corticosteroid. A severe COPD exacerbation is an exacerbation that required hospitalization or an Emergency Department visit.], and C) patient has chronic bronchitis, and D) patient tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, olodaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone).</p> <p>CONTINUATION THERAPY, COPD: both (A and B): A) patient continues to receive combination therapy with a LABA and a LAMA, and B) patient has beneficial response defined by one of the following: reduced COPD symptoms, reduced COPD exacerbations, reduced COPD-related hospitalizations, reduced emergency department or urgent care visits, or improved lung function parameters.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ROMVIMZA

Products Affected

- ROMVIMZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	TENOSYNOVIAL GIANT CELL TUMOR (PIGMENTED VILLONODULAR SYNOVITIS)-tumor is not amenable to improvement with surgery.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ROZLYTREK

Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG
- ROZLYTREK ORAL PELLETS IN PACKET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	NSCLC-18 years and older, Solid Tumors-1 month and older, Pediatric Diffuse High-Grade Glioma-less than 18 years old
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Solid Tumors-Approve if the patient's tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic OR surgical resection of tumor will likely result in severe morbidity. Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease and the mutation was detected by an approved test. Pediatric Diffuse High-Grade Glioma- approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the medication is used either as adjuvant therapy or for recurrent or progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pediatric Diffuse High-Grade Glioma
Part B Prerequisite	No
Prerequisite Therapy Required	No

RUBRACA

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if (A, B and C): A) the patient is in complete or partial response after a platinum-based chemotherapy regimen, and B) meets (i or ii): i) the patient is in complete or partial response to first-line primary treatment or ii) patient has recurrent disease and has a BRCA mutation, and C) for new starts, the patient has tried the preferred product Lynparza, unless the prescriber indicates that Lynparza is inappropriate for the patient's specific clinical situation. Castration-Resistant Prostate Cancer - Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND B) The patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy AND C) The patient has been previously treated with at least one androgen receptor-directed therapy, and D) for new starts, the patient has tried one of the preferred products, Lynparza or Talzenna, unless the prescriber indicates that both Lynparza and Talzenna are inappropriate for the patient's specific clinical situation. Pancreatic adenocarcinoma-approve if pt has a BRCA mutation or PALB2 mutation AND pt has tried platinum-based chemotherapy AND has not had disease progression following the most recent platinum-based chemotherapy.</p>

PA Criteria	Criteria Details
	Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Uterine Leiomyosarcoma, Pancreatic Adenocarcinoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RUFINAMIDE

Products Affected

- *rufinamide*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Patients 1 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Initial therapy-approve if rufinamide is being used for adjunctive treatment. Continuation-approve if the patient is responding to therapy
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Treatment-Refractory Seizures/Epilepsy
Part B Prerequisite	No
Prerequisite Therapy Required	No

RYDAPT

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For AML, FLT3 status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML-approve if the patient is FLT3-mutation positive as detected by an approved test. Myeloid or lymphoid Neoplasms with eosinophilia-approve if the patient has an FGFR1 rearrangement or has an FLT3 rearrangement. Indolent systemic mastocytosis-pt has symptomatic disease and has tried at least one systemic regimen. Smoldering systemic mastocytosis-pt has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid or lymphoid Neoplasms with eosinophilia, indolent systemic mastocytosis, smoldering systemic mastocytosis
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SAPROPTERIN

Products Affected

- *javygtor*
- *sapropterin*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Palynziq
Required Medical Information	Diagnosis, Phe concentration
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy)
Coverage Duration	Initial-12 weeks, Continuation-1 year
Other Criteria	Initial - approve. Continuation (Note-if the patient has received less than 12 weeks of therapy or is restarting therapy with sapropterin should be reviewed under initial therapy) - approve if the patient has had a response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SAVAYSA

Products Affected

- SAVAYSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior medication history (as described in Other Criteria)
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Atrial fib/flutter/DVT/PE treatment-1 year
Other Criteria	Atrial Fibrillation (or Atrial Flutter). Approve if the patient meets both of the following criteria (A and B): A) The patient has an estimated creatinine clearance (CrCl) less than or equal to 95 mL/min AND B) The patient has tried Eliquis or Xarelto. Deep Vein Thrombosis or Pulmonary Embolism, Treatment. Approve if the patient meets one of the following-patient has tried Eliquis or Xarelto OR patient is currently receiving Savaysa for this condition.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SCSEMBLIX

Products Affected

- SCSEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Chronic Myeloid Leukemia (CML)-approve if the patient meets the following (A and B): A) Patient has Philadelphia chromosome-positive or BCR::ABL1-positive chronic myeloid leukemia, AND B) Patient meets one of the following (i, ii or iii): i. Patient has newly diagnosed disease, OR ii. The chronic myeloid leukemia is T315I-positive, OR iii. Patient has tried at least one other tyrosine kinase inhibitor. Note: Examples of tyrosine kinase inhibitors include imatinib, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), dasatinib, and nilotinib capsules. Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has an ABL1 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid/Lymphoid Neoplasms with Eosinophilia
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SIGNIFOR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
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	Pending CMS Review
Other Criteria	Cushing's disease, initial therapy - approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Cushing's disease, continuation therapy - approve if the patient has already been started on Signifor/Signifor LAR and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SILIQ

Products Affected

- SILIQ

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Previous medication use
Age Restrictions	18 years of age and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist (initial therapy)
Coverage Duration	Approve through end of plan year
Other Criteria	Initial therapy-Plaque Psoriasis-Approve if (A, B, C and D): A) the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Skyrizi, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya, [a trial of a non-preferred adalimumab or a non-preferred ustekinumab also count] and B) patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy, and C) pt does not have moderately severe to severe depression, and D) the past 5 years, the patient does not have a history of suicidal ideation or suicidal behavior. Continuation Therapy - approve if (A, B, C and D): A) the patient had a response as determined by the prescriber, and B) patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy, and C) pt does not have moderately severe to severe depression, and D) pt does not have suicidal ideation or suicidal behavior. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred ustekinumab products include Selarsdi, Yesintek.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

SIMPONI

Products Affected

- SIMPONI SUBCUTANEOUS PEN INJECTOR 100 MG/ML, 50 MG/0.5 ML
- SIMPONI SUBCUTANEOUS SYRINGE 100 MG/ML, 50 MG/0.5 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous therapies tried.
Age Restrictions	All dx-18 years and older (initial therapy)
Prescriber Restrictions	All dx-initial only-RA/Ankylosing spondylitis, prescribed by or in consultation with a rheumatologist. Psoriatic arthritis, prescribed by or in consultation with a rheumatologist or dermatologist. UC-prescribed by or in consultation with a gastroenterologist
Coverage Duration	Approve through end of plan year
Other Criteria	AS, initial -approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Xeljanz/XR, Cosentyx. Note: A previous trial of a nonpreferred adalimumab product would also count. PsA, initial-approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Cosentyx, Tremfya, a preferred ustekinumab product, Otezla, Rinvoq, Skyrizi, Xeljanz/XR. Note: A previous trial of a nonpreferred adalimumab/ustekinumab product would also count. RA, initial- approve if the patient has tried two of the following drugs in the past: Enbrel, a preferred adalimumab product, Rinvoq or Xeljanz/XR. Note: A previous trial of a nonpreferred adalimumab product would also count. Ulcerative colitis, initial - approve if the patient has had a trial with TWO of the following drugs: a preferred adalimumab product, a preferred infliximab product, a preferred ustekinumab product, Rinvoq, Tremfya, Skyrizi. Note: A previous trial of a nonpreferred adalimumab/infliximab/ustekinumab product would also count. Continuation tx - approve if the pt had a response as determined by the prescriber. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab

PA Criteria	Criteria Details
	products include Remicade, infliximab IV (brand name product), Zymfentra. Preferred ustekinumab products include Selarsdi, Yesintek.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SIRTURO

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Diagnosis, concomitant therapy
Age Restrictions	Pending CMS Review
Prescriber Restrictions	Prescribed by, or in consultation with an infectious diseases specialist
Coverage Duration	9 months
Other Criteria	Tuberculosis (Pulmonary) -Approve if the patient has Mycobacterium tuberculosis resistant to at least rifampin and isoniazid and the requested medication is prescribed as part of a combination regimen with other anti-tuberculosis agents
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SKYCLARYS

Products Affected

- SKYCLARYS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	16 years and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, or a physician who specializes in ataxias and/or neuromuscular disorders
Coverage Duration	1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SKYRIZI

Products Affected

- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE
- SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR 180 MG/1.2 ML (150 MG/ML), 360 MG/2.4 ML (150 MG/ML)

PA Criteria	Criteria Details
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/UC/CD/PsA-18 years of age and older (initial therapy)
Prescriber Restrictions	PP-Prescribed by or in consultation with a dermatologist (initial therapy), PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy), CD/UC-presc/consult-gastro (initial therapy)
Coverage Duration	Approve through end of plan year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SOFOSBUVIR/VELPATASVIR

Products Affected

- SOFOSBUVIR-VELPATASVIR

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin.
Required Medical Information	Diagnosis
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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No
Prerequisite Therapy Required	No

SOHONOS

Products Affected

- SOHONOS ORAL CAPSULE 1 MG, 1.5 MG, 10 MG, 2.5 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Female-8 years or older. Male-10 years or older.
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, orthopedist, rheumatologist or physician who specializes in bone disease.
Coverage Duration	1 year
Other Criteria	Fibrodysplasia ossificans progressive-Approve if the patient meets A and B: A)Patient has had a genetic test confirming a mutation in Activin A Type 1 Receptor (ACVR1)R206H consistent with a diagnosis of fibrodysplasia ossificans progressive, AND B) Patient has heterotopic ossification as confirmed by radiologic testing. Note: Examples of radiologic testing are x-ray, computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET) scan.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SOLARAZE

Products Affected

- *diclofenac sodium topical gel 3 %*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 6 months.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SOMAVERT

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapy, concomitant therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	1 year
Other Criteria	ACROMEGALY (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SORAFENIB

Products Affected

- *sorafenib*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Bone cancer, approve if the patient has recurrent chordoma or has osteosarcoma and has tried one standard chemotherapy regimen. GIST, approve if the patient has tried TWO of the following: imatinib mesylate, avapritinib, sunitinib, dasatinib, ripretinib or regorafenib. Differentiated (ie, papillary, follicular, oncocytic) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has tried at least one systemic therapy. AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test and the medication is used in combination with azacitidine or decitabine or patient has had an allogeneic stem cell transplant and is in remission. Renal cell carcinoma (RCC)-approve if the patient has relapsed or advanced clear cell histology and the patient has tried at least one systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and sorafenib is used in combination with topotecan. HCC-approve if the patient has unresectable or metastatic disease. Soft tissue sarcoma-approve if the patient has angiosarcoma or desmoid tumors (aggressive fibromatosis) or solitary fibrous tumor/hemangiopericytoma. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement. Please note for all diagnoses: Part B before Part D Step Therapy applies only to beneficiaries enrolled in an MA-PD plan</p>

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bone cancer, Soft tissue sarcoma, gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, ovarian, fallopian tube, primary peritoneal cancer, myeloid/lymphoid neoplasms with eosinophilia
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SOTYKTU

Products Affected

- SOTYKTU

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs). Concurrent use with other potent immunosuppressants, including methotrexate.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist (initial)
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY, PLAQUE PSORIASIS - approve if pt has tried TWO of the following: Enbrel, a preferred adalimumab, Skyrizi, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya. [A trial of a non-preferred adalimumab, a non-preferred ustekinumab, Cimzia, infliximab, Bimzelx, Siliq, Taltz, Ilumya will also count.] CONTINUATION, PLAQUE PSORIASIS: approve if the patient has responded to therapy. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred ustekinumab products include Selarsdi, Yesintek.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SOVALDI

Products Affected

- SOVALDI ORAL PELLETS IN PACKET 150 MG, 200 MG
- SOVALDI ORAL TABLET 200 MG, 400 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Genotype 1 and 4 -18 years or older, Genotype 2 and 3-3 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
Coverage Duration	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance (Note-For genotypes 5 and 6, coverage will be approved only when used in combination with other agents according to AASLD/IDSA guidelines). And, patients with genotype 1, 4, 5, or 6 must try TWO of the following: ledipasvir/sofosbuvir, velpatasvir/sofosbuvir, Mavyret, Vosevi, unless ledipasvir/sofosbuvir, velpatasvir/sofosbuvir, Mavyret and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Genotype 2 or 3 must try TWO of the following: velpatasvir/sofosbuvir, Mavyret, Vosevi, unless velpatasvir/sofosbuvir, Mavyret and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SPEVIGO SC

Products Affected

- SPEVIGO SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with another biologic or disease modifying antirheumatic drugs (DMARD) prescribed for treatment of generalized pustular psoriasis.
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist (initial therapy)
Coverage Duration	Initial-6 months, Continuation-1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SPRYCEL

