

ABRYSVO

Products Affected

- ABRYSVO (PF)

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | Non-pregnant individuals: 50 years of age or older OR adults aged 18 through 49 years who are at increased risk for lower respiratory tract disease |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 months |
| Other Criteria | The patient has not already received an RSV vaccine. For Pregnant Individuals: patient is between 32 through 36 weeks gestational age. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ACITRETIN

Products Affected

- *acitretin*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 12 months |
| Other Criteria | For initial therapy in the treatment of psoriasis: trial and failure, contraindication, or intolerance to methotrexate or cyclosporine is required. For continuation of therapy, approve if patient has already been started on Acitretin. |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 mutation 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 mutation linked to severe, malignant osteopetrosis. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 |

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 |

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 |
| Age Restrictions | 6 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 1 year |
| Other Criteria | Migraine headache prevention in adults: 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 Ajovy, the pt has had significant clinical benefit from the medication. Preventive treatment of episodic migraine in pediatric patients: Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 and less than 15 migraine headache days per month (prior to initiating a migraine-preventative medication), and B) if the pt is currently taking Ajovy, 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 Ajovy was initiated. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 |

ALDURAZYME

Products Affected

- ALDURAZYME

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, genetic and lab test results |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders |
| Coverage Duration | 1 year |
| Other Criteria | Approve if the patient has a laboratory test demonstrating deficient alpha-L-iduronidase activity in leukocytes, fibroblasts, plasma, or serum OR has a molecular genetic test demonstrating biallelic pathogenic or likely pathogenic alpha-L-iduronidase gene variants. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | 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 adjunctive 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 |

ALOSETRON

Products Affected

- *alosetron*

| 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 | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ALPHA 1 PROTEINASE INHIBITORS

Products Affected

- GLASSIA

| 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 |

ALUNBRIG

Products Affected

- ALUNBRIG

| 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 Lorbrena 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 |

ALYFTREK

Products Affected

- ALYFTREK

| 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 |

AMBRISENTAN

Products Affected

- *ambrisentan*

| 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 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, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ANKTIVA

Products Affected

- ANKTIVA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | 18 and older (initial therapy) |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or urologist (initial/maintenance therapy) |
| Coverage Duration | Initial-6 months, Maintenance-3 months |
| Other Criteria | Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. INITIAL-NON-MUSCLE INVASIVE BLADDER CANCER-all of (i, ii, iii): i) Patient has Bacillus Calmette-Guerin (BCG) unresponsive disease, AND ii) Patient has carcinoma in situ with or without papillary tumors, AND iii) Medication is used in combination with BCG. MAINTENANCE THERAPY-NON-MUSCLE INVASIVE BLADDER CANCER-all of (i and ii): i) Patient has an ongoing complete response defined as ONE of the following (a or b): a) Patient has negative cystoscopy and meets ONE of the following [(1) or (2)]: 1. Negative urine cytology, OR 2. Malignant urine cytology if cancer found in the upper tract or prostatic urethra and random bladder biopsies are negative, OR b) Patient has positive cystoscopy with biopsy-proven benign or low-grade Ta non-muscle invasive bladder cancer and negative urine cytology, AND ii) Medication is used in combination with BCG. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ANTIBIOTICS (INJECTABLE)

Products Affected

- *amikacin injection solution 1,000 mg/4 ml, 500 mg/2 ml*
- *ampicillin sodium injection recon soln 1 gram, 10 gram, 2 gram, 250 mg, 500 mg*
- *ampicillin sodium intravenous*
- *ampicillin-sulbactam*
- *azithromycin intravenous*
- *aztreonam*
- BICILLIN L-A
- CEFEPIME INTRAVENOUS
- *cefotetan injection*
- *cefoxitin*
- *cefoxitin in dextrose, iso-osm*
- *ceftazidime*
- *cefuroxime sodium injection recon soln 750 mg*
- *cefuroxime sodium intravenous*
- *ciprofloxacin in 5 % dextrose*
- CLINDAMYCIN IN 0.9 % SOD CHLOR
- CLINDAMYCIN IN 5 % DEXTROSE
- *clindamycin phosphate injection*
- *colistin (colistimethate na)*
- *doxy-100*
- *doxycycline hyclate intravenous*
- ERYTHROCIN INTRAVENOUS RECON SOLN 500 MG
- *erythromycin lactobionate*
- EXTENCILLINE
- *gentamicin in nacl (iso-osm) intravenous piggyback 100 mg/100 ml, 60 mg/50 ml, 80 mg/100 ml, 80 mg/50 ml*
- GENTAMICIN IN NACL (ISO-OSM) INTRAVENOUS PIGGYBACK 100 MG/50 ML, 120 MG/100 ML
- *gentamicin injection*
- *gentamicin sulfate (ped) (pf)*
- *levofloxacin in d5w*
- *lincomycin*
- *linezolid in dextrose 5%*
- LINEZOLID-0.9% SODIUM CHLORIDE
- *metro i.v.*
- *metronidazole in nacl (iso-os)*
- MOXIFLOXACIN-SOD.ACE,SUL-WATER
- *moxifloxacin-sod.chloride(iso)*
- *nafcillin in dextrose iso-osm intravenous piggyback 2 gram/100 ml*
- *nafcillin injection*
- *oxacillin*
- *penicillin g potassium*
- *pfizerpen-g*
- SIVEXTRO INTRAVENOUS
- STREPTOMYCIN
- *sulfamethoxazole-trimethoprim intravenous*
- *tazicef*
- TEFLARO
- *tigecycline*
- *tobramycin sulfate*

| 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 |

ANTIFUNGALS (IV)

Products Affected

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

| 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 |

ANTIFUNGALS, POLYENE

Products Affected

- *amphotericin b*
- *amphotericin b liposome*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 6 months |
| Other Criteria | B vs D coverage determination |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ANTINEOPLASTICS, MONOCLONAL ANTIBODIES

Products Affected

- ABRAXANE
- ADCETRIS
- ADSTILADRIN
- ALIQOPA
- BAVENCIO
- BESPONSA
- BIZENGRI
- BORTEZOMIB INJECTION RECON SOLN 1 MG, 2.5 MG
- *bortezomib injection recon soln 3.5 mg*
- BORUZU
- COLUMVI
- CYRAMZA
- DANYELZA
- DARZALEX
- DARZALEX FASPRO
- DATROWAY
- ELAHERE
- ELREXFIO
- ELZONRIS
- EMPLICITI
- ENHERTU
- EPKINLY
- *eribulin*
- EVOMELA
- FYARRO
- GAZYVA
- HALAVEN
- IMFINZI
- IMJUDO
- INLEXZO
- JEMPERLI
- KADCYLA
- KANJINTI
- KEYTRUDA
- KEYTRUDA QLEX
- KIMMTRAK
- LIBTAYO
- LUNSUMIO
- LYNOZYFIC
- MARGENZA
- MONJUVI
- MVASI
- MYLOTARG
- OGIVRI
- ONIVYDE
- OPDIVO
- OPDIVO QVANTIG
- OPDUALAG
- PACLITAXEL PROTEIN-BOUND
- PADCEV
- *pemetrexed disodium intravenous recon soln 1,000 mg, 100 mg, 500 mg*
- PEMETREXED DISODIUM INTRAVENOUS RECON SOLN 750 MG
- PERJETA
- PHESGO
- POLIVY
- POTELIGEO
- RUXIENCE
- RYBREVA
- SARCLISA
- TALVEY
- TECENTRIQ
- TECENTRIQ HYBREZA
- TECVAYLI
- TEVIMBRA
- *thiotepa*
- TIVDAK
- TRAZIMERA
- TRODELVY
- TRUXIMA
- UNITUXIN
- VECTIBIX
- YERVOY
- YONDELIS
- ZEPZELCA
- ZIRABEV
- ZYNLONTA
- ZYNYZ

| 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 | B vs D coverage determination |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 confirms a mutation 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 |

AREXVY

Products Affected

- AREXVY (PF)

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | 50 years of age or older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 months |
| Other Criteria | The patient has not already received an RSV vaccine. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 |

ATYPICAL ANTIPSYCHOTIC

Products Affected

- FANAPT
- FANAPT TITRATION PACK A
- FANAPT TITRATION PACK B
- FANAPT TITRATION PACK C
- *paliperidone*

| 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 | Approve if the patient has tried two of the following: olanzapine, quetiapine fumarate, risperidone, ziprasidone. Approve requests for paliperidone ER in Schizoaffective Disorder without the trial of other treatment. |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

AUGTYRO

Products Affected

- AUGTYRO

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | NSCLC - 18 and older, Solid tumors - 12 and older, Pediatric Diffuse High-Grade Glioma-less than 18 |
| 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. Note: If the patient has non-small cell lung cancer with neurotrophic receptor tyrosine kinase (NTRK) gene fusion, see Solid Tumors indication. 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. Pediatric Diffuse High-Grade Gliomas - approve if tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the medication is used 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 Gliomas |
| Part B Prerequisite | No |