Products Affected

- *dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which dasatinib is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For melanoma, cutaneous- KIT mutation and previous therapies.
Age Restrictions	GIST/bone cancer/ melanoma, cutaneous-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	For CML, patient must have Ph-positive or BCR::ABL1-positive CML. For ALL, patient must have Ph-positive ALL or ABL-class translocation. For Bone Cancer-approve if patient has chondrosarcoma or chordoma. GIST - approve if the patient has tried imatinib or avapritinib. For melanoma, cutaneous - approve if patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	GIST, bone cancer, melanoma cutaneous
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

STIMUFEND

Products Affected

- STIMUFEND

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation. Radiation syndrome-prescribed by or in consultation with a physician who has expertise in treating acute radiation syndrome.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC-1 mo. Radiation Syndrome -1 mo.
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) 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), 2) 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 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status or HIV infection patients with low CD4 counts), OR 3) patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. Patients are required to try Fulphila and Nyvepria and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a

PA Criteria	Criteria Details
	significant allergy or serious adverse reaction prior to approval of Stimufend unless patient has a diagnosis of radiation syndrome.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

STIVARGA

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For GIST, (A or B): A) patient has previously been treated with (i and ii): i) imatinib or Ayvakit and ii) sunitinib or Sprycel, or B) medication is used as first-line therapy for succinate dehydrogenase (SDH)-deficient disease. For HCC, patient must have previously been treated with at least one systemic regimen. Soft tissue sarcoma, advanced or metastatic disease-approve if the patient has non-adipocytic sarcoma, angiosarcoma, or pleomorphic rhabdomyosarcoma. Bone Cancer-approve if the patient has relapsed/refractory or metastatic disease AND the patient has tried one systemic chemotherapy regimen AND pt has Ewing sarcoma or osteosarcoma. Colon and Rectal cancer/Appendiceal cancer-approve if the patient has advanced or metastatic disease, has been previously treated with a fluoropyrimidine, oxaliplatin, irinotecan and if the patient meets one of the following (i or ii): i. patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type), the patient has tried Erbitux or Vectibix or the patient's tumor did not originate on the left side of the colon (from the splenic fixture to rectum) or ii. the patient's tumor or metastases has a RAS mutation (either KRAS mutation or NRAS mutation). CNS tumors (Glioblastoma or H3-mutated high-grade glioma)-approve if the patient has recurrent or progressive disease. Uterine sarcoma- (A and B): A) pt has recurrent, advanced, inoperable, or metastatic disease, and B) tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SUCRAID

Products Affected

- SUCRAID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results (as specified in the Other Criteria field)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, gastroenterologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of congenital diarrheal disorders
Coverage Duration	1 year
Other Criteria	Approve if the patient meets the following criteria (A and B): A) The diagnosis is established by one of the following (i or ii): i. Patient has endoscopic biopsy of the small bowel with disaccharidase levels consistent with congenital sucrose-isomaltase deficiency as evidenced by ALL of the following (a, b, c, and d): a) Decreased (usually absent) sucrase (normal reference: greater than 25 U/g protein), b) Decreased or normal isomaltase (palatinase) [normal reference: greater than 5 U/g protein], c) Decreased maltase (normal reference: greater than 100 U/g protein), d) Decreased or normal lactase (normal reference: greater than 15 U/g protein) OR ii. Patient has a molecular genetic test demonstrating homozygous or compound heterozygous pathogenic or likely pathogenic sucrase-isomaltase gene variant AND B) Patient has symptomatic congenital sucrose-isomaltase deficiency (e.g., diarrhea, bloating, abdominal cramping).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

SUNITINIB

Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Gastrointestinal stromal tumors (GIST), approve if the patient has tried imatinib or Ayvakit or if the patient has succinate dehydrogenase (SDH)-deficient GIST. Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Medullary thyroid carcinoma, approve if the patient has tried at least one systemic therapy. Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried at least one systemic chemotherapy. Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or advanced disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease. Pheochromocytoma/paraganglioma-approve if the patient has unresectable or metastatic disease. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pending CMS Review
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

SUNOSI

Products Affected

- SUNOSI

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Sunosi with an oxybate product and/or Wakix (pitolisant tablets)
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Excessive daytime sleepiness associated with narcolepsy-prescribed by or in consultation with a sleep specialist physician or neurologist
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Excessive sleepiness associated with Obstructive Sleep Apnea-Approve if the patient has tried generic modafinil or generic armodafinil. Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil or Nuvigil. Excessive daytime sleepiness associated with Narcolepsy-Approve if patient has been evaluated using polysomnography and a multiple sleep latency test (MSLT) and the diagnosis of narcolepsy has been confirmed and if the patient has tried CNS stimulant, generic modafinil or generic armodafinil. Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil or Nuvigil.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SYMDEKO

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with other CF transmembrane conductance regulator modulators
Required Medical Information	Diagnosis, specific CFTR gene mutations
Age Restrictions	Six years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF - Approve if the pt meets A, B and C: A) pt has at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is considered to be pathogenic or likely pathogenic or patient has TWO copies of the F508 del mutation, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SYMLIN

Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

SYNAREL

Products Affected

- SYNAREL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Endometriosis-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Central Precocious Puberty-12 months, Endometriosis-6 months
Other Criteria	Central precocious puberty-approve. Endometriosis-approve if the patient has tried one of the following, unless contraindicated, a contraceptive, an oral progesterone or a depo-medroxyprogesterone injection. Note: An exception to the requirement for a trial of the above therapies can be made if the patient has previously used a gonadotropin-releasing hormone (GnRH) agonist or antagonist for endometriosis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TABRECTA

Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has advanced or metastatic disease AND the tumor is positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping or high-level MET amplification, as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer with high-level MET amplification.
Part B Prerequisite	No
Prerequisite Therapy Required	No

TADALAFIL

Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Treatment of erectile dysfunction (ED)
Required Medical Information	Indication for which tadalafil is being prescribed.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 mos.
Other Criteria	Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed as once daily dosing, to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TADLIQ

Products Affected

- TADLIQ

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, right heart cath results
Age Restrictions	N/A
Prescriber Restrictions	For PAH, prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Raynaud's Phenomenon-approve if the patient has tried one calcium channel blocker or if use of a calcium channel blocker is contraindicated. Patient must have tried generic sildenafil 20 mg tablets, Alyq, or generic tadalafil 20 mg tablets unless the patient cannot swallow or has difficulty swallowing generic sildenafil 20 mg tablets, Alyq or generic tadalafil 20 mg tablets or if the patient requires administration of a dose that cannot be obtained with generic tadalafil 20 mg tablets.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Raynaud's Phenomenon
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TAFAMIDIS

Products Affected

- VYNDAMAX
- VYNDAQEL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other medications indicated for polyneuropathy of hereditary transthyretin-mediated amyloidosis or transthyretin-mediated amyloidosis-cardiomyopathy (e.g., Amvuttra (vutrisiran subcutaneous injection), Attruby (acoramidis tablets), Onpattro (patisiran lipid complex intravenous infusion), Tegsedi (inotersen subcutaneous injection), or Wainua [eplontersen subcutaneous injection]). Concurrent use of Vyndaqel and Vyndamax.
Required Medical Information	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
Age Restrictions	18 years and 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 patient meets (A, B and C): A) the diagnosis was confirmed by one of the following (i, ii or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy), ii. tissue biopsy with confirmatory TTR amyloid typing by mass spectrometry, immunoelectron microscopy or immunohistochemistry OR iii. patient had genetic testing which, according to the prescriber, identified a TTR pathogenic variant AND B) Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum), and C) patient has heart failure but does not have NYHA class IV disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

TAFINLAR

Products Affected

- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Low grade glioma, solid tumors- 1 year and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Low grade glioma- approve if pt has BRAF V600 mutation-positive disease and this medication will be taken with Mekinist (trametinib). Melanoma with BRAF V600 mutation AND patient has unresectable, advanced (including Stage III or Stage IV disease) or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. NSCLC-approve if pt has recurrent, advanced, or metastatic disease AND BRAF V600 mutation-positive disease. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or oncocytic) AND recurrent or metastatic disease AND the patient has BRAF-positive disease. Histiocytic neoplasm-approve if (A and B): A) patient has Langerhans cell histiocytosis or Erdheim Chester disease AND B) patient has BRAF V600-mutation positive disease. Solid tumors [examples: biliary tract cancer, brain metastases due to melanoma, high-grade gliomas, ovarian/fallopian tube/primary peritoneal cancer, differentiated thyroid carcinoma, gastrointestinal stromal tumors, gastric cancer, esophageal and esophagogastric junction cancers, salivary gland tumors, occult primary, pancreatic adenocarcinoma, neuroendocrine tumors, ampullary adenocarcinoma]-approve if BRAF V600 mutation-positive disease AND</p>

PA Criteria	Criteria Details
	medication will be taken in combination with Mekinist (trametinib). Hairy Cell Leukemia, approve if pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Mekinist. Small bowel adenocarcinoma, approve if pt has BRAF V600E mutation-positive advanced or metastatic disease and this will be used with Mekinist AND (i or ii): i) this will be used as initial therapy and pt has received previous FOLFOX/CAPEOX therapy in the adjuvant setting within the past 12 months or has a contraindication, or (ii) this will be used as second-line and subsequent therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Histiocytic neoplasm, hairy cell leukemia
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TAGRISO

Products Affected

- TAGRISO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>NSCLC-EGFR Mutation Positive (other than EGFR T790M-Positive Mutation)- approve if the patient has advanced or metastatic disease, has EGFR mutation-positive NSCLC as detected by an approved test. Note-examples of EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. NSCLC-EGFR T790M mutation positive-approve if the patient has advanced or metastatic EGFR T790M mutation-positive NSCLC as detected by an approved test and has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors. NSCLC- Post resection-approve if the patient has completely resected disease and has received previous adjuvant chemotherapy or if the patient is ineligible to receive platinum based chemotherapy and the patient has EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test. NSCLC- Unresectable Stage III - approve if the patient has locally advanced, unresectable (stage III) disease AND EGFR exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an approved test AND not had disease progression during or following platinum-based chemoradiation therapy. (Note: Patients could have received concurrent or sequential chemoradiation therapy.)</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TAKHZYRO

Products Affected

- TAKHZYRO

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other HAE Prophylactic Therapies (e.g., Cinryze, Haegarda)
Required Medical Information	Diagnosis, lab values
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders (initial and continuation).
Coverage Duration	1 year
Other Criteria	Prophylaxis, initial therapy-approve if the patient meets all of the following criteria: 1) patient has HAE due to C1 Inhibitor (C1-INH) deficiency (Type I or II), AND 2) patient has low levels of functional C1-INH protein (less than 60 percent of normal) at baseline, as defined by the laboratory reference values, AND 3) patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Prophylaxis, continuation therapy-approve if the patient meets all of the following criteria: 1) patient is currently receiving Takhzyro for HAE type I or II, AND 2) according to the prescribing physician, the patient has had a favorable clinical response to therapy (e.g., decrease in number of HAE acute attack frequency, decrease in HAE attack severity, decrease in duration of HAE attacks).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

TALTZ

Products Affected

- TALTZ AUTOINJECTOR
- TALTZ SYRINGE SUBCUTANEOUS SYRINGE 20 MG/0.25 ML, 40 MG/0.5 ML, 80 MG/ML

PA Criteria	Criteria Details
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-6 years and older (initial therapy), all other dx-18 years of age and older (initial therapy)
Prescriber Restrictions	All dx initial therapy only-PP-Prescribed by or in consultation with a dermatologist. PsA prescribed by or in consultation with a rheumatologist or a dermatologist. AS/spondylo-prescribed by or in consultation with a rheum.
Coverage Duration	Approve through end of plan year
Other Criteria	PP, initial therapy - approve if pt has tried TWO of the following: Enbrel, a preferred adalimumab, Skyrizi, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya. [A trial of a non-preferred adalimumab or a non-preferred ustekinumab also count.] PsA, initial therapy - approve if pt has tried TWO of the following: Enbrel, a preferred adalimumab, Skyrizi, a preferred ustekinumab product, Otezla, Rinvoq, Cosentyx (IV or SC) or Tremfya. A trial of a non-preferred adalimumab, a non-preferred ustekinumab, Cimzia, infliximab, Simponi Aria/SC will also count. AS, initial therapy - approve if pt has tried TWO of the following: Enbrel, a preferred adalimumab, Rinvoq or Cosentyx (IV or SC). A trial of a non-preferred adalimumab, Cimzia, infliximab, Simponi Aria/SC will also count. Non-radiographic axial spondyloarthritis, initial therapy- approve if the patient has tried Cosentyx (IV or SC) or Rinvoq. For all covered indications for continuation of therapy, approve if the pt has responded to therapy. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred ustekinumab products include Selarsdi, Yesintek.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TALZENNA

Products Affected

- TALZENNA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Recurrent or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive disease. Prostate cancer - approve if the patient has metastatic castration resistant prostate cancer, AND is using this medication concurrently with a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy AND the patient has homologous recombination repair (HRR) gene-mutated disease [Note: HRR gene mutations include ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C] AND the medication is used in combination with Xtandi (enzalutamide capsules and tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TARPEYO

Products Affected

- TARPEYO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	10 months total therapy
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Pending CMS Review

TASCENSO

Products Affected

- TASCENSO ODT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agent used for multiple sclerosis.
Required Medical Information	Diagnosis
Age Restrictions	10 years and older
Prescriber Restrictions	Prescribed by or after consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAVALISSE

Products Affected

- TAVALISSE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Pending CMS Review
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by, or in consultation with a hematologist (initial therapy)
Coverage Duration	Initial-3 months, cont-1 year.
Other Criteria	Initial-Approve if the patient has a platelet count less than 30,000 microliters or less than 50,000 microliters and is at an increased risk of bleeding and has tried Promacta and Doptelet. A trial of Alvaiz would also count. Continuation-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TAVNEOS

Products Affected

- TAVNEOS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist (initial)
Coverage Duration	Initial-6 months, continuation-1 year
Other Criteria	<p>Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, initial-approve if the patient meets (i, ii, iii and iv): i. Patient has granulomatosis with polyangiitis or microscopic polyangiitis, Note: Granulomatosis with polyangiitis is also known as Wegener's granulomatosis AND ii. Patient has active disease, Note: This includes patients that have newly diagnosed or relapsed disease. This does not include patients already in remission. AND iii. Patient is positive for proteinase 3 antibodies, or anti-neutrophil cytoplasmic autoantibody (ANCA) or myeloperoxidase antibodies, AND iv. Patient is using this medication in combination with at least one immunosuppressant Note: Examples of immunosuppressants include methotrexate, rituximab, azathioprine, or mycophenolate mofetil. Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, continuation-approve if the patient meets at least one of the following (a or b): a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Tavneos), OR Note: Examples of objective measure include improvement in estimated glomerular filtration rate, decrease in urinary albumin creatinine ratio, or improvement in the Birmingham Vasculitis Activity Score [BVAS]. b) Compared with baseline (prior to receiving Tavneos), patient experienced an improvement in at least one symptom, such as joint pain, ulcers, myalgia, persistent</p>

PA Criteria	Criteria Details
	cough, skin rash or abdominal pain, or improvement in function or activities of daily living.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAZAROTENE

Products Affected

- ARAZLO
- FABIOR
- *tazarotene topical cream*
- TAZAROTENE TOPICAL FOAM
- *tazarotene topical gel*

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic uses
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAZVERIK

Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Epithelioid Sarcoma-16 years and older, Follicular Lymphoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Epithelioid Sarcoma-approve if the patient has metastatic or locally advanced disease and the patient is not eligible for complete resection. Follicular Lymphoma-approve if the patient has relapsed or refractory disease and there are no appropriate alternative therapies or the patient has tried at least two prior systemic therapies.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TEPMETKO

Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NSCLC-approve if the patient has advanced or metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutations or patient has high-level MET amplification, as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-small cell lung cancer with high-level MET amplification.
Part B Prerequisite	No
Prerequisite Therapy Required	No

TERIPARATIDE

Products Affected

- BONSITY
- *teriparatide (preferred ndcs starting with 47781)*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	High risk for fracture-2 yrs, Not high risk-approve a max of 2 yrs of therapy (total)/lifetime.
Other Criteria	<p>INITIAL THERAPY: Postmenopausal Osteoporosis (PMO) Treatment, Increase Bone Mass in Men (see Note 1 below) with Primary or Hypogonadal Osteoporosis, and Treatment of Glucocorticosteroid-Induced Osteoporosis (GIO): (one of A, B, C, D or E): A) tried one oral bisphosphonate or cannot take due to swallowing difficulties or inability to remain upright after administration, B) pre-existing gastrointestinal condition (e.g., esophageal lesions/ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), C) tried an IV bisphosphonate (PMO-ibandronate or zoledronic acid, all other diagnoses-zoledronic acid), D) severe renal impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past.</p> <p>CONTINUATION THERAPY: ALL INDICATIONS: if the patient has taken teriparatide for two years, approve if the patient is at high risk for fracture. Examples of high risk for fracture include a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, and very low bone mineral density. Note 1: a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.</p>
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TETRABENAZINE

Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.
Part B Prerequisite	No
Prerequisite Therapy Required	No

THALOMID

Products Affected

- THALOMID ORAL CAPSULE 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	MM, histiocytic neoplasms-18 years and older, medulloblastoma- less than 18 years old
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Erythem Nodosum Leprosum-approve. Multiple Myeloma-approve. Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried at least two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Prurigo nodularis, approve. Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried at least two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). Kaposi Sarcoma-approve if the patient has tried at least one medication AND has relapsed or refractory disease. Castleman disease-approve if the patient has multicentric disease and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). Histiocytic neoplasms-approve if (A or B): A) pt has Langerhans cell histiocytosis with either (i or ii): i) single-system multifocal skin disease or ii) relapsed or refractory disease, or B) pt has Rosai-Dorfman cutaneous disease. Medulloblastoma- approve if pt has recurrent or progressive disease AND medication is being used as a part of the MEMMAT regimen (i.e. Thalomid, celecoxib, fenofibrate, oral etoposide, cyclophosphamide, bevacizumab, and intraventricular etoposide).

PA Criteria	Criteria Details
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Discoid lupus erythematosus or cutaneous lupus erythematosus, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi Sarcoma, Castleman Disease, histiocytic neoplasms, medulloblastoma.
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TIBSOVO

Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, IDH1 Status
Age Restrictions	All diagnoses (except chondrosarcoma)-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML- approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive, as detected by an approved test. Cholangiocarcinoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive and has been previously treated with at least one chemotherapy regimen (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan). Chondrosarcoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. Central nervous system cancer-approve if the patient has oligodendroglioma or astrocytoma. Myelodysplastic Syndrome-approve if patient has isocitrate dehydrogenase-1 (IDH1) mutation-positive disease AND relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chondrosarcoma, Central nervous system cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TIOPRONIN

Products Affected

- *tiopronin*
- *venxxiva*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, weight, laboratory testing, therapies tried
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a nephrologist, urologist, or physician who specializes in the treatment of cystinuria
Coverage Duration	Authorization will be for 1 year
Other Criteria	Cystinuria- approve if the patient weighs greater than or equal to 20 kilograms AND cystinuria has been confirmed based on laboratory testing (e.g., urinary cystine crystals present on microscopy, quantitative urine cystine assay) AND patient has had an inadequate response to high fluid intake, dietary modification, and urinary alkalization.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOBRAMYCIN (NEBULIZATION)

Products Affected

- KITABIS PAK
- *tobramycin inhalation*
- *tobramycin in 0.225 % nacl*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Bronchiectasis, Non-cystic fibrosis-18 years and older
Prescriber Restrictions	CF-prescr/consult w/pulm/phys specializes in tx of CF.Bronchiectasis, non CF-prescr/consult w/pulm
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Cystic fibrosis/Bronchiectasis, non-cystic fibrosis-approve if the patient has pseudomonas aeruginosa in the culture of the airway.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bronchiectasis, non-cystic fibrosis
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOLCAPONE

Products Affected

- *tolcapone*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, current medications and medication history (as described in Other Criteria)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's disease-approve if the patient is currently receiving carbidopa/levodopa therapy AND the patient has tried entacapone or Ongentys (opicapone) and according to the prescriber, experienced significant intolerance or inadequate efficacy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TOLSURA

Products Affected

- TOLSURA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, current medications and medication history (as described in Other Criteria)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Pending CMS Review
Other Criteria	Blastomycosis-pulmonary or extrapulmonary, treatment, Histoplasmosis (Including Chronic Cavitory Pulmonary Disease and Disseminated, Non-Meningeal)-treatment, Aspergillosis-pulmonary or extrapulmonary, treatment-approve if the patient has tried itraconazole capsules or oral solution OR if the patient is currently receiving Tolsura for the diagnosis provided
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TOLVAPTAN

Products Affected

- *tolvaptan*

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Jynarque.
Required Medical Information	Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 30 days for initial therapy, 3 months for continuation of therapy
Other Criteria	Hyponatremia, initial therapy (including new starts, patients on therapy for less than 30 days, and patients restarting therapy) - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on tolvaptan and has received less than 30 days of therapy. Hyponatremia, continuation of therapy for patients established on therapy for at least 30 days - approve if the serum sodium level has increased from baseline (prior to initiating the requested drug) OR if the patient experienced improvement in at least one symptom, such as nausea, vomiting, headache, lethargy, or confusion.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOPICAL AGENTS FOR ATOPIC DERMATITIS

Products Affected

- EUCRISA
- *pimecrolimus*
- *tacrolimus topical*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TOPICAL ALPHA-ADRENERGIC AGENTS FOR ROSACEA

Products Affected

- *brimonidine topical*

PA Criteria	Criteria Details
Exclusion Criteria	Use in the treatment of erythema not caused by rosacea (ie, transient) [eg, during times of stress, sunburn, or skin irritation from cosmetic products].
Required Medical Information	N/A
Age Restrictions	18 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOPICAL RETINOID PRODUCTS

Products Affected

- *adapalene topical cream*
- *adapalene topical gel 0.3 %*
- AKLIEF
- ALTRENO
- *tretinoin topical*

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for cosmetic use.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOPIRAMATE/ZONISAMIDE

Products Affected

- *topiramate oral capsule, sprinkle 15 mg, 25 mg*
- *topiramate oral capsule, extended release 24hr*
- *topiramate oral capsule, sprinkle, er 24hr*
- *topiramate oral solution*
- *topiramate oral tablet*
- ZONISADE
- *zonisamide*

PA Criteria	Criteria Details
Exclusion Criteria	Coverage is not provided for weight loss or smoking cessation.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRANSDERMAL FENTANYL

Products Affected

- *fentanyl*

PA Criteria	Criteria Details
Exclusion Criteria	Acute (i.e., non-chronic) pain.
Required Medical Information	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, 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. Patients with cancer, sickle cell disease, in hospice or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids (including transdermal fentanyl products) require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Pending CMS Review

TRELSTAR

Products Affected

- TRELSTAR INTRAMUSCULAR
SUSPENSION FOR RECONSTITUTION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prostate cancer: Prescribed by or in consultation with a oncologist or urologist. Head and neck cancer - salivary gland tumors: Prescribed by or in consultation with a oncologist.
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Prostate cancer: Patients new to therapy, are required to try Eligard prior to approval of Trelstar. Head and neck cancer - salivary gland tumors: approve if patient has recurrent, unresectable, or metastatic disease and androgen receptor-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Head and neck cancer - salivary gland tumors
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TREMFYA SC

Products Affected

- TREMFYA PEN INDUCTION PK-CROHN
- TREMFYA PEN SUBCUTANEOUS PEN INJECTOR 200 MG/2 ML
- TREMFYA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis
Age Restrictions	PP/UC/CD/PsA-18 years of age and older (initial therapy)
Prescriber Restrictions	PP-Prescribed by or in consultation with a dermatologist (initial therapy only). PsA-prescribed by or in consultation with a dermatologist or rheumatologist (initial therapy). UC/CD-prescribed by or in consultation with a gastroenterologist (initial therapy).
Coverage Duration	Approve through end of plan year
Other Criteria	PP, initial therapy - approve if the pt meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: a biologic that is not a biosimilar of the requested product will also count) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. ULCERATIVE COLITIS- pt will receive 3 induction doses with Tremfya IV within 3 months of initiating Tremfya SC AND (A or B): A) tried a systemic therapy (e.g., 6-MP, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a CS) or B) has pouchitis and tried therapy with an antibiotic, probiotic, CS enema, or mesalamine (Rowasa) enema. CROHN'S DISEASE (CD) [one of A, B, C, or D]: A) tried or currently taking corticosteroid (CS) or CS is contraindicated, B) tried one other conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX], certolizumab, infliximab, ustekinumab, vedolizumab), C) had ileocolonic resection, or D) enterocutaneous (perianal or abdominal) or rectovaginal fistulas. PP/PsA/UC/CD continuation of therapy - approve if the pt is responding to therapy.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TRIENTINE