AUSTEDO

Products Affected

- AUSTEDO
- 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 | Chorea-prescribed by or in consult with a neuro. TD-Prescribed by or in consultation with a neurologist or a psychiatrist |
| 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 |

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 |

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 |

BALVERSA

Products Affected

- BALVERSA

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

BENLYSTA

Products Affected

- BENLYSTA INTRAVENOUS

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Concurrent Use with Other Biologics or Lupkynis |
| Required Medical Information | Diagnosis |
| Age Restrictions | 5 years and older (initial). |
| 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 |

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 | Prescribed by or in consultation with a hematologist or an oncologist |
| Coverage Duration | 1 year |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BETASERON

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 | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BEXAROTENE (ORAL)

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 | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BOSULIF

Products Affected

- BOSULIF

| 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. 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 |

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 as part of a combination regimen for colon or rectal cancer. 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 carcinoma |
| Part B Prerequisite | No |

BRUKINSA

Products Affected

- BRUKINSA

| 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). Mantle Cell Lymphoma/CLL/SLL - approve. 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, mantle cell lymphoma (not candidate for systemic tx, OR in combination with rituximab OR with TP53 mutation in combination with venetoclax) |
| Part B Prerequisite | 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 | <p>Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. 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 a vascular endothelial growth factor receptor (VEGFR)-targeted therapy. 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.</p> <p>Neuroendocrine tumors- approve if (A and B): A) pt has locally advanced, unresectable, or metastatic disease, and B) meets (i or ii): i) patient has well-differentiated neuroendocrine tumors, or ii) patient has pancreatic or extra-pancreatic neuroendocrine tumors and the medication will be used as subsequent therapy. Adrenal gland tumor- approve if pt has locoregional unresectable or metastatic adrenocortical carcinoma.</p> <p>Pheochromocytoma/paraganglioma- approve if pt has locally unresectable disease.</p> |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|----------------------------|---|
| 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 |

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 |

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 |

CAPRELSA

Products Affected

- CAPRELSA

| 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 |

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 than 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. |
| Off-Label Uses | N/A |
| Part B Prerequisite | 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 |

CEREZYME

Products Affected

- CEREZYME INTRAVENOUS RECON
SOLN 400 UNIT

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Concomitant use with other approved therapies for Gaucher disease such as Cerdelga (eliglustat capsules), Elelyso (taliglucerase alfa injection), Vpriv (velaglucerase alfa injection), and Zavesca (miglustat capsules). |
| Required Medical Information | Diagnosis, genetic tests and lab results |
| Age Restrictions | Greater than or equal to 2 years of age |
| Prescriber Restrictions | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorder |
| Coverage Duration | 1 year |
| Other Criteria | Gaucher Disease, Type 1 (non-neuronopathic Gaucher disease)-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting biallelic pathogenic variants in the glucocerebrosidase (GBA) gene. Gaucher Disease, Type 3 (chronic neuronopathic Gaucher disease)-approve if both (A and B): A) there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting biallelic pathogenic variants in the glucocerebrosidase (GBA) gene, and B) medication is not being used for management of neurological manifestations AND is being used for management of impaired growth, hematologic, or visceral symptoms. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Type 3 Gaucher Disease |
| Part B Prerequisite | 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 |

CHORIONIC GONADOTROPIN

Products Affected

- CHORIONIC GONADOTROPIN,
HUMAN INTRAMUSCULAR

| 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 |

CINRYZE

Products Affected

- CINRYZE

| 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, 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 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 Cinryze as prophylactic therapy compared with baseline. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | 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 (a or b): a) one of the following: lamotrigine, topiramate, rufinamide, felbamate, Fintepla, Epidiolex or valproic acid OR b) at least two other antiepileptic drugs (e.g., valproic acid, levetiracetam, zonisamide, Fycompa/perampanel, vigabatrin). 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 |

COMETRIQ

Products Affected

- COMETRIQ

| 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 with RET Gene Rearrangements - approve. 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 a Vascular Endothelial Growth Factor Receptor (VEGFR)-targeted therapy. |
| 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 |

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 one systemic regimen (e.g., Imbruvica (ibrutinib capsules, tablets and oral solution), Venclexta (venetoclax tablets), rituximab, Gazyva (obinutuzumab intravenous infusion), chlorambucil, fludarabine, cyclophosphamide, bendamustine, high-dose methylprednisolone, Campath (alemtuzumab intravenous infusion), Calquence (acalabrutinib capsules), Brukinsa (zanubrutinib capsules), or Arzerra (ofatumumab intravenous infusion). 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 |

CORLANOR

Products Affected

- CORLANOR ORAL TABLET
- *ivabradine*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | CHF: Previous use of a Beta-blocker, LVEF. IST: Previous use of a Beta-blocker |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 12 months |
| Other Criteria | Chronic HF, adults- must have LVEF of less than or equal 35 percent (currently or prior to initiation of Corlanor or ivabradine therapy) AND tried or is currently receiving a Beta-blocker for HF (e.g., metoprolol succinate sustained-release, carvedilol, bisoprolol, carvedilol ER) unless the patient has a contraindication to the use of beta blocker therapy (e.g., bronchospastic disease such as COPD and asthma, severe hypotension or bradycardia). Heart failure due to dilated cardiomyopathy, children-approve. IST - tried or is currently receiving a Beta-blocker unless the patient has a contraindication to the use of beta blocker therapy (e.g., bronchospastic disease such as COPD and asthma, severe hypotension or bradycardia). |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | inappropriate sinus tachycardia (IST) |
| Part B Prerequisite | No |

COSENTYX

Products Affected

- COSENTYX
- COSENTYX (2 SYRINGES)
- COSENTYX PEN
- COSENTYX PEN (2 PENS)
- 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 |

COTELLIC

Products Affected

- COTELLIC

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Melanoma initial - must have BRAF V600 mutation. |
| 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. 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) Ganglioglioma/neuroglioma/glioneuronal tumor OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c or d): a) glioma/circumscribed glioma OR b) isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma or d) Oligodendroglioma 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 AND C) Patient has BRAF V600 mutation-positive 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 |

CYSTEAMINE (OPHTHALMIC)

Products Affected

- 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 |

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 | Initial-4months, Continuation-1 year. |
| 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 |

DANZITEN

Products Affected

- DANZITEN

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | ALL - 15 years and older, GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 1 year |
| Other Criteria | CML- approve if BCR::ABL1-mutation positive or Philadelphia chromosome positive. ALL-Philadelphia chromosome positive. Pigmented villonodular synovitis/tenosynovial giant cell tumor-patient has tried Turalio or Romvimza or cannot take Turalio or Romvimza. 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. 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 | Acute lymphoblastic leukemia, Pigmented villonodular synovitis/Tenosynovial giant cell tumor, GIST, cutaneous melanoma and myeloid/lymphoid neoplasms with eosinophilia |
| Part B Prerequisite | No |