Products Affected

- CUVRIOR
- *trientine oral capsule 250 mg*
- TRIENTINE ORAL CAPSULE 500 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.
Coverage Duration	Authorization will be for 1 year
Other Criteria	For Wilson's Disease, approve if the patient meets A and B: A) Diagnosis of Wilson's disease is confirmed by ONE of the following (i or ii): i. Genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals), OR ii. Confirmation of at least two of the following (a, b, c, or d): a. Presence of Kayser-Fleischer rings, OR b. Serum ceruloplasmin levels less than 20mg/dL, OR c. Liver biopsy findings consistent with Wilson's disease, OR d. 24-hour urinary copper greater than 40 micrograms/24 hours, AND B) Patient meets ONE of the following: 1) Patient has tried a penicillamine product and per the prescribing physician the patient is intolerant to penicillamine therapy, OR 2) Per the prescribing physician, the patient has clinical features indicating the potential for intolerance to penicillamine therapy (ie, history of any renal disease, congestive splenomegaly causing severe thrombocytopenia, autoimmune tendency), OR 3) Per the prescribing physician, the patient has a contraindication to penicillamine therapy, OR 4) The patient has neurologic manifestations of Wilson's disease, OR 5) The patient is pregnant , OR 6) the patient has been started on therapy with trientine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TRIKAFTA

Products Affected

- TRIKAFTA ORAL GRANULES IN PACKET, SEQUENTIAL
- TRIKAFTA ORAL TABLETS, SEQUENTIAL

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with other CF transmembrane conductance regulator modulators.
Required Medical Information	Diagnosis
Age Restrictions	2 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF -Approve if the pt meets A, B and C: A) pt has at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is considered to be pathogenic or likely pathogenic variant, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations or (iii) abnormal nasal potential difference.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRUQAP

Products Affected

- TRUQAP

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast Cancer-Approve if the patient meets the following (A, B, C, D and E): A) Patient has locally advanced or metastatic disease, AND B) Patient has hormone receptor positive (HR+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has at least one phosphatidylinositol 3-kinase (PIK3CA), serine/threonine protein kinase (AKT1), or phosphatase and tensin homolog (PTEN)-alteration, AND E) Patient meets one of the following (i or ii): i. Patient has had progression with at least one endocrine-based regimen in the metastatic setting (Note: Examples of endocrine therapy include anastrozole, exemestane, and letrozole.) and has had progression with at least one cyclin-dependent kinase (CDK) 4/6 inhibitor in the metastatic setting (Note: Examples of CDK4/6 inhibitor include: Ibrance (palbociclib tablets or capsules), Verzenio (abemaciclib tablets), Kisqali (ribociclib tablets), Kisqali Femara Co-Pack (ribociclib and letrozole tablets) OR ii. Patient has recurrence on or within 12 months of completing adjuvant endocrine therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

TRYNGOLZA

Products Affected

- TRYNGOLZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by a cardiologist, an endocrinologist, or a physician who focuses in the treatment of disorders related to severe hypertriglyceridemia.
Coverage Duration	1 year
Other Criteria	FAMILIAL CHYLOMICRONEMIA SYNDROME (all of A, B and C): A) Fasting triglyceride level greater than or equal to 880 mg/dL, AND B) Patient has undergone genetic testing and meets ONE of the following (i or ii): i. Molecular genetic test results demonstrate biallelic pathogenic variants in at least one gene causing familial chylomicronemia syndrome. Note: Examples of genes causing Familial Chylomicronemia Syndrome include lipoprotein lipase (LPL), glycosylphosphatidylinositol-anchored high-density lipoprotein-binding protein 1 (GPIHBP1), apolipoprotein A-V (APOA5), apolipoprotein C-II (APOC2), or lipase maturation factor 1 (LMF1), OR ii. Molecular genetic test results are inconclusive and the patient has ONE of the following (a, b, c, d, or e): a) Familial chylomicronemia syndrome score greater than or equal to 10, OR b) North American familial chylomicronemia syndrome score greater than or equal to 45, OR c) History of pancreatitis, OR d) History of eruptive xanthomas, OR e) History of lipemia retinalis, AND C) The medication will be used concomitantly with a low-fat diet.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

TRYVIO

Products Affected

- TRYVIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>HYPERTENSION-approve if the patient has tried, or is currently receiving, at least TWO other antihypertensive agents for the treatment of hypertension from at least TWO of the following pharmacological classes (i, ii, iii, iv, v, vi, vii, viii, ix, x) [A combination product from two or more different classes would count as an alternative from each class]:</p> <p>i. Angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) [e.g., benazepril, lisinopril, candesartan, losartan], ii. Non-dihydropyridine calcium channel blocker (e.g., diltiazem, verapamil), iii. Dihydropyridine calcium channel blocker (e.g., amlodipine, felodipine), iv. Diuretic (e.g., hydrochlorothiazide, chlorthalidone, amiloride), v. Mineralocorticoid receptor antagonist e.g., spironolactone, eplerenone), vi. Beta blocker (e.g., atenolol, metoprolol), vii. Alpha-adrenergic blocker (e.g., doxazosin, terazosin), viii. Central alpha-adrenergic agonist (e.g., clonidine, guanfacine), ix. Direct vasodilator (e.g., hydralazine, minoxidil), x.Direct renin inhibitor (e.g., aliskiren).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

TUKYSA

Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast Cancer-approve if the patient has recurrent 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. Colon/Rectal Cancer-approve if the requested medication is used in combination with trastuzumab, patient has unresectable or metastatic disease, human epidermal growth factor receptor 2 (HER2)-amplified disease, AND Patient's tumor or metastases are wild-type RAS (KRAS wild-type and NRAS wild-type). Biliary tract cancer- approve if the patient meets all of (a, b, c, and d): a) unresectable or metastatic disease, b) HER2 positive disease, c) tried at least one systemic regimen, d) will use in combination with trastuzumab.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Biliary tract cancer
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

TURALIO

Products Affected

- TURALIO ORAL CAPSULE 125 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis)-approve if, according to the prescriber, the tumor is not amenable to improvement with surgery. Histiocytic Neoplasms-approve if the patient has a colony stimulating factor 1 receptor (CSF1R) mutation AND has one of the following conditions (i, ii, or iii): i. Langerhans cell histiocytosis OR ii. Erdheim-Chester disease OR iii. Rosai-Dorfman disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Histiocytic Neoplasms
Part B Prerequisite	No
Prerequisite Therapy Required	No

TYENNE SC

Products Affected

- TYENNE AUTOINJECTOR
- TYENNE SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	Interstitial lung disease-18 years and older (initial and continuation). GCA/RA-18 years and older (initial only). SJIA/PJIA-2 years and older (initial only).
Prescriber Restrictions	RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont)
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA) [A or B]: A) tried one of the following: Enbrel, preferred adalimumab product (see Example 1), Rinvoq or Xeljanz/XR (Note: trials with the following will also count: Cimzia, infliximab, Kevzara, golimumab SC/IV, non-preferred adalimumab product, Orencia), or B) heart failure or a previously treated lymphoproliferative disorder. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) [A or B]: A) tried one of the following: Enbrel, Rinvoq, Xeljanz, preferred adalimumab product. (Note: trials with Kevzara, infliximab, Orencia or a non-preferred adalimumab product will also count), or B) heart failure or a previously treated lymphoproliferative disorder. SYSTEMIC-ONSET JIA (SJIA) [one of A, B, or C]: A) tried one other systemic agent (e.g., corticosteroid [CS], conventional synthetic DMARD [e.g., MTX, leflunomide, sulfasalazine], or B) tried Kineret (anakinra) or Ilaris (canakinumab for SC injection), or C) one-month trial of an NSAID. GIANT CELL ARTERITIS: tried one systemic CS. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS (A and B): A) elevated acute phase reactants and B) diagnosis confirmed by high-resolution computed tomography. CONTINUATION THERAPY: ALL INDICATIONS: patient had a

PA Criteria	Criteria Details
	response to therapy. Example 1: preferred adalimumab products include Hadlima, Simlandi.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TYMLOS

Products Affected

- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, calcitonin nasal spray [Fortical], Forteo), Evenity, except calcium and Vitamin D. Previous use of Tymlos for a combined total no greater than 2 years duration during a patient's lifetime.
Required Medical Information	Previous medications tried, renal function
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 2 years of total therapy over a patient's lifetime
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TYVASO DPI

Products Affected

- TYVASO DPI INHALATION 16(112)-32(112) -48(28) MCG, 32 MCG, CARTRIDGE WITH INHALER 16 MCG, 48 MCG, 64 MCG

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with oral or parenteral prostacyclin agents used for pulmonary hypertension
Required Medical Information	Diagnosis
Age Restrictions	Pulmonary Hypertension w/Interstitial lung disease - 18 years and older (initial/cont)
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist or a pulmonologist (initial and continuation).
Coverage Duration	PAH, WHO Group 1-1 year (initial/cont). Pulmonary HTN w/lung disease- Initial-4 months, cont-1 year
Other Criteria	PAH, WHO Group 1, initial therapy-approve if the patient has had a right heart catheterization to confirm the diagnosis and if the patient meets i or ii: i. Patient has Functional Class III or IV or, ii. Patient is in Functional Class II and the patient has tried or is currently receiving one of Opsumit, Adempas or Uptravi OR the patient has tried one inhaled or parenteral prostacyclin product for PAH. Note: A trial of any other endothelin receptor antagonist, PDE5 inhibitor, inhaled prostacyclin product or oral prostacyclin product would also count if the patient has not tried Opsumit, Adempas Or Uptravi. Continuation-approve if the patient has had a right heart catheterization to confirm the diagnosis. Pulmonary Hypertension associated with interstitial lung disease, WHO Group 3 (this involves diagnosis such as idiopathic interstitial pneumonia, combined pulmonary fibrosis and emphysema, WHO Group 3 connective disease and chronic hypersensitivity pneumonitis), initial therapy - approve if (A, B and C): A) the patient has had a right heart catheterization to confirm the diagnosis and B) if the patient has connective tissue disease, the pt must have a baseline forced vital capacity less than 70 percent and C) the patient has evidence of diffuse parenchymal lung disease on computed tomography of the chest. Continuation- approve if the patient has had a right heart catheterization to confirm the diagnosis and has had a response to therapy.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

UBRELVY

Products Affected

- UBRELVY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Migraine, Acute treatment-approve if the patient has tried at least one triptan or has a contraindication to triptans.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

UDENYCA

Products Affected

- UDENYCA
- UDENYCA AUTOINJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation. Radiation syndrome-prescribed by or in consultation with a physician who has expertise in treating acute radiation syndrome.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC/Radiation Syndrome-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) 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), 2) 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 according to the prescribing physician (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status or HIV infection patients with low CD4 counts), or 3) patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. Patients are required to try Fulphila and Nyvepria and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or

PA Criteria	Criteria Details
	surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Udenyca unless patient has a diagnosis of radiation syndrome.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

UPTRAVI

Products Affected

- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLETS,DOSE PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Inhaled or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension.
Required Medical Information	Confirmation of right heart catheterization, medication history (as described in Other Criteria)
Age Restrictions	N/A
Prescriber Restrictions	PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Patient new to Upravi therapy must meet a) OR b): a) tried one or is currently taking one oral therapy for PAH for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, or epoprostenol injection).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

USTEKINUMAB SC

Products Affected

- OTULFI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- PYZCHIVA SUBCUTANEOUS SOLUTION
- PYZCHIVA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- SELARSDI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- STELARA SUBCUTANEOUS SOLUTION
- STEQEYMA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- USTEKINUMAB SUBCUTANEOUS SOLUTION
- USTEKINUMAB-AEKN SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- USTEKINUMAB-TTWE SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- WEZLANA SUBCUTANEOUS SOLUTION
- WEZLANA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- YESINTEK SUBCUTANEOUS SOLUTION
- YESINTEK SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	PP/PsA-6 years and older (initial therapy). UC/CD-18 years and older (initial therapy)
Prescriber Restrictions	Plaque psoriasis.Prescribed by or in consultation with a dermatologist (initial therapy only). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy only). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy only).
Coverage Duration	Approve through end of plan year
Other Criteria	INITIAL THERAPY: PLAQUE PSORIASIS (PP) [A or B]: A) tried one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, psoralen plus PUVA) for at least 3 months, unless intolerant or B) contraindication to MTX. (Note: a 3-month trial or intolerance of at least one biologic that is not ustekinumab also counts.) CROHN'S DISEASE (CD) [A and B]: A) receiving/received single IV loading dose within 2

PA Criteria	Criteria Details
	<p>months of initiating therapy with ustekinumab SC, and B) (a, b, c or d): a) tried or is currently taking corticosteroids (CS), or CS are contraindicated, b) tried one conventional systemic therapy, c) has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, or d) had ileocolonic resection to reduce the chance of CD recurrence. ULCERATIVE COLITIS (UC) [A and B]: A) receiving/received single IV loading dose within 2 months of initiating therapy with ustekinumab SC and B) meets one of the following (a or b): a) tried one systemic agent or b) has pouchitis and tried an antibiotic, probiotic, CS enema or mesalamine enema.</p> <p>CONTINUATION THERAPY: PP/PsA/CD/UC: patient has responded to therapy. ALL INDICATIONS, INITIAL AND CONTINUATION in addition to the above criteria: patients requesting a non-preferred ustekinumab product must try two of the following preferred ustekinumab products first: Selarsdi, Yesintek.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VALCHLOR

Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Cutaneous lymphoma-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
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 smoldering subtype of adult T-cell leukemia/lymphoma. Langerhans cell histiocytosis-approve if the patient has unifocal Langerhans cell histiocytosis with isolated skin disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Adults with T-cell leukemia/lymphoma, Langerhans Cell Histiocytosis
Part B Prerequisite	No
Prerequisite Therapy Required	No

VALTOCO

Products Affected

- VALTOCO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, other medications used at the same time
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiseizure medication(s).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VANCOMYCIN

Products Affected

- *vancomycin oral capsule 125 mg, 250 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	2 weeks
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VANFLYTA

Products Affected

- VANFLYTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Acute Myeloid Leukemia: approve if the patient has FLT3-ITD mutation-positive disease as detected by an approved test. Myeloid or lymphoid neoplasms: approve if patient has eosinophilia and the tumor has FLT3 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Myeloid or lymphoid neoplasms
Part B Prerequisite	No
Prerequisite Therapy Required	No

VANRAFIA

Products Affected

- VANRAFIA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other medications indicated for the treatment of immunoglobulin A nephropathy
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist (initial and continuation)
Coverage Duration	9 months
Other Criteria	<p>PRIMARY IMMUNOGLOBULIN A NEPHROPATHY, INITIAL-All of the following (i and ii): i. Diagnosis has been confirmed by biopsy, AND ii. Patient is at high risk of disease progression, defined by meeting BOTH of the following (a and b): a. Patient meets ONE of the following [(1) or (2)]: 1. Proteinuria greater than or equal to 0.5 g/day, OR 2. Urine protein-to-creatinine ratio greater than or equal to 1.5 g/g, AND b. Patient has received or is currently receiving the maximum or maximally tolerated dose of ONE of the following prior to starting Vanrafia [(1) or (2)]: 1. Angiotensin converting enzyme inhibitor, OR 2. Angiotensin receptor blocker. PRIMARY IMMUNOGLOBULIN A NEPHROPATHY, CONTINUATION- All of the following (i and ii): i. Diagnosis has been confirmed by biopsy, AND ii. Patient has had a response to Vanrafia, Note: Examples of a response are a reduction in urine protein-to-creatinine ratio from baseline, reduction in proteinuria from baseline.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

VELSIPITY

Products Affected

- VELSIPITY

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs) or with other potent immunosuppressants.
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist (initial therapy only)
Coverage Duration	Approve through end of plan year
Other Criteria	Ulcerative colitis, initial therapy-approve if the patient has had a trial of TWO of the following: a preferred adalimumab product, a preferred ustekinumab product, Skyrizi, Tremfya, a preferred infliximab product, Rinvoq. A trial of a non-preferred infliximab product, a non-preferred ustekinumab, Simponi SC, Entyvio IV/SC, Omvoh IV/SC, or a Non-Preferred adalimumab product will also count. Ulcerative colitis, continuation-approve if the patient has had a response. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand name product), Zymfentra. Preferred ustekinumab products include Selarsdi, Yesintek.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VENCLEXTA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy
Age Restrictions	18 years and older (all diagnoses except ALL)
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML-approve if used in combination with azacitidine, decitabine, or cytarabine. CLL/SLL- approve. ALL- approve if relapsed/refractory disease and will be used in combination with chemotherapy. Hairy cell leukemia- approve if disease resistance to BRAF inhibitor therapy. Mantle Cell Lymphoma- approve if (A or B): A) the patient has tried at least one systemic regimen or B) patient has TP53 mutation and will use this as induction therapy in combination with Brukinsa (zanubrutinib) and Gazyva (obinutuzumab intravenous infusion). MDS- approve if pt meets (A and B): A) pt meets (i or ii): (i) has chronic myelomonocytic leukemia-2 or (ii) has higher risk disease (note: includes international prognostic scoring system (IPSS-R) intermediate-, high-, or very-high risk disease) and B) will use in combination with azacitidine or decitabine. Myeloproliferative neoplasm- approve if pt has accelerated or blast phase disease and will use in combination with azacitidine or decitabine. Multiple Myeloma- approve if the patient has t (11,14) translocation AND has tried at least one systemic regimen for multiple myeloma AND Venclexta will be used in combination with dexamethasone. Systemic light chain amyloidosis-approve if the patient has t (11, 14) translocation and has tried at least one systemic regimen. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Mantle Cell Lymphoma, waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, multiple myeloma, systemic light chain amyloidosis, acute lymphoblastic leukemia, hairy cell leukemia, myelodysplastic syndrome, myeloproliferative neoplasm
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VEOZAH

Products Affected

- VEOZAH

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VERKAZIA

Products Affected

- VERKAZIA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	4 years and older
Prescriber Restrictions	Prescribed by or in consultation with an optometrist or ophthalmologist
Coverage Duration	1 year
Other Criteria	<p>Vernal keratoconjunctivitis-approve if the patient has moderate to severe vernal keratoconjunctivitis and patient meets one of the following (i or ii):</p> <p>i. Patient has tried two single-action ophthalmic medications (i.e., ophthalmic mast-cell stabilizers or ophthalmic antihistamines) for the maintenance treatment of vernal keratoconjunctivitis Note: Examples of single-action ophthalmic medications for the maintenance treatment of vernal keratoconjunctivitis include ophthalmic mast-cell stabilizers (e.g., cromolyn ophthalmic solution, Alomide ophthalmic solution) and ophthalmic antihistamines (e.g., Zerviate [cetirizine solution]), OR ii. Patient has tried one dual-action ophthalmic mast-cell stabilizer/antihistamine product for the maintenance treatment of vernal keratoconjunctivitis. Note: Examples of dual-action ophthalmic mast-cell stabilizer/antihistamine products include azelastine ophthalmic solution, beoptastine ophthalmic solution, epinastine ophthalmic solution, ketotifen ophthalmic solution, Lastacraft, and olopatadine ophthalmic solution. Note: An exception to the requirement for a trial of two single-action ophthalmic medications (i.e., ophthalmic mast-cell stabilizers or ophthalmic antihistamines) or one dual-action ophthalmic mast-cell stabilizer/antihistamine product for the maintenance treatment of vernal keratoconjunctivitis can be made if the patient has already tried at least one ophthalmic cyclosporine product (e.g., Cequa [cyclosporine 0.09%</p>

PA Criteria	Criteria Details
	ophthalmic solution], Restasis [cyclosporine 0.05% ophthalmic emulsion]) other than the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VERZENIO

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Breast Cancer, Early-pt meets (A,B,C and D): A)Pt HR+disease, AND B) HER2-negative breast cancer, AND C)node-positive disease at high risk of recurrence AND D)meets 1 of the following (i or ii): i.Verzenio will be used in combo w/anastrozole, exemestane, or letrozole AND pt meets one of the following (a,b, or c): a)Pt is postmenopausal woman, OR b)Pt is pre/perimenopausal woman and meets one of the following 1 or 2:1-Pt receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Pt had surgical bilateral oophorectomy or ovarian irradiation, OR c)Pt is man and pt is receiving a GnRH analog, OR ii.Verzenio will be used in combo with tamoxifen AND pt meets 1 of the following (a or b): a)Pt is postmenopausal woman or man OR b)Pt is pre/perimenopausal woman and meets 1 of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Pt had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer-Recurrent or Metastatic in Women-pt meets (A, B and C): A)has HR+ disease, AND B)Pt meets 1 of following criteria (i or ii): i.Pt is postmenopausal woman, OR ii.Pt is pre/perimenopausal woman and meets 1 of the following (a or b): a)receiving ovarian suppression/ablation with a GnRH agonist, OR b)Pt had surgical bilateral oophorectomy or ovarian irradiation, AND C) either (1 or 2): 1) HER2-negative breast cancer and Pt meets 1 of following criteria (i, ii, or iii): i.Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with</p>

PA Criteria	Criteria Details
	<p>fulvestrant, OR iii.pt meets following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least 1 prior endocrine therapy, AND c)has tried chemo for metastatic breast cancer or 2)has HER2-positive breast cancer and has received at least 3 prior anti-HER2-based regimens in metastatic setting and will use this in combo with fulvestrant and trastuzumab.Breast Cancer-Recurrent or Metastatic in Men-pt meets following criteria (A and B): A)HR+ disease, AND B)either (1 or 2): 1) HER2-negative disease and Pt meets 1 of following criteria (i, ii, or iii): i.Pt meets BOTH of the following conditions (a and b): a)receiving a GnRH analog, AND b)Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.Pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least 1 prior endocrine therapy, AND c)Pt has tried chemo for metastatic breast cancer, or 2) has HER2-positive disease and has received at least 3 prior anti-HER2-based regimen in metastatic setting and will use this medication in combo with fulvestrant and trastuzumab. Endometrial cancer-pt meets all of (A, B, And C): A)has recurrent or metastatic disease, and B)has estrogen receptor (ER)-positive tumors, and C)will be using in combination with letrozole.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Endometrial cancer
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VIGABATRIN

Products Affected

- *vigabatrin*
 - *vigadrone*
- VIGAFYDE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medication history (complex partial seizures)
Age Restrictions	Refractory complex partial seizures - patients 2 years of age or older. Infantile spasms - patients less than or equal to 2 years of age
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist
Coverage Duration	Infantile spasms- 6 mo. Treatment-Refractory Partial Seizures-initial therapy 3 mo, cont-1 year
Other Criteria	Infantile spasms-requested medication is being used as monotherapy. Treatment refractory complex partial seizures intial-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs. Treatment refractory complex partial seizures continuation- the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VIJOICE

Products Affected

- VIJOICE ORAL GRANULES IN PACKET
- VIJOICE ORAL TABLET 125 MG, 250 MG/DAY (200 MG X1-50 MG X1), 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a physician that specializes in treatment of genetic disorder (initial therapy)
Coverage Duration	Initial-6 months, continuation- 1 year
Other Criteria	<p>PIK3CA-Related Overgrowth Spectrum (PROS), initial therapy-Approve if the patient has at least one severe clinical manifestation of PROS and the patient has a PIK3CA mutation as confirmed by genetic testing Note: Examples of severe clinical manifestations include excessive tissue growth, blood vessel malformations, scoliosis, vascular tumors, cardiac or renal manifestations, and those that require systemic treatment. PIK3CA-Related Overgrowth Spectrum (PROS), continuation-Approve if the patient has been established on Vioice for at least 6 months and has experienced a reduction in volume from baseline (prior to initiating Vioice) in at least one lesion as confirmed by measurement and has experienced an improvement in at least one sign or symptom of PROS from baseline (prior to initiating Vioice) Note: Examples of signs or symptoms of PROS include pain, fatigue, vascular malformation, limb asymmetry, or disseminated intravascular coagulation.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

VITRAKVI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, NTRK gene fusion status
Age Restrictions	Pediatric Diffuse High-Grade Glioma- less than or equal to 21 years old
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Solid tumors - approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity. Pediatric diffuse high grade glioma - approve if (A and B): A) tumor is positive for NTRK gene fusion and B) meets (i or ii): i) medication is used as adjuvant therapy or ii) medication is used for recurrent or progressive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pediatric Diffuse High-Grade Glioma
Part B Prerequisite	No
Prerequisite Therapy Required	No

VIVJOA

Products Affected

- VIVJOA

PA Criteria	Criteria Details
Exclusion Criteria	Patients must not be pregnant or breastfeeding or have reproductive potential (a person who is NOT of reproductive potential is defined as a person who is a biological female who is postmenopausal or has another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy))
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Monotherapy-12 weeks, Combination use with fluconazole-14 weeks
Other Criteria	Recurrent vulvovaginal candidiasis, initial therapy-approve if the patient has had at least three episodes of vulvovaginal candidiasis in a 12-month period and has tried oral fluconazole as maintenance therapy and had inadequate efficacy [Note: Maintenance dosing should be for 30 days], OR Patient meets one of the following (a, b, or c): a. Oral fluconazole is not clinically appropriate for the patient due to drug-drug interactions, as determined by the prescriber, OR b. Patient has a fluconazole allergy or intolerance, as determined by the prescriber, OR c. Patient is being treated for a Candida species that is not susceptible to fluconazole, as determined by the prescriber. Recurrent vulvovaginal candidiasis, continuation-approve if the patient has already started on Vivjoa therapy (to complete the course of treatment).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

VIZIMPRO

Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, EGFR status, exon deletions or substitutions
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	NSCLC-approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VONJO

Products Affected

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Myelofibrosis (MF), including primary MF, post-polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient meets either (A, B, or C): (A) meets (i and ii): i) the patient has a platelet count of less than $50 \times 10^9 /L$ (less than 50,000/mcL) and (ii): meets (a or b): a) has higher-risk disease or b) has lower-risk disease and at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis) OR (B) Patient has a platelet count of greater than or equal to $50 \times 10^9 /L$ (greater than or equal to 50,000/mcL) and has higher-risk disease and has at least one disease-related symptom, OR (C) patient has myelofibrosis-associated anemia. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease-related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Accelerated or blast phase myeloproliferative neoplasm
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