DAURISMO

Products Affected

- DAURISMO

| 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 |

DEFERASIROX

Products Affected

- *deferasirox oral tablet*

| 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 |

DIABETIC SUPPLIES

Products Affected

- ADVOCATE PEN NEEDLE NEEDLE 32 GAUGE X 5/32"
- *alcohol pads*
- ALCOHOL PREP PADS
- ALCOHOL SWABS
- ALCOHOL WIPES
- ASSURE ID INSULIN SAFETY SYRINGE 1 ML 29 GAUGE X 1/2"
- BD SAFETYGLIDE INSULIN SYRINGE SYRINGE 1 ML 29 GAUGE X 1/2", 1 ML 31 GAUGE X 15/64"
- CARETOUCH ALCOHOL PREP PAD
- CURITY ALCOHOL SWABS
- CURITY GAUZE TOPICAL SPONGE 2 X 2 "
- DROPLET MICRON PEN NEEDLE
- DROPLET PEN NEEDLE NEEDLE 30 GAUGE X 5/16"
- DROPSAFE ALCOHOL PREP PADS
- DROPSAFE PEN NEEDLE NEEDLE 31 GAUGE X 3/16"
- EASY COMFORT ALCOHOL PAD
- EASY COMFORT SAFETY PEN NEEDLE NEEDLE 31 GAUGE X 3/16"
- EASY TOUCH ALCOHOL PREP PADS
- GAUZE PAD TOPICAL BANDAGE 2 X 2 "
- INCONTROL PEN NEEDLE NEEDLE 32 GAUGE X 5/32"
- INSULIN SYRINGE-NEEDLE U-100 SYRINGE 0.3 ML 29 GAUGE, 1 ML 29 GAUGE X 1/2", 1/2 ML 28 GAUGE
- IV PREP WIPES
- MAXICOMFORT SAFETY PEN NEEDLE NEEDLE 29 GAUGE X 5/16"
- NANO PEN NEEDLE
- NOVOFINE 32
- NOVOFINE PLUS
- PEN NEEDLE, DIABETIC NEEDLE 29 GAUGE X 1/2"
- PENTIPS PEN NEEDLE
- PRO COMFORT ALCOHOL PADS
- PURE COMFORT ALCOHOL PADS
- TECHLITE INSULIN SYRINGE SYRINGE 1 ML 30 GAUGE X 1/2", 1 ML 31 GAUGE X 15/64", 1 ML 31 GAUGE X 5/16
- TECHLITE INSULN SYR(HALF UNIT) SYRINGE 0.3 ML 31 GAUGE X 15/64", 0.3 ML 31 GAUGE X 5/16", 0.5 ML 30 GAUGE X 1/2", 0.5 ML 31 GAUGE X 15/64", 0.5 ML 31 GAUGE X 5/16"
- TECHLITE PEN NEEDLE NEEDLE 29 GAUGE X 1/2", 31 GAUGE X 3/16", 31 GAUGE X 5/16", 32 GAUGE X 1/4", 32 GAUGE X 5/32"
- TRUE COMFORT ALCOHOL PADS
- TRUE COMFORT PRO ALCOHOL PADS
- TRUEPLUS INSULIN
- TRUEPLUS PEN NEEDLE
- ULTRA-FINE INSULIN SYRINGE SYRINGE 0.5 ML 30 GAUGE X 1/2", 1 ML 31 GAUGE X 5/16
- ULTRA-FINE PEN NEEDLE NEEDLE 31 GAUGE X 3/16", 31 GAUGE X 5/16", 32 GAUGE X 1/4"
- UNIFINE PENTIPS MAXFLOW
- UNIFINE PENTIPS NEEDLE 29 GAUGE X 1/2", 31 GAUGE X 1/4", 31 GAUGE X 3/16", 31 GAUGE X 5/16", 32 GAUGE X 1/4", 32 GAUGE X 5/32", 33 GAUGE X 5/32"
- UNIFINE PENTIPS PLUS
- UNIFINE PENTIPS PLUS MAXFLOW
- UNIFINE SAFECONTROL PEN NEEDLE NEEDLE 30 GAUGE X 3/16", 30 GAUGE X 5/16", 32 GAUGE X 5/32"
- UNIFINE ULTRA PEN NEEDLE
- VERIFINE PLUS PEN NEEDLE-SHARP

| 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 |

DICLOFENAC

Products Affected

- *diclofenac sodium topical drops*

| 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 | Patients must try a generic oral NSAID or generic diclofenac 1 percent gel. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DIHYDROERGOTAMINE MESYLATE

Products Affected

- *dihydroergotamine nasal*

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

DIMETHYL FUMARATE PDP ASSURANCE

Products Affected

- *dimethyl fumarate*

| 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 |

DOPTelet

Products Affected

- DOPTelet (10 TAB PACK)
- DOPTelet (15 TAB PACK)
- DOPTelet (30 TAB PACK)
- DOPTelet SPRINKLE

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | Thrombocytopenia in chronic liver disease - 18 years and older |
| 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 |

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 |

DUAVEE

Products Affected

- DUAVEE

| 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 | For the prevention of postmenopausal osteoporosis, trial, failure, or intolerance of raloxifene is required prior to the use of Duavee. |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DUPIXENT

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concurrent use with Xolair or another Anti-interleukin (IL) Monoclonal Antibody (i.e., Adbry, Cinqair, Fasenra, Nucala, Tezspire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical]. |
| Required Medical Information | Diagnosis, prescriber specialty, other medications tried and length of trials. COPD INITIAL: meets (all of A, B, and C): A) blood eosinophil at least 300 cells per microliter within previous 6 weeks or prior to Dupixent or another monoclonal antibody, and B) received at least 3 months of combination therapy with at least two of LAMA, LABA or ICS, and, and C) meets (i or ii): i) two or more COPD exacerbations in previous 12 months requiring systemic CS or antibiotics or ii) COPD exacerbation requiring hospitalization in previous 12 months. COPD CONTINUATION (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). CSU INITIAL: urticaria for greater than 6 weeks (prior to Dupixent), with symptoms at least 3 days/week despite daily non-sedating H1 antihistamine tx. CSU CONTINUATION (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. Bullous Pemphigoid Initial: Approve. Bullous Pemphigoid Continuous: meets both (i and ii): i. received at least 6 months of therapy with Dupixent AND ii. experienced a beneficial clinical response, defined by decreased area of skin involvement, lesions, including blisters or erosions (bullae), urticaria, erythema, or reduced or no need for systemic or topical corticosteroid therapy. |
| 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/BP-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 |

| PA Criteria | Criteria Details |
|-------------------|---|
| | allergist, immunologist or otolaryngologist. Esophagitis-prescr/consult-allergist or gastro. COPD-prescribed by or in consultation with an allergist, immunologist, or pulmonologist. BP-prescr/consult with derm |
| Coverage Duration | AD-Init-4mo, Cont-1 yr, asthma/Rhinosinusitis/esophagitis/PN/COPD/CSU/BP-init-6 mo, cont 1 yr |
| Other Criteria | <p>INITIAL CRITERIA: AD: tried at least 1 medium to super-high-potency topical corticosteroid (CS), unless topical CS therapy not advisable or pt is less than 2 years old. ASTHMA (all of A, B, and C): A) blood eosinophil greater than or equal to 150 cells per microliter within previous 6 weeks or within 6 weeks prior to Dupixent or another monoclonal antibody or has oral CS-dependent asthma, B) used an 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 (one of a, b, c, d, or e): a) two or more asthma exacerbations requiring oral CS in the past year, b) one or more asthma exacerbations requiring hospital/urgent care/ED visit in the past year, c) FEV1 less than 80 percent predicted (adults only), d) FEV1/FVC less than 0.8, or e) worsened asthma with oral CS taper. CRSwNP (all of A, B, C and D): A) concurrent use with nasal CS, B) presence of at least two of the following symptoms for 6 months: nasal congestion, nasal obstruction, nasal discharge, reduction/loss of smell, C) received oral CS at least 5 days in last 2 years (unless contraindicated) or patient had prior surgery for nasal polyps, and D) diagnosis confirmed by direct exam, endoscopy, or sinus CT. EoE (all of A, B, C, and D): A) weighs 15 kg or more, B) endoscopic biopsy demonstrating greater than or equal to 15 intraepithelial eosinophils per high-power field, C) does not have a secondary cause of EoE, and D) received an Rx-strength PPI for at least 8 weeks. PRURIGO NODULARIS approve if pt has pruritus lasting at least 6 weeks. CONTINUATION CRITERIA: AD: responding positively to therapy. ASTHMA: responding positively to therapy and concurrent use with ICS. 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.</p> |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Part B Prerequisite | No |

ELAPRASE

Products Affected

- ELAPRASE

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, genetic and lab test results |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders |
| Coverage Duration | 1 year |
| Other Criteria | Approve if the patient has laboratory test demonstrating deficient iduronate-2-sulfatase activity in leukocytes, fibroblasts, serum or plasma OR a molecular genetic test demonstrating iduronate-2-sulfatase gene variant. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

EMRELIS

Products Affected

- EMRELIS

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist. |
| Coverage Duration | 1 year |
| Other Criteria | Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. NON-SMALL CELL LUNG CANCER- ALL of the following (A, B and C): A. Patient has locally advanced or metastatic, non-squamous disease, AND B. Tumor has high c-Met protein overexpression, defined as a greater than or equal to 50 percent of tumor cells with strong [3+] staining, as determined by an approved test, AND C. Patient has received at least one prior systemic therapy. Note: Examples are cisplatin, carboplatin, pemetrexed, Keytruda (pembrolizumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Imfinzi (durvalumab intravenous infusion), Libtayo (cemiplimab-rwlc intravenous infusion) |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 | PP-4 years and older (initial therapy) |
| Prescriber Restrictions | Initial only-RA/AS/JIA/JRA,prescribed by or in consult w/ rheum. 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. Uveitis, prescribed by or in consultation with an ophthalmologist. Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist. |
| Coverage Duration | End of the plan year |
| Other Criteria | RA/PsA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor for RA/PsA are not required to step back and try a conventional synthetic DMARD). JIA/JRA-initial-approve if the patient meets ONE of the following: patient has tried one other medication for this condition for at least 3 months (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID), biologic or JAK inhibitor) OR patient has aggressive disease. PP initial, approve if the patient 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: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. Uveitis initial, tried one of the following: periocular, intraocular, or |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | systemic corticosteroid, immunosuppressives or other biologic therapy. GVHD, approve. Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Continuation-approve if the patient has had a response as determined by the prescriber. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Graft versus host disease (GVHD), Uveitis, Behcet's disease |
| Part B Prerequisite | No |

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 |

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-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-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs. Tuberous Sclerosis Complex-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs. Continuation of therapy-approve if the patient is responding to therapy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

EPOETIN ALFA

Products Affected

- 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-1yr, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr |
| Other Criteria | <p>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 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. Anemia in patients with chronic renal failure on dialysis -</p> |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | 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 |

ERIVEDGE

Products Affected

- ERIVEDGE

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | BCC (La or Met) - must not have had disease progression while on Odomzo. |
| Required Medical Information | N/A |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 1 year |
| Other Criteria | Basal cell carcinoma, locally advanced-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 |

ERLEADA

Products Affected

- ERLEADA

| 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 |

ERLOTINIB

Products Affected

- *erlotinib*

| 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 has recurrent or advanced non-clear cell histology RCC or if the patient had hereditary leiomyomatosis and renal cell carcinoma and 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 |

EVEROLIMUS

Products Affected

- *everolimus (antineoplastic)*

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Breast Cancer-HER2 status, hormone receptor (HR) status. |
| Age Restrictions | All dx except TSC associated SEGA, renal angiomyolipoma or partial onset seizures-18 years and older. |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 1 year |
| Other Criteria | <p>Breast Cancer-pt meets the following (A,B,C,D,E, and F):A)recurrent or metastatic,HR+ disease AND B)HER2-negative breast cancer AND C)tried at least 1 prior endocrine therapy AND D)meets 1 of the following conditions (i or ii):i.postmenopausal woman or man OR ii.pre/perimenopausal woman AND receiving ovarian suppression/ablation with GnRH agonist, or had surgical bilateral oophorectomy or ovarian irradiation AND E)meets 1 of the following conditions (i or ii): i.Everolimus used in combo w/exemestane and meets 1 of the following:male and receiving a GnRH analog or woman or ii.Everolimus will be used in combo with fulvestrant or tamoxifen AND F)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, has tried 1 prior systemic therapy(e.g., Inlyta, Votrient, Sutent, Cabometyx, Nexavar).TSC Associated SEGA-requires therapeutic intervention but cannot be curatively resected.Thymomas and Thymic Carcinomas-has tried chemo or cannot tolerate chemo.TSC associated renal angiomyolipoma-approve.WM/LPL-has progressive or relapsed disease or if has not responded to primary therapy.Thyroid Carcinoma, differentiated-refractory to radioactive iodine therapy.Endometrial Carcinoma- Everolimus will be used in combo with letrozole.GIST-has tried 2 of the following drugs: Sutent, Sprycel, Stivarga, Ayvakit, Qinlock</p> |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | <p>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-has perivascular epitheloid cell tumors (PE Coma) or recurrent angiomyolipoma/lymphangiomyomatosis.Classic hodgkin lymphoma-has relapsed or refractory disease AND has tried at least three prior lines of chemotherapy.Histiocytic neoplasm-has Erdheim-Chester disease or, Rosai-Dorfman disease or Langerhans cell histiocytosis.Pt must also have PIK3CA mutation. Meningioma-has recurrent or progressive disease AND has surgically inaccessible disease and radiation therapy is not possible AND medication will be used in combination with a somatostatin analogue. Uterine Sarcoma-has advanced, recurrent, metastatic, or inoperable disease, AND has perivascular epithelioid cell tumor (PEComa), AND has tried at least 1 systemic regimen.Note: Examples of include doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine. For all covered diagnoses, if the request is for brand Afinitor-pt is required to have tried generic everolimus tablets AND cannot use the generic product due to formulation diff in the inactive ingredient(s) between Brand and generic product which would result in a significant allergy or serious adverse reaction.</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 |

EYLEA

Products Affected

- EYLEA

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | Administered by or under the supervision of an ophthalmologist |
| Coverage Duration | 3 years |
| Other Criteria | BvsD Coverage Determination |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

FARYDAK

Products Affected

- FARYDAK

| 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 | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | 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 |

FORTEO

Products Affected

- FORTEO

| 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 | Treatment of PMO, approve if pt has tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR pt has severe renal impairment (creatinine clearance less than 35 mL/min) or CKD or pt has had an osteoporotic fracture or fragility fracture. Increase bone mass in men (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) with primary or hypogondal osteoporosis/Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture. Patients who |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | have already taken teriparatide for 2 years - approve if the patient is at high risk for fracture. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 |

FRUZAQLA

Products Affected

- FRUZAQLA

| 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 | Colon cancer, rectal cancer, or appendiceal cancer-Approve if the patient meets the following (A and B): A.Patient has advanced or metastatic disease, AND B.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 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 |

GATTEX

Products Affected

- GATTEX 30-VIAL
- GATTEX ONE-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 |

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 RET fusion-positive or RET-mutation-positive disease. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Medullary Thyroid Cancer, Anaplastic Thyroid Cancer |
| Part B Prerequisite | 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 |

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. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Head and neck cancer |
| Part B Prerequisite | No |

GLATIRAMER

Products Affected

- *glatiramer*
- *glatopa*

| 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 |

GLP-1 AGONISTS

Products Affected

- MOUNJARO MG/3 ML), 1 MG/DOSE (4 MG/3 ML), 2
- OZEMPIC SUBCUTANEOUS PEN 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 |

GOMEKLI

Products Affected

- GOMEKLI

| 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 |

GONADOTROPIN-RELEASING HORMONE AGONISTS - ONCOLOGY

Products Affected

- TRIPTODUR

| 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 | 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 |

GROWTH HORMONES - GENOTROPIN

Products Affected

- GENOTROPIN
- GENOTROPIN MINIUICK

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | 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 |
| Age Restrictions | ISS 5 y/o or older, SGA 2 y/o or older, SBS 18 y/o or older |
| Prescriber Restrictions | GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, Noonan (initial), Prader Willi (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 | ISS - 6 mos initial, 12 months cont tx, SBS-1 month, others 12 mos |
| Other Criteria | GHD initial in adults and adolescents 1. endocrine must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | <p>AND 3. meets one of the following - A. has known perinatal insults or congenital or genetic defects or structural hypothalamic pituitary defects, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, IGF1 less than 84 mcg/L (Esoterix RIA), AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L (BMI is less than or equal to 25), less than or equal to 3 and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH deficiency, less than or equal to 1 and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH deficiency or less than or equal to 1 mcg/L (BMI is greater than 30), if insulin and glucagon contraindicated then Arginine test with peak of less than or equal to 0.4 mcg/L, or Macrilen peak less than 2.8 ng/ml AND BMI is less than or equal to 40 AND if a transitional adolescent must be off tx for at least one month before retesting. Cont tx - endocrine must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than the 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts greater than or equal to 5 or b. growth velocity is less than 10th percentile for age/gender. Cont tx - prescriber confirms response to therapy. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by chromo analysis, open epiphyses, height less than 3rd percentile for age/gender. SGA initial - baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). Cont tx - prescriber confirms response to therapy. Cont Tx for CKD, Noonan, PW in child/adolescents, SHOX, and TS - prescriber confirms response to therapy. SBS initial pt receiving specialized nutritional support. Cont tx - 2nd course if pt responded to tx with a decrease in the requirement for specialized nutritional support.</p> |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | SBS |
| Part B Prerequisite | No |

HERNEXEOS

Products Affected

- HERNEXEOS

| 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 the following (A, B, C, and D): A) Unresectable or metastatic disease, AND B) Human epidermal growth factor receptor 2 (HER2) (ERBB2) activating mutation, AND C) Mutation was detected by an approved test, AND D) Received at least one prior systemic therapy. Note: Examples include checkpoint inhibitors such as Keytruda (pembrolizumab intravenous infusion), Libtayo (cemiplimab-rwlc intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), or Imjudo (tremelimumab-actl intravenous infusion) in combination with chemotherapy (e.g., carboplatin, cisplatin, pemetrexed, paclitaxel, albumin-bound paclitaxel, bevacizumab), chemotherapy alone (e.g., docetaxel, gemcitabine, etoposide, vinorelbine, other chemotherapy noted above). |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HETLIOZ

Products Affected

- *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 |

HIGH RISK MEDICATIONS - BENZTROPINE

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 medically-accepted indications, approve if the prescriber confirms he/she has assessed risk versus benefit in prescribing benztropine 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 |

HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

Products Affected

- *cyclobenzaprine oral tablet 10 mg, 5 mg*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | Patients aged less than 65 years, approve. |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 months. |
| Other Criteria | The physician 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 |

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

Products Affected

- *hydroxyzine hcl oral tablet*
- *hydroxyzine pamoate*
- *promethazine 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 | Authorization will be for 12 months. |
| Other Criteria | For hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. Approve hydroxyzine hydrochloride if the patient has tried at least two other FDA-approved products for the management of anxiety. Prior to approval of promethazine and hydroxyzine, approve if 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 |