VORANIGO

Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	GLIOMAS-All of (A, B and C): A. Susceptible isocitrate dehydrogenase-1 (IDH1) or IDH2 mutation-positive disease, AND B. Grade 2 oligodendroglioma OR Grade 2 astrocytoma, AND C. Prior surgery, including biopsy, sub-total resection, or gross total resection
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VORICONAZOLE (ORAL)

Products Affected

- *voriconazole*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Aspergillus-Prophy, systemic w/risk neutropenia-Prophy, systemic w/HIV-Prophy/Tx-6 mo, others-3 mo
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Aspergillus Infections - prophylaxis, oropharyngeal candidiasis (fluconazole-refractory) - treatment, candidia endophthalmitis - treatment, blastomycosis - treatment, fungal infections (systemic) in patients at risk of neutropenia - prophylaxis, fungal infections (systemic) in patients with human immunodeficiency virus (HIV) - prophylaxis or treatment.
Part B Prerequisite	No
Prerequisite Therapy Required	No

VOSEVI

Products Affected

- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
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	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No
Prerequisite Therapy Required	No

VOTRIENT

Products Affected

- *pazopanib*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Soft tissue sarcoma other than GIST-approve if the patient has advanced or metastatic disease and has ONE of the following: alveolar soft part sarcoma, angiosarcoma, desmoid tumors (aggressive fibromatosis, dermatofibrosarcoma protuberans with fibrosarcomatous transformation, non-adipocytic sarcoma or pleomorphic rhabdomyosarcoma.</p> <p>Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Uterine sarcoma, approve if the patient has recurrent or metastatic disease. Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or advanced disease or VonHippel-Lindau disease. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease. GIST - approve if the patient has succinate dehydrogenase (SDH)-deficient GIST OR the patient has tried TWO of the following: Gleevec, Ayvakit, Sutent, Sprycel, Qinlock or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried at least one systemic therapy. Bone cancer-approve if the patient has chondrosarcoma and has metastatic widespread disease.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Differentiated (ie, papillary, follicular, oncocytic carcinoma) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or

PA Criteria	Criteria Details
	Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma, bone cancer.
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VOWST

Products Affected

- VOWST

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	30 days
Other Criteria	Prevention of recurrence of clostridioides difficile infection (CDI)-approve if the patient has completed a bowel prep, will not eat or drink for at least 8 hours prior to the first dose and will complete their antibacterial treatment for recurrent CDI 2-4 days before initiating treatment with Vowst and Vowst will not be used for the TREATMENT of CDI.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VOXZOGO

Products Affected

- VOXZOGO

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent treatment with growth hormone (e.g., somatropin), long acting growth hormone (e.g., lonapegsomatropin), or insulin-like growth factor-1 (IGF-1) [i.e., Increlex]
Required Medical Information	Diagnosis
Age Restrictions	Less than 18 years old (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	<p>Achondroplasia-approve if the patient meets ONE of the following criteria (A or B): A) Initial Therapy or Patient Has Been on Voxzogo less than 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, and iv): i. The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene, AND ii. Patient's epiphyses are open, AND iii. Patient will not have limb-lengthening surgery during treatment with Voxzogo, AND iv. The prescriber has confirmed the patient is able to drink approximately 240 to 300 mL of fluid in the hour prior to Voxzogo administration B) Patient Has Been Receiving Voxzogo for greater than or equal to 1 Year. Approve if the patient meets ALL of the following (i, ii, iii, iv, and v): i. The diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene, AND ii. Patient's epiphyses are open, AND iii. Patient will not have limb-lengthening surgery during treatment with Voxzogo, AND iv. The prescriber has confirmed the patient is able to drink approximately 240 to 300 mL of fluid in the hour prior to Voxzogo administration, AND v. Patient's most recent annualized growth velocity continues to be above their baseline annualized growth velocity value (i.e., before the patient started on Voxzogo).</p>
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VOYDEYA

Products Affected

- VOYDEYA

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Empaveli (pegcetacoplan subcutaneous injection) or Fabhalta (iptacopan capsules).
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with a hematologist (initial/continuation)
Coverage Duration	Initial-3 months, Continuation-1 year
Other Criteria	<p>INITIAL THERAPY-PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)-All of (i, ii, iii): i) peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol-anchored proteins on at least two cell lineages and ii) prescribed in combination with Soliris (eculizumab intravenous infusion) or Ultomiris (ravulizumab-cwvz intravenous infusion) and iii) clinically significant extravascular hemolysis (while receiving Soliris or Ultomiris) as evidenced by objective laboratory findings (see Note 1).</p> <p>CONTINUATION THERAPY-PNH-medication is prescribed in combination with Soliris (eculizumab intravenous infusion) or Ultomiris (ravulizumab intravenous infusion) AND patient is continuing to derive benefit from Voydeya (see Note 2). Note 1: Examples of objective laboratory findings include reduction in hemoglobin levels, elevated reticulocyte counts, increased transfusion requirements, transfusion-dependence. Note 2: Examples of benefit include increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis, improvement in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

VTAMA

Products Affected

- VTAMA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	PP-18 years and older, AD-2 years and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	1 year
Other Criteria	<p>Plaque Psoriasis-patient meets ALL of the following criteria (A, B and C):</p> <p>A) Patient has psoriasis involvement estimated to affect less than or equal to 20 percent of the body surface area, AND B) Patient meets one of the following criteria (i or ii): i. Patient meets all of the following criteria (a and b): a) Patient has tried at least one medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid, AND b) Inadequate efficacy was demonstrated with this topical corticosteroid, according to the prescriber, OR ii. Patient is treating psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia, AND C) Patient meets ALL of the following criteria (i and ii): i. Patient has tried at least one topical vitamin D analog, AND Note: Examples of topical vitamin D analogs include calcipotriene 0.005% foam (Sorilux, authorized generic), calcipotriene 0.005% cream (Dovonex, generic), calcipotriene 0.005% ointment (generic only), calcitriol 3 mcg/g ointment (Vectical, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% foam (Enstilar) , calcipotriene 0.005% and betamethasone dipropionate 0.064% cream (Wynzora), calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment (Taclonex, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% suspension (Taclonex, generic. Concomitant use of a topical vitamin d analog and a topical corticosteroid would meet the requirement ii. Inadequate efficacy was demonstrated with this topical vitamin D analog, according to the</p>

PA Criteria	Criteria Details
	prescriber. Atopic Dermatitis-Try TWO of the following: pimecrolimus cream (Elidel cream, generics), tacrolimus ointment, Eucrisa, or topical corticosteroid.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VUITY

Products Affected

- *pireokarpine hcl ophthalmic (eye) drops* 1.25 %
- VUITY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VUMERITY

Products Affected

- VUMERITY

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
Required Medical Information	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
Age Restrictions	N/A
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 1 year.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VYKAT XR

Products Affected

- VYKAT XR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	4 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or geneticist
Coverage Duration	1 year
Other Criteria	PRADER-WILLI SYNDROME-diagnosis has been established by identification of abnormal DNA methylation of chromosome 15q11.2Q13, AND patient has hyperphagia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

VYVGART

Products Affected

- VYVGART HYTRULO
SUBCUTANEOUS SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant Use with Another Neonatal Fc Receptor Blocker, a Complement Inhibitor, or a Rituximab Product
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist (initial and continuation)
Coverage Duration	Initial-6 months, Continuation-1 year
Other Criteria	<p>CIDP (Vyvgart Hytrulo only), Initial Therapy - approve if diagnosis was supported by electrodiagnostic studies AND pt previously received treatment with an intravenous or subcutaneous immune globulin and had inadequate efficacy or significant intolerance or patient has a contraindication to IV or SC immune globulin.. Generalized myasthenia gravis, Initial Therapy-Approve if the patient meets the following criteria (A, B, and C): A. Patient has confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis, AND B. Patient has evidence of unresolved symptoms of generalized myasthenia gravis, such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility) AND C. patient has myasthenia gravis foundation of america classification of II to IV. CIDP (Vyvgart Hytrulo only), Cont therapy - pt has clinically significant improvement in neurologic symptoms (Examples include improvement in disability: nerve conduction study results improved or stabilized, physical examination shows improvement in neurological symptoms, strength, and sensation). Generalized myasthenia gravis, Continuation Therapy-Approve if patient is continuing to derive benefit from Vyvgart. For gMG: All treatment cycles should be no more frequent than every 50 days from the start of the previous treatment cycle.</p>

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

WAINUA

Products Affected

- WAINUA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with other medications indicated for polyneuropathy of hereditary transthyretin-mediated amyloidosis or transthyretin-mediated amyloidosis-cardiomyopathy (e.g., Amvuttra (vutrisiran subcutaneous injection), Attruby (acoramidis tablets), Onpattro (patisiran intravenous infusion), Tegsedi (inotersen subcutaneous injection), or a tafamidis product.)
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.
Coverage Duration	1 year
Other Criteria	Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR)-Approve if the patient meets ALL of the following (A, B and C): A) Patient has a transthyretin pathogenic variant as confirmed by genetic testing, AND B) Patient has symptomatic polyneuropathy, Note: Examples of symptomatic polyneuropathy include reduced motor strength/coordination, and impaired sensation (e.g., pain, temperature, vibration, touch). Examples of assessments for symptomatic disease include history and clinical exam, electromyography, or nerve conduction velocity testing. AND C) Patient does not have a history of liver transplantation.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

WAKIX

Products Affected

- WAKIX

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of Wakix with an oxybate product and/or Sunosi (solriamfetol tablets).
Required Medical Information	Diagnosis
Age Restrictions	EDS with narcolepsy - 6 years and older. Cataplexy with narcolepsy - 18 years and older
Prescriber Restrictions	Prescribed by or in consult with a sleep specialist physician or a neurologist
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Excessive daytime sleepiness associated with Narcolepsy-Approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT) AND (1 or 2): 1) patient is 18 years and older and has tried a CNS stimulant (ex: methylphenidate, dextroamphetamine), generic modafinil or generic armodafinil (Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil or Nuvigil) or patient is less than 18 and has tried a CNS stimulant or generic modafinil (Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil) OR 2) patient has a history of substance use disorder and a wakefulness-promoting agent that is not a controlled substance is necessary, per the prescriber. Cataplexy treatment in patients with narcolepsy-approve if the patient has been evaluated using polysomnography and a multiple sleep latency test (MSLT) and the diagnosis of narcolepsy has been confirmed.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

WELIREG

Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Pending CMS Review
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Renal Cell Carcinoma- approve if patient meets the following (A, B, C and D): A) pt has advanced disease AND B) has clear cell histology AND C) has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor AND D) has tried at least one a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). [Note: Examples of PD-1 inhibitor or PD-L1 inhibitor include: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), and Bavencio (avelumab intravenous infusion). Examples of VEGF-TKI include Cabometyx (cabozantinib tablets), Lenvima (lenvatinib capsules), Inlyta (axitinib tablets), Fotivda (tivozanib capsules), pazopanib, sunitinib, and sorafenib.]</p> <p>Van Hippel-Lindau Disease-approve if the patient meets the following (A, B, and C): A) Patient has a von Hippel-Lindau (VHL) germline alteration as detected by genetic testing, B) Does not require immediate surgery and C) Patient requires therapy for ONE of the following conditions (i, ii, iii, or iv): i. Central nervous system hemangioblastomas, OR ii. Pancreatic neuroendocrine tumors, OR iii. Renal cell carcinoma, OR iv. Retinal hemangioblastoma.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

WINLEVI

Products Affected

- WINLEVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Acne vulgaris-Approve if the patient has tried one prescription topical retinoid and one other prescription topical therapy (e.g., dapsone gel, Azelex, topical clindamycin, topical erythromycin, topical minocycline).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

WINREVAIR

Products Affected

- WINREVAIR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation)
Coverage Duration	Initial-6 months, Continuation-1 year
Other Criteria	INITIAL THERAPY-PULMONARY ARTERIAL HYPERTENSION (PAH) WHO GROUP 1-All of (A, B, C): A) right-heart catheterization to confirm the diagnosis, and B) Functional Class II or III, and C) One of (a or b): a)currently receiving at least two other PAH therapies from the following different pharmacologic categories, each for greater than or equal to 60 days: phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), and prostacyclins or b) currently receiving at least one other PAH therapy for greater than or equal to 60 days and is intolerant to combination therapy with a phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), or prostacyclin. CONTINUATION THERAPY-PAH WHO GROUP 1-patient has had a right heart catheterization to confirm the diagnosis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