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. |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HUMIRA

Products Affected

- HUMIRA PEN (PREFERRED NDC'S STARTING WITH 0074)
- HUMIRA SUBCUTANEOUS SYRINGE KIT 40 MG/0.8 ML (PREFERRED NDC'S STARTING WITH 0074)
- HUMIRA(CF) (PREFERRED NDC'S STARTING WITH 0074)
- HUMIRA(CF) PEN (PREFERRED NDC'S STARTING WITH 0074)
- HUMIRA(CF) PEN CROHNS-UC-HS (PREFERRED NDC'S STARTING WITH 0074)
- HUMIRA(CF) PEN PSOR-UV-ADOL HS (PREFERRED NDC'S STARTING WITH 0074)
- YUFLYMA(CF)
- YUFLYMA(CF) AI CROHN'S-UC-HS
- YUFLYMA(CF) AUTOINJECTOR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Concurrent use with biologic therapy or targeted synthetic DMARD. |
| Required Medical Information | Diagnosis |
| Age Restrictions | Initial therapy only: Crohn's disease (CD)-6 or older, Ulcerative colitis (UC)-5 or older, PP/ Pyoderma gangrenosum/ sarcoidosis/ scleritis/ sterile corneal ulceration/ non-radiographic axial spondyloarthritis-18 years and older, Behcet's disease-2 years and older |
| Prescriber Restrictions | Initial therapy only 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, derm, ophthalmol, gastro, neuro. Sarcoidosis, pulm, ophthalmol, derm. |
| Coverage Duration | End of the plan year |
| Other Criteria | RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA-initial-approve if the patient meets ONE of the following: patient has tried one other medication for this condition for at least 3 months (Note: Examples of other medications for |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | <p>JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID), biologic or JAK inhibitor) OR patient has aggressive disease. PP initial, approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine (CSA), acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial, approve. UC initial, approve. Uveitis initial, tried one of the following: periocular, intraocular, or systemic corticosteroid, immunosuppressives or other biologic therapy. HS initial, tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). 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-approve if the patient has had a response as determined by the prescriber. Clinical criteria incorporated into the Humira 40 mg quantity limit edit allow for approval of additional quantities to accommodate induction dosing. The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling.</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 |

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 | 3 years |
| Other Criteria | Breast cancer - approve recurrent or metastatic, hormone receptor positive (HR+) [i.e., estrogen receptor positive- {ER+} and/or progesterone receptor positive {PR+}] disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and Ibrance will be used in combination with anastrozole, exemestane, or letrozole 2, pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonists, or has had surgical bilateral oophorectomy, or ovarian irradiation AND meets one of the following conditions: Ibrance will be used in combination with anastrozole, exemestane, or letrozole or Ibrance will be used in combination with fulvestrant (with or without Itovebi) 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 Ibrance will be used in combination with anastrozole, exemestane or letrozole or Ibrance will be used in combination with fulvestrant (with or without Itovebi) 4. Pt is postmenopausal and Ibrance will be used in combination with fulvestrant (with or without Itovebi). Liposarcoma- approve if the patient has well-differentiated/dedifferentiated liposarcoma (WD-DDLS). |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Liposarcoma |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Part B Prerequisite | No |

IBTROZI

Products Affected

- IBTROZI

| 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-locally advanced or metastatic disease and ROS1-positive non-small cell lung cancer as detected by an approved test. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 |

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. Chronic myeloid leukemia-approve. 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 |

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 |

IMATINIB

Products Affected

- *imatinib*
- 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-PDGFRB or PDGFRB rearrangement. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Chordoma, desmoid tumors (aggressive fibromatosis), cKit positive metastatic or unresectable cutaneous melanoma, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia, GVHD, chronic. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Part B Prerequisite | No |

IMBRUVICA

Products Affected

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

| 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, thiotepea, 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 |

IMDELLTRA

Products Affected

- IMDELLTRA

| 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 |
| Coverage Duration | 1 year |
| Other Criteria | Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. SMALL CELL LUNG CANCER-patient has relapsed or refractory extensive stage disease and has previously received platinum-based chemotherapy. Note: Examples of platinum medications include cisplatin and carboplatin. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | 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 |

INCRELEX

Products Affected

- INCRELEX

| PA Criteria | Criteria Details |
|------------------------------|----------------------------------|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | Patients 2 years of age or 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 |

INFLECTRA

Products Affected

- INFLECTRA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concurrent use with Biologic DMARD or Targeted Synthetic. |
| Required Medical Information | Diagnosis, concurrent medication, previous medications tried |
| Age Restrictions | CD and UC- Pts aged 6 years or more (initial therapy). PP-18 years and older (initial therapy) |
| Prescriber Restrictions | All dx Initial therapy only -prescribed by or in consultation with: RA/AS/Still's disease/JIA/JRA-rheumatologist, PP/Pyoderma gangrenosum/Hidradenitis suppurativa-dermatologist, Psoriatic Arthritis-rheum or derm, CD/UC-gastroenterologist, Uveitis ophthalmologist, GVHD-a physician affiliated with a transplant center, oncologist, or hematologist, Behcet's Disease- rheum, derm, ophthalmologist, gastroenterologist, or neurologist, Sarcoidosis-pulmonol, ophthalmol, cardio, neuro, or derm |
| Coverage Duration | GVHD intl-1 mo, cont-3 mo.Pyoderma Gangrenosum-intl 4 mo, cont 1 yr.all others-intl 6 mo, cont-12 mo |
| Other Criteria | RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA-initial-approve if the patient meets ONE of the following: patient has tried one other medication for this condition for at least 3 months (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID), biologic or JAK inhibitor OR Patient has aggressive disease. PP initial, approve if the patient 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: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. Uveitis initial, tried one of the following: periocular, intraocular, or |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | <p>systemic corticosteroid, immunosuppressives or other biologic therapy. GVHD, approve. CD initial, approve. UC initial, approve. HS initial, tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Behcet's initial, patient has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa) or at least one tumor necrosis factor for Behcet's disease OR has ophthalmic manifestations. Still's Disease initial, tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant. Prev trial of one biologic other than requested drug or biosimilar of the requested drug also counts. Sarcoidosis initial. tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG) initial, tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to one of these agents. Continuation-approve if the patient has had a response as determined by the prescriber.</p> |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | <p>Patients already started on infliximab for a covered use, Behcet's disease, Still's disease, Uveitis, Pyoderma gangrenosum, Hidradenitis suppurativa,, Graft-versus-host disease, Juvenile Idiopathic Arthritis (JIA)/JRA, Sarcoidosis</p> |
| Part B Prerequisite | No |

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 |

INLYTA

Products Affected

- INLYTA

| 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 |

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/Myeloproliferative Neoplasm Overlap Neoplasms |
| Part B Prerequisite | 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 intermediate-2 or high-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 |

ITOVEBI

Products Affected

- ITOVEBI

| 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, 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 has disease recurrence on or after completing adjuvant endocrine therapy, Note: Examples 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 |
| Part B Prerequisite | No |

IVERMECTIN

Products Affected

- *ivermectin oral*

| 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 | 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 |

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 |

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/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 |

JAYPIRCA

Products Affected

- JAYPIRCA

| 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>Mantle cell lymphoma-approve if the patient has tried at least one systemic 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, dexamethasone, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, 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</p> |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | regimen. Marginal Zone 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 |

JYLAMVO

Products Affected

- JYLAMVO

| 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 | N/A |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

JYNARQUE

Products Affected

- *tolvaptan (polycystic kidney dis) oral tablet*

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Patient is currently receiving another tolvaptan product. |
| 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 |

KALYDECO

Products Affected

- KALYDECO ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Combination use with Orkambi, Trikafta or Symdeko |
| 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 CFTR 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 CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | 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 | <p>Diabetic kidney disease, initial-approve if the patient meets the following criteria (i, and ii): i. Patient has a diagnosis of type 2 diabetes, AND ii. Patient meets one of the following (a or b): a)Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b)According to the prescriber, patient has a contraindication or has experienced significant intolerance to ACE inhibitor or ARB therapy. Diabetic kidney disease, continuation-approve if the patient meets the following criteria (i, and ii): i. Patient has a diagnosis of type 2 diabetes, AND ii. Patient meets one of the following (a or b): a. Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b. According to the prescriber, patient has a contraindication or has experienced significant intolerance to ACE inhibitor or ARB therapy. Heart failure-initial-Pt meets all (i and ii): i) has left ventricular ejection fraction of at least 40 percent AND ii) tried one of the following SGLT-2 inhibitors: Farxiga (dapagliflozin tabs, authorized generic) Inpefa (sotagliflozin tabs), or Jardiance (empagliflozin tabs) OR has contraindication or has experienced significant intolerance to SGLT-2 inhibitors. Heart failure-continuation-Pt meets all (i and ii): i) has left ventricular ejection fraction of at least 40 percent AND ii) tried one of the following SGLT-2 inhibitors: Farxiga (dapagliflozin tabs, authorized generic) Inpefa or (sotagliflozin tabs), or Jardiance (empagliflozin tabs) or</p> |

| PA Criteria | Criteria Details |
|--------------------------------|---|
| | has contraindication or has experienced significant intolerance to SGLT-2 inhibitors. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 |

KISQALI

Products Affected

- KISQALI
- KISQALI FEMARA CO-PACK ORAL TABLET 400 MG/DAY(200 MG X 2)-2.5 MG, 600 MG/DAY(200 MG X 3)-2.5 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 | 1 year |
| Other Criteria | <p>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</p> <ol style="list-style-type: none"> 1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND 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 will be used in combination with anastrozole, exemestane or letrozole. 4. Patient 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 Kisqali (not Co-Pack) will be used in combination with fulvestrant. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane or letrozole. <p>Endometrial cancer - approve if pt meets all of (A,</p> |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | B and C): A) pt has recurrent or metastatic disease, and B) has estrogen receptor (ER)-positive tumors, and C) if request is for Kisqali (not Co-Pack), 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 |

KORLYM

Products Affected

- *mifepristone oral tablet 300 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 syndrome. |
| Coverage Duration | Endogenous Cushing's Synd-1 yr. Pt awaiting surgery or response after radiotherapy-4 months |
| Other Criteria | Endogenous Cushing's Syndrome-Approve if, according to the prescribing physician, the patient is not a candidate for surgery or surgery has not been curative AND if mifepristone is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Patients with Endogenous Cushing's Syndrome, awaiting surgery. Patients with Endogenous Cushing's syndrome, awaiting a response after radiotherapy |
| Part B Prerequisite | No |

KOSELUGO

Products Affected

- KOSELUGO ORAL CAPSULE

| 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 1 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, or iv): 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 all of the following (a, b, and c): a) Patient has single system bone disease, AND b) Patient has not responded to treatment with a bisphosphonate, AND c) Patient has more than 2 bone lesions, OR iv. Patient has central nervous system 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 |

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 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 |

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 | HER2-positive recurrent or metastatic breast cancer, approve if lapatinib will be used in combination with capecitabine OR trastuzumab and the patient has tried at least two prior anti-HER2 based regimens OR the medication will be used in combination with an aromatase inhibitor and the patient has HR+ disease and the patient is a postmenopausal woman or the patient is premenopausal or perimenopausal woman and is receiving ovarian suppression/ablation with a GnRH agonist, surgical bilateral oophorectomy or ovarian irradiation OR the patient is a man and is receiving a GnRH analog. Colon or rectal cancer-approve if the patient has unresectable advanced or metastatic disease that is human epidermal receptor 2 (HER2) amplified and with wild-type RAS and BRAF disease and the patient has tried at least one chemotherapy regimen or is not a candidate for intensive therapy and the medication is used in combination with trastuzumab and the patient has not been previously treated with a HER2-inhibitor. Bone Cancer-approve if the patient has recurrent chordoma and if the patient has epidermal growth-factor receptor (EGFR)-positive disease. |
| 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 |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Part B Prerequisite | No |

LAZCLUZE

Products Affected

- LAZCLUZE

| 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 |

LENALIDOMIDE

Products Affected

- *lenalidomide*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis and previous therapies or drug regimens tried. |
| Age Restrictions | 18 years and older (except Kaposi's Sarcoma, Castleman's Disease, CNS Lymphoma) |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 1 year |
| Other Criteria | <p>Follicular lymphoma-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one prior therapy. MCL-approve -if the patient is using lenalidomide in combination with rituximab or has tried at least two other therapies or therapeutic regimens. MZL-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one other therapy or therapeutic 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]). B-cell-lymphoma (other)-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve. CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical-approve if the patient has tried at least three other I222 regimens. Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi's 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</p> |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | neoplasms-approve if the patient has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman disease. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma, Central nervous system lymphoma, Kaposi's sarcoma, histiocytic neoplasm. |
| Part B Prerequisite | No |

LENVIMA

Products Affected

- LENVIMA

| 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 | 3 years |
| Other Criteria | <p>DTC - must be refractory to radioactive iodine treatment for approval.</p> <p>RCC, advanced disease- approve if the pt meets i or ii: i. Lenvima is being used in combination with pembrolizumab OR ii. Lenvima is used in combination with everolimus 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. New starts for all RCC must have tried Cabometyx. 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 mismatch repair proficient (pMMR) or is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) 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. Thymic carcinoma-approve if the patient has tried at least one chemotherapy regimen. New starts for Hepatocellular Carcinoma: For first line systemic therapy, sorafenib must be tried first. For subsequent-line system therapy if disease progression, Cabometyx must be tried first. 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</p> |

| PA Criteria | Criteria Details |
|--------------------------------|--|
| | death receptor-1 (PD-1)/programmed 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 |

LIDOCAINE PATCH

Products Affected

- *lidocaine topical adhesive patch, medicated 5 %*

| 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 |

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 |
| Prescriber Restrictions | Prescribed by or in consultation with a hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center. |
| Coverage Duration | 2 months |
| Other Criteria | Cytomegalovirus Infection, Treatment-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. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

LONSURF

Products Affected

- LONSURF

| 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 | 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. Colon and rectal cancer-approve per labeling if the patient has been previously treated with a fluopyrimidine, oxaliplatin, irinotecan and if the patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type) they must also try Erbitux or Vectibix. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

LOQTORZI

Products Affected

- LOQTORZI

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 1 year |
| Other Criteria | <p>Nasopharyngeal carcinoma-approve if the patient has recurrent, unresectable, oligometastatic, or metastatic disease AND the patient meets ONE of the following (i or ii): i. Patient meets BOTH of the following (a and b): a) Loqtorzi is used for first-line treatment AND b) Loqtorzi is used in combination with cisplatin and gemcitabine, OR ii. Patient meets both of the following (a and b): a) Loqtorzi is used for subsequent treatment AND b) Loqtorzi is used as a single agent or in combination with cisplatin and gemcitabine. Anal carcinoma- approve if patient meets (A and B): A) meets (i or ii): i) locally recurrent, progressive disease and medication is administered before proceeding to abdominoperineal resection, or ii) metastatic disease, medication is used as subsequent therapy and patient has not received prior immunotherapy [ex: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Libtayo (cemiplimab intravenous infusion), and Jemperli (dostarlimab intravenous infusion)], and B) medication is used as a single agent. Small bowel adenocarcinoma- approve if patient meets (A, B, C and D): A) locally unresectable or medically inoperable disease, B) ultra-hypermutated phenotype (defined as tumor mutation burden greater than 50 mutations/megabase), C) patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation positive disease, and D) medication is used as a single agent.</p> |

| PA Criteria | Criteria Details |
|--------------------------------|--|
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Anal carcinoma, small bowel adenocarcinoma |
| Part B Prerequisite | No |

LORBRENA

Products Affected

- LORBRENA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, ALK status, ROS1 status, previous therapies |
| 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 IMT with ALK translocation. 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 |

LUMAKRAS

Products Affected

- LUMAKRAS

| 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 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) unresectable, advanced, or metastatic disease, and B) KRAS G12C mutation-positive disease, and C) medication is prescribed as part of a combination regimen for colon or rectal cancer [Ex: Lumakras plus cetuximab or panitumumab] 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. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma |
| Part B Prerequisite | No |

LUMIZYME

Products Affected

- LUMIZYME

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, genetic and lab test results |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a geneticist, neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders |
| Coverage Duration | 1 year |
| Other Criteria | Approve if the patient has a laboratory test demonstrating deficient acid alpha-glucosidase activity in blood, fibroblasts, or muscle tissue OR patient has a molecular genetic test demonstrating biallelic pathogenic or likely pathogenic acid alpha-glucosidase (GAA) gene variants. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

LUPRON DEPOT

Products Affected

- LEUPROLIDE ACETATE (3 MONTH)
- *leuprolide subcutaneous kit*
- LUPRON DEPOT
- LUPRON DEPOT (3 MONTH)
- LUPRON DEPOT (4 MONTH)
- LUPRON DEPOT (6 MONTH)
- LUPRON DEPOT-PED
- LUPRON DEPOT-PED (3 MONTH)
- LUTRATE DEPOT (3 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 Depot 7.5mg, patients are required to try Orgovyx or 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 |

| PA Criteria | Criteria Details |
|--------------------------------|--|
| | disorders including premenstrual syndrome and premenstrual dysphoric 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 |

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 | 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 |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | 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. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Uterine Leiomyosarcoma |
| Part B Prerequisite | No |