XALKORI

Products Affected

- XALKORI ORAL CAPSULE
- XALKORI ORAL PELLETT 150 MG, 20 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Anaplastic large cell lymphoma/IMT-patients greater than or equal to 1 year of age. All other diagnoses-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Metastatic non-small cell lung cancer-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease, as detected by an approved test and patients new to therapy must have a trial of Alecensa or Lorbrena prior to approval of Xalkori. Metastatic non-small cell lung cancer, approve if the patient has ROS1 rearrangement positive disease, as detected by an approved test. Anaplastic Large Cell Lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Histiocytic neoplasm-approve if the patient has ALK rearrangement/fusion-positive disease and meets one of the following criteria (i, ii, or iii): (i. Patient has Langerhans cell histiocytosis, OR ii. Patient has Erdheim-Chester disease OR iii. Patient has Rosai-Dorfman disease. NSCLC with MET mutation-approve if the patient has high level MET amplification or MET exon 14 skipping mutation. Inflammatory Myofibroblastic Tumor-approve if the patient has ALK positive disease and the patient has advanced, recurrent or metastatic disease or the tumor is inoperable. Melanoma, cutaneous-approve if the patient has ALK fusion disease or ROS1 fusion disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	NSCLC with high level MET amplification or MET Exon 14 skipping mutation, Histiocytic neoplasms, melanoma, cutaneous.
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XDEMZY

Products Affected

- XDEMZY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

XELJANZ

Products Affected

- XELJANZ ORAL SOLUTION
- XELJANZ XR
- XELJANZ ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a Targeted Synthetic DMARD for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil].
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restrictions	AS/PsA/RA/UC-18 years and older (initial therapy), JIA/JRA-2 years and older (initial therapy)
Prescriber Restrictions	RA, JIA/JRA/AS prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist. (all apply to initial therapy only)
Coverage Duration	Approve through end of plan year
Other Criteria	RA initial-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. PsA initial, approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. UC-Approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least ONE tumor necrosis factor inhibitor for ulcerative colitis or was unable to tolerate a 3-month trial. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthropathy/active sacroiliac arthritis]-initial-approve Xeljanz immediate release tablets or solution if the patient meets the following: patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AS-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis

PA Criteria	Criteria Details
	factor inhibitor or was unable to tolerate a 3 month trial. Continuation Therapy - Patient must have responded, as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XERMELO

Products Affected

- XERMELO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapy, concomitant therapy
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XIFAXAN

Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Traveler's diarrhea - 12 years of age or older. Hepatic encephalopathy, irritable bowel syndrome with diarrhea - 18 years of age or older.
Prescriber Restrictions	Pouchitis - prescribed by or in consultation with a gastroenterologist
Coverage Duration	Enceph-6 mo, IBS w/diarrhea-14 days, TD-3 days, intest bact overgrowth-14 days, Pouchitis - 1 year
Other Criteria	Hepatic Encephalopathy-approve Xifaxan 550 mg tablets if the patient has previously had overt hepatic encephalopathy and the requested medication will be used concomitantly with lactulose, unless the patient has a contraindication or significant intolerance to treatment with lactulose. Irritable bowel syndrome with diarrhea-approve Xifaxan 550 mg tablets. Travelers Diarrhea-approve Xifaxan 200 mg tablets if the patient is afebrile and does not have blood in the stool. Small intestine bacterial overgrowth-approve Xifaxan 200mg or 550 mg tablets if the diagnosis has been confirmed by a glucose hydrogen breath test, lactulose hydrogen breath test, or small bowel aspiration and culture. Chronic antibiotic-dependent pouchitis- approve Xifaxan 200mg or 550mg tablets if patient meets all of (a, b, c and d): a) recurrent pouchitis (Note: recurrent pouchitis is typically considered history of at least 3 pouchitis episodes within a 12 month period), and b) episodes of pouchitis respond to antibiotic therapy but relapse shortly after antibiotic discontinuation, and c) alternative causes of recurrent pouchitis have been ruled out, and d) has tried long-term antibiotic therapy trials (at least 4 weeks) of BOTH ciprofloxacin and metronidazole for remission maintenance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Small intestine bacterial overgrowth, chronic antibiotic-dependent pouchitis
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XOLAIR

Products Affected

- XOLAIR SUBCUTANEOUS AUTO-INJECTOR 150 MG/ML, 300 MG/2 ML, 75 MG/0.5 ML
- XOLAIR SUBCUTANEOUS RECON SOLN
- XOLAIR SUBCUTANEOUS SYRINGE 150 MG/ML, 300 MG/2 ML, 75 MG/0.5 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another monoclonal antibody therapy.
Required Medical Information	Diagnosis
Age Restrictions	Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Polyps-18 years and older. Food Allergy-1 yr and older
Prescriber Restrictions	Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist. Polyps-prescribed by or in consult with an allergist, immunologist, or otolaryngologist. Food allergy- allergist or immunologist
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XOLREMDI

Products Affected

- XOLREMDI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	12 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with an immunologist, hematologist or dermatologist (initial)
Coverage Duration	1 year
Other Criteria	<p>INITIAL THERAPY-WARTS, HYPOGAMMAGLOBULINEMIA, INFECTIONS AND MYELOKATHEXIS (WHIM) SYNDROME-genetic testing confirms pathogenic and or likely pathogenic variants in the CXCR4 gene and at baseline the patient has an absolute neutrophil count less than or equal to 400 cells/microliter, or at baseline, patient had a white blood cell count less than or equal to 400 cells/microliter.</p> <p>CONTINUATION-WHIM SYNDROME-patient is continuing to derive benefit from Xolremdi as determined by the most recent (i.e., within the past 6 months) objective measurement. Note: Examples of objective measurements of a response to Xolremdi therapy are reduced frequency, duration, or severity of infections, less frequent treatment with antibiotics, fewer warts, or improved or stabilized clinical signs/symptoms of WHIM syndrome (e.g., absolute neutrophil count, white blood cell count, and absolute lymphocyte count).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

XOSPATA

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, FLT3-mutation status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	AML - approve if the disease is FLT3-mutation positive as detected by an approved test. Lymphoid, Myeloid Neoplasms-approve if the patient has eosinophilia and the disease is FLT3-mutation positive as detected by an approved test.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Lymphoid, Myeloid Neoplasms
Part B Prerequisite	No
Prerequisite Therapy Required	No

XPOVIO

Products Affected

- XPOVIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Multiple Myeloma-Approve if the patient meets the following (A and B):</p> <p>A) The medication will be taken in combination with dexamethasone AND</p> <p>B) Patient meets one of the following (i, ii, or iii): i. Patient has tried at least four prior regimens for multiple myeloma OR ii. Patient meets both of the following (a and b): a) Patient has tried at least two prior regimens for multiple myeloma AND b) The medication will be taken in combination with Pomalyst (pomalidomide) OR iii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with bortezomib, Darzalex (daratumumab infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Kyprolis (carfilzomib intravenous infusion). Note: Examples of prior regimens include Darzalex (daratumumab intravenous infusion)/bortezomib/lenalidomide/dexamethasone, bortezomib/lenalidomide/dexamethasone, Kyprolis (carfilzomib infusion)/lenalidomide/dexamethasone, Darzalex (daratumumab injection)/bortezomib or Kyprolis/dexamethasone, or other regimens containing a proteasome inhibitor, immunomodulatory drug, and/or anti-CD38 monoclonal antibody. Diffuse large B-cell lymphoma Note:this includes patients with histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma)-approve if the patient has tried at least two prior therapies. B-Cell lymphoma-approve if (A and B): A) pt has high-</p>

PA Criteria	Criteria Details
	grade B-cell lymphoma or HIV-related B-cell lymphoma or post-transplant lymphoproliferative disorders and B) has tried at least two prior therapies.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Treatment of multiple myeloma in combination with daratumumb or pomalidomide, B-cell lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XTANDI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Xtandi is being used.
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Prostate cancer-castration-resistant [Metastatic or Non-metastatic] and Prostate cancer-metastatic, castration sensitive-approve if Xtandi will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy. Prostate cancer- Non-Metastatic, Castration-Sensitive - approve if pt has biochemical recurrence and is at high risk for metastasis. [Note: High-risk biochemical recurrence is defined as prostate-specific antigen (PSA) doubling time less than or equal to 9 months.]
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

XYREM

Products Affected

- SODIUM OXYBATE (PREFERRED NDCS STARTING WITH 00054)
- XYREM

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Xywav, Wakix or Sunosi
Required Medical Information	Medication history (as described in Other Criteria field)
Age Restrictions	7 years and older
Prescriber Restrictions	Prescribed by a sleep specialist physician or a Neurologist
Coverage Duration	12 months.
Other Criteria	For Excessive daytime sleepiness (EDS) in patients with narcolepsy - narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). In addition, patients requesting brand name Xyrem-approve if the patient has tried sodium oxybate. Patients requesting sodium oxybate who are 18 years or older-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil. Patients less than 18 years old requesting sodium oxybate-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextramphetamine) or modafinil. Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XYWAV

Products Affected

- XYWAV

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of sodium oxybate, Xyrem, Wakix, Sunosi
Required Medical Information	Medication history (as described in Other Criteria field)
Age Restrictions	Narcolepsy-7 years and older, Idiopathic hypersomnia-18 years and older
Prescriber Restrictions	Prescribed by a sleep specialist physician or a Neurologist
Coverage Duration	12 months
Other Criteria	For Excessive daytime sleepiness (EDS) in patients with narcolepsy - narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT) and the patient has tried sodium oxybate, unless the patient has a concomitant diagnosis of heart failure, hypertension, or renal impairment according to the prescriber. Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Idiopathic hypersomnia-approve if the diagnosis has been confirmed using polysomnography and a multiple sleep latency test and if the patient has tried modafinil.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

YONSA

Products Affected

- YONSA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, concomitant medications
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Metastatic castration-resistant prostate cancer (mCRPC) - approve if the patient will be using Yonsa in combination with methylprednisolone or dexamethasone and the patient meets ONE of the following criteria (i or ii): i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog [examples: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] OR ii. The patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZARXIO

Products Affected

- ZARXIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer/AML, MDS, ALL-oncologist or a hematologist. Cancer patients receiving BMT and PBPC-prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. Radiation-expertise in acute radiation.SCN-hematologist. HIV/AIDS neutropenia-infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT/Radiation- 1 mo.
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)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), 2)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 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL) renal dysfunction (CrCl less than 50 mL/min), poor performance status, or HIV infection patients with low CD4 counts), 3)patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy, has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia

PA Criteria	Criteria Details
	<p>[absolute neutrophil count less than 100 cells/mm³], neutropenia expected to be greater than 10 days in duration, pneumonia or other clinically documented infection, invasive fungal infection, hospitalization at the time of fever, prior episode of febrile neutropenia). For all diagnoses except PBPC, patients are required to try Releuko and Nivestym and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Zarxio unless patient has initiated therapy with Zarxio and requires additional medication to complete the current cycle of chemotherapy. For PBPC, patients are required to try Nivestym and cannot continue to use the preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in a significant allergy or serious adverse reaction prior to approval of Zarxio, unless patient has initiated therapy with Zarxio and requires additional medication to complete the current cycle of chemotherapy.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZAVZPRET

Products Affected

- ZAVZPRET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Migraine, acute treatment-approve if the patient has tried Nurtec and one triptan, unless the patient has a contraindication to triptans. Note: Examples of contraindications to triptans include a history of coronary artery disease, cardiac accessory conduction pathway disorders, history of stroke, transient ischemic attack, or hemiplegic or basilar migraine, peripheral vascular disease, ischemic bowel disease, uncontrolled hypertension, or severe hepatic impairment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZEJULA

Products Affected

- ZEJULA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy - approve if the patient is in complete or partial response after platinum-based chemotherapy regimen and if the patient is new to therapy they must have a trial of Lynparza prior to approval of Zejula. Patients who have had a complete or partial response to first-line platinum based chemotherapy and do not have BRCA altered disease are not required to try Lynparza. Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen. In addition, patients new to therapy must have a trial of Lynparza prior to approval of Zejula.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Uterine Leiomyosarcoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZELAPAR

Products Affected

- ZELAPAR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, medication history (as described in Other Criteria)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Parkinson's Disease-approve if the patient is experiencing off episodes such as muscle stiffness, slow movements or difficulty starting movements, is currently receiving carbidopa/levodopa therapy and has tried oral selegiline tablets/capsules or rasagiline tablets and according to the prescriber had significant intolerance or has difficulty swallowing tablets/or capsules.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZELBORAF

Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	BRAFV600 mutation status required.
Age Restrictions	All diagnoses (except CNS cancer)-18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e., papillary, follicular, or oncocytic carcinoma) with BRAF-positive disease, Central Nervous System Cancer, Histiocytic Neoplasm
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZEPATIER

Products Affected

- ZEPATIER

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin or Sovaldi.
Required Medical Information	Diagnosis
Age Restrictions	12 years or older
Prescriber Restrictions	Prescribed by or in consultation w/ GI, hepatologist, ID, or liver transplant MD.
Coverage Duration	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. And, patients with genotype 1 or 4 must try TWO of the following: ledipasvir/sofosbuvir, velpatasvir/sofosbuvir, Mavyret, Vosevi, unless ledipasvir/sofosbuvir, velpatasvir/sofosbuvir, Mavyret and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Indications consistent with current AASLD/IDSA guidance
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZEPOSIA

Products Affected

- ZEPOSIA
- ZEPOSIA STARTER KIT (28-DAY)
- ZEPOSIA STARTER PACK (7-DAY)

PA Criteria	Criteria Details
Exclusion Criteria	Pending CMS Review
Required Medical Information	Diagnosis
Age Restrictions	UC-18 years and older
Prescriber Restrictions	MS-Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. UC-Prescribed by or in consultation with a gastroenterologist
Coverage Duration	MS-1 year, UC initial, 6 months, cont-1 year
Other Criteria	MS-approve. Ulcerative Colitis, initial-approve if the patient has tried TWO of the following: a preferred adalimumab product, a preferred ustekinumab product, a preferred infliximab product, Rinvoq, Skyrizi, Tremfya. Note-a trial of Simponi SC, Entyvio IV/SC, Omvoh IV/SC, a non-preferred adalimumab product, a non-preferred ustekinumab product or a non-preferred infliximab would also count). Cont tx-approve if the patient has been established on Zeposia. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand name product), Zymfentra. Preferred ustekinumab products include Selarsdi, Yesintek.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZIEXTENZO

Products Affected

- ZIEXTENZO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation. Radiation-expertise in acute radiation.
Coverage Duration	Cancer pts receiving chemo-6 mo. PBPC/radiation-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) 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), 2) 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 according to the prescribing physician (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status or HIV infection patients with low CD4 counts), or 3) patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. For all diagnoses except acute radiation syndrome, patients are required to try Fulphila and Nyvepria and cannot continue to use the preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which would result in

PA Criteria	Criteria Details
	a significant allergy or serious adverse reaction prior to approval of Ziextenzo.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients undergoing PBPC collection and therapy
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZILBRYSQ

Products Affected

- ZILBRYSQ

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with another complement inhibitor, a neonatal Fc receptor blocker, or a rituximab Product
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial/continuation)
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Initial-6 months, continuation 1 year
Other Criteria	Generalized myasthenia gravis, initial therapy-Approve if the patient meets the following (i, ii, iii and iv): i. Patient has confirmed anti-acetylcholine receptor antibody-positive generalized myasthenia gravis, AND ii. Patient meets both of the following (a and b): a) Myasthenia Gravis Foundation of America classification of II to IV, AND b) Myasthenia Gravis Activities of Daily Living (MG-ADL) score of greater than or equal to 6, AND iii. Patient meets one of the following (a or b): a) Patient received or is currently receiving pyridostigmine, OR b) Patient has had inadequate efficacy, a contraindication, or significant intolerance to pyridostigmine, AND iv. Patient has evidence of unresolved symptoms of generalized myasthenia gravis. Note: Evidence of unresolved symptoms of generalized myasthenia gravis includes difficulty swallowing, difficulty breathing, and a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility). Generalized myasthenia gravis, continuation-approve if the patient is continuing to derive benefit from Zilbrysq. Note: Examples of derived benefit include reductions in exacerbations of myasthenia gravis, improvements in speech, swallowing, mobility, and respiratory function.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZOLINZA

Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZORYVE 0.15% CREAM

Products Affected

- ZORYVE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	6 years and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	1 year
Other Criteria	ATOPIC DERMATITIS-Try TWO of: pimecrolimus cream (Elidel cream, generics), tacrolimus ointment, Eucrisa, or topical corticosteroid.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZORYVE CREAM

Products Affected

- ZORYVE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	6 years and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	1 year
Other Criteria	<p>Plaque Psoriasis-patient meets ALL of the following criteria (A, B and C):</p> <p>A) Patient has psoriasis involvement estimated to affect less than or equal to 20 percent of the body surface area, AND B) Patient meets one of the following criteria (i or ii): i. Patient meets all of the following criteria (a and b): a) Patient has tried at least one medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid, AND b) Inadequate efficacy was demonstrated with this topical corticosteroid, OR ii. Patient is treating psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia, AND C) Patient meets ALL of the following criteria (i and ii): i. Patient has tried at least one topical vitamin D analog, AND Note: Examples of topical vitamin D analogs include calcipotriene 0.005% foam (Sorilux, authorized generic), calcipotriene 0.005% cream (Dovonex, generic), calcipotriene 0.005% ointment (generic only), calcitriol 3 mcg/g ointment (Vectical, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% foam (Enstilar) , calcipotriene 0.005% and betamethasone dipropionate 0.064% cream (Wynzora), calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment (Taclonex, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% suspension (Taclonex, generic. Concomitant use of a topical vitamin d analog and a topical corticosteroid would meet the requirement ii. Inadequate efficacy was demonstrated with this topical vitamin D analog.</p>

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZORYVE FOAM

Products Affected

- ZORYVE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	9 years and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	1 year
Other Criteria	Seborrheic dermatitis-approve if the patient has tried a generic topical corticosteroid or a generic topical antifungal. Note-A trial of a combination product containing a topical antifungal or topical corticosteroid would also count.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZTALMY

Products Affected

- ZTALMY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	2 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZURZUVAE

Products Affected

- ZURZUVAE ORAL CAPSULE 20 MG, 25 MG, 30 MG

PA Criteria	Criteria Details
Exclusion Criteria	Previous treatment with Zurzuvae during the current episode of postpartum depression
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist
Coverage Duration	14 days
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZYDELIG

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	CLL/SLL-approve if the patient has tried at least one Bruton tyrosine kinase inhibitor (examples: ibrutinib, zanubrutinib, acalabrutinib, pirtobrutinib) and at least one Venclexta (venetoclax)-based regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	small lymphocytic lymphoma
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZYKADIA

Products Affected

- ZYKADIA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Pending CMS Review
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Pending CMS Review
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZYMFENTRA

Products Affected

- ZYMFENTRA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic disease-modifying antirheumatic drug (DMARD).
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist (initial therapy)
Coverage Duration	Approve through end of plan year
Other Criteria	<p>Crohn's Disease, initial therapy-Approve if the patient meets the following (i. and ii.): i.The patient is currently receiving infliximab intravenous maintenance therapy or will receive induction dosing with an infliximab intravenous product within 3 months of initiating therapy with Zymfentra, AND ii. Patient meets ONE of the following (a, b, c, or d): a) Patient has tried or is currently taking systemic corticosteroids, or corticosteroids are contraindicated in this patient, Note: Examples of corticosteroids are prednisone and methylprednisolone. OR b) Patient has tried one conventional systemic therapy for Crohn's disease, Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. OR c) Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, OR d) Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). Crohn's Disease, continuation-approve if the patient has had a response to therapy.</p> <p>Ulcerative Colitis, initial therapy-Approve if the patient meets ALL of the following (i and ii): i.The patient is currently receiving infliximab intravenous maintenance therapy or will receive induction dosing with an infliximab intravenous product within 3 months of initiating therapy with</p>

PA Criteria	Criteria Details
	<p>Zymfentra, AND ii. Patient meets ONE of the following (a or b): a) Patient had a trial of one systemic agent or was intolerant to one of these agents for ulcerative colitis, Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A previous trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. OR b) Patient meets BOTH of the following [(1) and (2)]: (1) Patient has pouchitis AND (2) Patient has tried therapy with an antibiotic, probiotic, corticosteroid enema, or Rowasa (mesalamine enema). Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema (Cortenema, generics). Ulcerative Colitis, continuation-approve if the patient has had a response to therapy.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZYTIGA

Products Affected

- *abiraterone oral tablet 250 mg, 500 mg*
- *abirtega*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Prostate Cancer-Metastatic, Castration-Resistant (mCRPC)-Approve if abiraterone is being used in combination with prednisone or dexamethasone and the medication is used concurrently used with a gonadotropin-releasing hormone (GnRH) analog (see Note 1) or the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration-sensitive (mCSPC)- approve if the medication is used in combination with prednisone and the medication is concurrently used with a GnRH analog (see Note 1) or the patient has had a bilateral orchiectomy. Prostate Cancer - Regional Risk Group - Approve if the patient meets all of the following criteria (A, B, and C): A) abiraterone is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i or ii): i. abiraterone with prednisone is used in combination with a GnRH analog (see Note 1) OR ii. Patient has had a bilateral orchiectomy. Prostate cancer-very-high-risk-group-approve if according to the prescriber the patient is in the very-high-risk group, the medication will be used in combination with prednisone, the medication will be used in combination with external beam radiation therapy and the patient meets one of the following criteria (i or ii): i. abiraterone is used in combination with a GnRH analog (see Note 1) OR ii. Patient has had a bilateral orchiectomy. Prostate cancer- radical prostatectomy or post radiation therapy-approve if patient meets (A, B, C and D): A) the medication is used in combination</p>

PA Criteria	Criteria Details
	<p>with prednisone, B) meets (i or ii): i) the patient has prostate specific antigen (PSA) persistence or recurrence following radical prostatectomy or ii) PSA recurrence or positive digital rectal examination (DRE) after radiation therapy, C) patient has pelvic recurrence or positive regional lymph nodes, and D) the medication will be used concurrently with GnRH analog (see Note 1) or the patient has had a bilateral orchiectomy. Salivary Gland Tumors- approve if (A, B and C): A) used in combination with prednisone, B) androgen receptor-positive (AR+) recurrent, unresectable or metastatic tumor, and C) used in combination with a GnRH analog (see Note 1). Note 1: examples of GnRH analogs are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Prostate Cancer-Regional Risk Group, Prostate cancer-very-high-risk group, Prostate cancer- radical prostatectomy or post radiation, Salivary Gland Tumors
Part B Prerequisite	No
Prerequisite Therapy Required	No

PART B VERSUS PART D

Products Affected

- *acetylcysteine*
- *acyclovir sodium intravenous solution*
- *albuterol sulfate inhalation solution for nebulization 0.63 mg/3 ml, 1.25 mg/3 ml, 2.5 mg /3 ml (0.083 %), 2.5 mg/0.5 ml*
- *amphotericin b*
- *amphotericin b liposome*
- *aprepitant*
- *arformoterol*
- ASTAGRAF XL
- *azathioprine*
- BOMYNTRA
- *budesonide inhalation suspension for nebulization 0.25 mg/2 ml, 0.5 mg/2 ml, 1 mg/2 ml*
- CLINIMIX 5%/D15W SULFITE FREE
- CLINIMIX 4.25%/D10W SULF FREE
- CLINIMIX 4.25%/D5W SULFIT FREE
- CLINIMIX 5%-D20W(SULFITE-FREE)
- CLINIMIX E 2.75%/D5W SULF FREE
- CLINIMIX E 4.25%/D10W SUL FREE
- CLINIMIX E 4.25%/D5W SULF FREE
- CLINIMIX E 5%/D15W SULFIT FREE
- CLINIMIX E 5%/D20W SULFIT FREE
- CLINISOL SF 15 %
- CLINOLIPID
- *cromolyn inhalation*
- *cyclophosphamide oral capsule*
- CYCLOPHOSPHAMIDE ORAL TABLET
- *cyclosporine modified*
- *cyclosporine oral capsule*
- ENGERIX-B (PF)
- ENGERIX-B PEDIATRIC (PF)
- ENVARSUS XR
- *everolimus (immunosuppressive)*
- *formoterol fumarate*
- *gengraf oral capsule*
- *granisetron hcl oral*
- HEPLISAV-B (PF)
- IMOVAX RABIES VACCINE (PF)
- *intralipid intravenous emulsion 20 %*
- INTRALIPID INTRAVENOUS EMULSION 30 %
- *ipratropium bromide inhalation*
- *ipratropium-albuterol*
- JYLAMVO
- JYNNEOS (PF)
- *levalbuterol hcl*
- MEDROL ORAL TABLET 2 MG
- *methotrexate sodium*
- *methotrexate sodium (pf) injection solution*
- *methylprednisolone oral tablet*
- *mycophenolate mofetil*
- *mycophenolate sodium*
- MYHIBBIN
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- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet, disintegrating 4 mg, 8 mg*
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- PLENAMINE
- *prednisolone oral tablet*
- *premasol 10 %*
- PROGRAF ORAL GRANULES IN PACKET
- PROSOL 20 %
- PULMOZYME
- RABAVERT (PF)
- RECOMBIVAX HB (PF)
- *sirolimus*
- *tacrolimus oral capsule*
- *travasol 10 %*
- TREXALL
- TROPHAMINE 10 %
- VARUBI
- WYOST
- XATMEP
- YUPELRI

Details

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

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