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 |

MAVYRET

Products Affected

- MAVYRET

| 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 | Chronic HCV- Criteria will be applied consistent with AASLD/IDSA guidance, Acute HCV-8 weeks |
| Other Criteria | For Chronic Hepatitis C Virus, criteria will be applied consistent with current AASLD/IDSA guidance. For Acute Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6: Approve if the patient meets (A, B and C): A) Does not have cirrhosis OR has compensated cirrhosis AND B) has quantifiable HCV RNA AND C) ONE of the following (i, ii, or iii): i. conversion of negative to positive results in anti-HCV antibody, HCV RNA, and/or HCV core antigen OR ii. signs and symptoms of acute hepatitis C virus OR iii. has engaged in a risk behavior for HCV infection within the prior 6 months. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Indications consistent with current AASLD/IDSA guidance |
| Part B Prerequisite | No |

MEGESTROL

Products Affected

- *megestrol oral suspension 400 mg/10 ml (10 ml), 400 mg/10 ml (40 mg/ml), 800 mg/20 ml (20 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 |

MEKINIST

Products Affected

- MEKINIST

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer and NSCLC must have documentation of BRAF V600 mutations |
| Age Restrictions | 1 year and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 1 year. |
| Other Criteria | 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. For NSCLC requires BRAF V600E Mutation and 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, unless intolerant 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 low-grade serous carcinoma or the patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafenlar. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafenlar. Central Nervous System Cancer-approve if the 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) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c or d): a) glioma OR b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma or d) Oligodendroglioma OR iii. Melanoma with brain |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | <p>metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Tafenlar (dabrafenib). Histiocytic neoplasm-approve if 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 patient has Erdheim Chester disease or Rosai-Dorfman disease. Metastatic or Solid Tumors-Approve if the patient meets the following (A, B, and C): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafenlar (dabrafenib capsules), AND C) Patient has no satisfactory alternative treatment options. 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.</p> |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Histiocytic Neoplasm, Hairy Cell Leukemia |
| Part B Prerequisite | No |

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 | 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 |

MODAFINIL

Products Affected

- *modafinil*

| 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 | Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD) - approve if the patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea syndrome-approve. Excessive daytime sleepiness associated with Narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Excessive daytime sleepiness (EDS) associated with myotonic dystrophy. Adjunctive/augmentation for treatment of depression in adults. |
| Part B Prerequisite | No |

MODEYSO

Products Affected

- MODEYSO

| 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 | HIGH-GRADE GLIOMA (Note: Examples of high-grade glioma include World Health Organization (WHO) Grade 3 or 4 gliomas, such as diffuse midline glioma or glioblastoma)-all the following (A, B and C): A) Histone 3 (H3) K27M mutation, AND B) Recurrent or progressive disease, AND C) Received at one least prior therapy. Note: Examples of prior therapy include radiation, temozolomide, procarbazine, lomustine, or vincristine. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

MRESVIA

Products Affected

- MRESVIA (PF)

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | 50 years of age or older OR adults aged 18 through 49 years who are at increased risk for lower respiratory tract disease |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 months |
| Other Criteria | The patient has not already received an RSV vaccine |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

NAGLAZYME

Products Affected

- NAGLAZYME

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, genetic and lab test results |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders |
| Coverage Duration | 1 year |
| Other Criteria | Approve if the patient has a laboratory test demonstrating deficient N-acetylgalactosamine 4-sulfatase (arylsulfatase B) activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating biallelic pathogenic or likely pathogenic arylsulfatase B gene variants. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 |

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 |

NEXLETOL

Products Affected

- NEXLETOL

| 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 | Patient has tried and failed or has a contraindication to a statin or the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of two statins and during both trials the skeletal-related symptoms resolved during discontinuation. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

NEXLIZET

Products Affected

- NEXLIZET

| 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 | Patient has tried and failed or has a contraindication to a statin or the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of two statins and during both trials the skeletal-related symptoms resolved during discontinuation. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | 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 - be used in combination with dexamethasone and lenalidomide or cyclophosphamide OR pt had received at least ONE previous therapy for multiple myeloma OR the agent will be used following autologous stem cell transplantation (ASCT). 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. |
| 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 |

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 or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), 3)patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, 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, invasive fungal infection). |
| 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 |

NMDA RECEPTOR ANTAGONIST

Products Affected

- *memantine oral solution*
- *memantine oral tablet*
- MEMANTINE ORAL TABLETS,DOSE PACK
- *memantine-donepezil*
- NAMZARIC ORAL CAPSULE,SPRINKLE,ER 24HR

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | Automatic approval if member is greater than 26 years of age. Prior Authorization is required for age 26 or younger. |
| 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 |

NON-INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- *testosterone transdermal gel*
- *testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %)*
- *testosterone transdermal gel in packet 1 % (25 mg/2.5gram)*
- TESTOSTERONE TRANSDERMAL GEL IN PACKET 1 % (50 MG/5 GRAM)

| 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 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- |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | 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 |

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 |

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 |

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 |

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 (initial and continuation)-approve. Preventive treatment of episodic migraine (initial)-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). Preventive treatment of episodic migraine (continuation) - 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 the patient has had a significant clinical benefit from the medication. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, or 3) patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Patients undergoing PBPC collection and therapy |
| Part B Prerequisite | No |

OCTREOTIDE INJECTABLE

Products Affected

- *octreotide acetate*

| 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-prescr/consult with oncologist. Diarrhea assoc w chemo-prescr/consult with oncologist/gastro. Small bowel bleed/angiodysplasia-prescr/consult gastroenterologist. |
| Coverage Duration | Enterocut fistula/diarrhea assoc w chemo-3 mos, all others 1yr |
| 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 and B) patient has tried at least one antimotility medication. SMALL BOWEL BLEEDS/ANGIODYSPLASIA RELATED BLEEDING: pt has chronic, recurrent gastrointestinal bleeds lasting greater than or equal to 3 months. |
| 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, small bowel bleeds/angiodysplasia related bleeding |
| Part B Prerequisite | 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 |

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 |

OGSIVEO

Products Affected

- OGSIVEO

| 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 |

OJEMDA

Products Affected

- OJEMDA

| 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 |

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) intermediate-risk or high-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 |

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 |

ORENCIA PDP

Products Affected

- ORENCIA
- ORENCIA CLICKJECT

| 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 | N/A |
| 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 | End of the plan year |
| Other Criteria | RA, approve if the patient has tried one of the following: Enbrel, a preferred adalimumab product, Rinvoq, Xeljanz. PsA, approve if the patient meets one of the following (i or ii): i. patient is 2 to 5 years of age OR ii. patient is 6 years of age or older and has tried one of the following: Enbrel, a preferred adalimumab product, Rinvoq, Stelara, Skyrizi, Xeljanz. JIA/JRA, approve if the patient has tried one of the following: Enbrel, a preferred adalimumab product, or Xeljanz. Continuation- approve if the patient has had a response as determined by the prescriber. Please Note: preferred adalimumab products include Humira (NDCs starting with - 00074), adalimumab-aaty and Yuflyma. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ORENITRAM

Products Affected

- ORENITRAM
- ORENITRAM MONTH 1 TITRATION KT
- ORENITRAM MONTH 2 TITRATION KT
- ORENITRAM MONTH 3 TITRATION KT

| 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). |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 |

ORKAMBI

Products Affected

- ORKAMBI

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | Combination use with Kalydeco, Trikafta or Symdeko. |
| 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 meets A, B and C: A) pt has two copies of the F508del mutation in the CFTR 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 CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ORSERDU

Products Affected

- ORSERDU

| 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 |

OTEZLA

Products Affected

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

| 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 | PP/PsA- 6 years and older (initial), All other dx - 18 years and older (initial) |
| 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 | End of the plan year |
| Other Criteria | PP, approve if the patient meets (A or B): A) has tried one of the following: traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA), TNF, JAK or biologic or B) patient has mild to moderate disease and the patient requires systemic therapy. PsA, approve if the patient has tried one of the following: traditional systemic agent (eg, MTX, cyclosporine, PUVA), TNF, JAK or biologic. Behcet's-patient has oral ulcers or other mucocutaneous involvement AND patient has tried one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, CSA, chlorambucil, cyclophosphamide] or interferon alfa) or a tumor necrosis factor. PsA/PP/Behcet's cont - pt has received 4 months of therapy and had a response, as determined by the prescribing physician. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Part B Prerequisite | No |

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 |

PEGASYS

Products Affected

- PEGASYS

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | HCV - patients 5 years of age or older, HBV - patients 3 years of age or 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 |

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 | Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease and the tumor has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test AND the patient has been previously treated with at least one systemic therapy regimen. 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 and the cancer is in chronic phase or blast phase. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PHENYL BUTYRATE

Products Affected

- 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 | Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval |
| 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 |

PHEOCHROMOCYTOMA

Products Affected

- *metyrosine*

| 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 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 |

PHOSPHATE BINDERS AND SIMILAR AGENTS

Products Affected

- *calcium acetate(phosphat bind)*
- *sevelamer carbonate*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | Patients on dialysis [non-D use]. |
| Required Medical Information | Diagnosis |
| 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 |

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Products Affected

- *sildenafil (pulm.hypertension) oral tablet*

| 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) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets require confirmation that the indication is PAH (ie, FDA labeled use) prior to reviewing for quantity exception. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PIQRAY

Products Affected

- PIQRAY

| 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) Piquay will be used in combination with fulvestrant injection. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PIRFENIDONE

Products Affected

- *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 |

POMALYST

Products Affected

- POMALYST

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | Kaposi Sarcoma/MM-18 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 1 year. |
| Other Criteria | CNS Lymphoma-approve if the patient has relapsed or refractory disease. 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 received at least one other Revlimid (lenalidomide tablets)-containing regimen. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Systemic Light Chain Amyloidosis, Central Nervous System (CNS) Lymphoma |
| Part B Prerequisite | No |

PROMACTA

Products Affected

- PROMACTA

| 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 | Imm Thrombo/MDS init-3mo,cont 1yr,AA-init-4mo,cont-1yr,Thrombo/HepC-1yr,Transplant-init 3mo,cont 6mo |
| Other Criteria | Thrombocytopenia in patients with immune thrombocytopenia, initial-approve if the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and the patient is at an increased risk for bleeding AND the patient has tried ONE other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Nplate, Tavalisse, Doptelet, rituximab) or has undergone a splenectomy. 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 initial - approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND if the patient has low platelet counts at baseline (eg, less than 75,000 microliters). Aplastic anemia initial - approve if the patient has low platelet counts at baseline/pretreatment (e.g., less than 30,000 microliter) AND tried one immunosuppressant therapy (e.g., cyclosporine) OR patient will be using Promacta in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response. MDS initial-approve if patient has low- to intermediate-risk MDS AND the |

| PA Criteria | Criteria Details |
|--------------------------------|--|
| | patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and is at an increased risk for bleeding. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Thrombocytopenia post-allogeneic transplantation, initial - approve if, according to the prescriber, the patient has poor graft function AND has a platelet count less than 50,000/mcL. Cont- patient demonstrated a beneficial clinical response. |
| 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 |

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 |

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 |

QUININE SULFATE

Products Affected

- *quinine sulfate*

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Excluded if used for treatment or prevention of nocturnal leg cramps. |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 1 month |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Babesiosis, uncomplicated Plasmodium vivax malaria. |
| Part B Prerequisite | No |

RADICAVA IV

Products Affected

- EDARAVONE
- RADICAVA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, 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 2. The 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. The 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 |

RELISTOR

Products Affected

- RELISTOR SUBCUTANEOUS SOLUTION
- RELISTOR SUBCUTANEOUS SYRINGE

| 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 |

REPATHA

Products Affected

- REPATHA PUSHTRONEX
- REPATHA SURECLICK
- REPATHA SYRINGE

| 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 | Authorization will be for 1 year |
| Other Criteria | <p>Hyperlipidemia with HeFH - approve if: 1) diagnosis of HeFH AND 2) tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) and LDL remains 70 mg/dL or higher unless pt is statin intolerant defined by experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the symptoms resolved upon discontinuation.</p> <p>Hyperlipidemia with ASCVD -approve if: 1) has one of the following conditions: prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, CAD, PAD, undergone a coronary or other arterial revascularization procedure, AND 2) tried ONE high intensity statin (defined above) and LDL remains 55 mg/dL or higher unless pt is statin intolerant (defined above). HoFH - approve if: 1) has one of the following: a) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR b) untreated LDL greater than 400 mg/dL (prior to treatment), OR c) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) tried ONE high intensity statin (defined above) for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH or TO REDUCE MAJOR ADVERSE CV</p> |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | EVENTS IN PTS AT INCREASED RISK THAT DO NOT HAVE ESTABLISHED CVD)-approve if all of the following are met: 1) coronary artery calcium or calcification (CAC) score 300 Agatston units or higher, AND 2) the patient has tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above). |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

RETEVMO

Products Affected

- RETEVMO ORAL TABLET

| 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, ii or iii: i. patient has anaplastic thyroid cancer OR ii. the disease requires treatment with systemic therapy and patient has medullary thyroid cancer or iii. the disease requires treatment with systemic therapy and the disease is radioactive iodine-refractory if radioactive iodine is appropriate. 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 |

REVUFORJ

Products Affected

- REVUFORJ

| 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 |

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 attestation 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 attestation 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 |

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 |

REZUROK

Products Affected

- REZUROCK

| 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 | Graft-versus-host disease-approve if the patient has chronic graft-versus-host disease and has tried at least two conventional systemic treatments (e.g., ibrutinib, cyclosporine) for chronic graft-versus-host disease. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

RINVOQ

Products Affected

- RINVOQ

| 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 | PsA/JIA - 2 years and older (initial therapy), RA/UC/AS/CD/nr-axSpA/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 | End of the plan year |
| Other Criteria | RA/PsA/UC/AS/CD/JIA initial - patient has tried a TNF blocker for at least 3 months. AD - patient has tried at one systemic agent for at least 3 months. Examples of traditional systemic therapies include azathioprine, cyclosporine, and mycophenolate mofetil. A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to step back and try a traditional systemic agent for atopic dermatitis. Non-Radiographic Axial Spondyloarthritis-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 sacroiliitis reported on MRI and patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3- month trial. GIANT CELL ARTERITIS: tried or is currently taking one systemic corticosteroid or corticosteroids are contraindicated. Continuation-approve if the patient has had a response as determined by the prescriber. |
| Indications | All FDA-approved Indications. |

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

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 |

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 | Authorization will be for 1 year. |
| Other Criteria | COPD, approve in patients who meet all of the following conditions: Patients has severe COPD or very severe COPD, AND Patient has a history of exacerbations, AND Patient has tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, indacaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone). |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ROMIDEPSIN

Products Affected

- *romidepsin intravenous recon soln*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis and past medication history. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 12 months |
| Other Criteria | Use of romidepsin is considered medically necessary for the treatment of cutaneous T-cell lymphoma in patients that have tried and failed at least 1 prior therapy. B vs D coverage determination. |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 |

ROZLYTREK

Products Affected

- ROZLYTREK

| 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 patients 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 |

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 | Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if the patient is in complete or partial response after a platinum-based chemotherapy regimen and the patient is in complete or partial response to first-line primary treatment or if the patient has recurrent disease and has a BRCA mutation. Castration-Resistant Prostate Cancer - Approve if the patient meets the following criteria (A, B and C): 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. 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. 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 |

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 |

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. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Myeloid or lymphoid Neoplasms with eosinophilia |
| Part B Prerequisite | No |

SABRIL

Products Affected

- *vigabatrín*
- *vigadrone*
- VIGAFYDE
- *vigpoder*

| 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/West Syndrome - patients 1 month to 2 years of age |
| 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 |

SAPROPTERIN

Products Affected

- *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 |

SCEMBLIX

Products Affected

- SCEMBLIX

| 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 |

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 | Cushing's disease/syndrome-Initial therapy - 4 months, Continuation therapy - 1 year. |
| 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 |

SIRTURO

Products Affected

- SIRTURO

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Patients weighing less than 8 kg |
| Required Medical Information | Diagnosis, concomitant therapy |
| Age Restrictions | Patients 2 years of age or older |
| Prescriber Restrictions | Prescribed by, or in consultation with an infectious diseases specialist or pulmonologist |
| Coverage Duration | 9 months |
| Other Criteria | Tuberculosis (Pulmonary) -Approve if the patient has multidrug-resistant tuberculosis or 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 |

SKYRIZI

Products Affected

- SKYRIZI

| 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 | PP/UC-18 years of age and older (initial therapy) |
| Prescriber Restrictions | PP-Prescribed by or in consultation with a dermatologist (initial therapy). Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD/UC, prescribed by or in consultation with a gastroenterologist (initial therapy). |
| Coverage Duration | End of the plan year |
| Other Criteria | PP initial, approve if the patient 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: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. PsA initial - approve. CD initial, approve. UC initial, approve. Continuation-approve if the patient has had a response as determined by the prescriber. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

SOMATULINE

Products Affected

- SOMATULINE DEPOT

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, previous treatments/therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | Acromegaly-prescribed by or in consultation with an endocrinologist. Carcinoid syndrome-prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. All neuroendocrine tumors-prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescribed by or in consultation with an endo/onc/neuro. |
| Coverage Duration | 1 year |
| Other Criteria | Acromegaly-approve if the patient has a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)-approve. Carcinoid Syndrome-approve. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Pheochromocytoma/paraganglioma, Neuroendocrine tumors of the gastrointestinal tract, lung, thymus (carcinoid tumor) and pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas) |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Part B Prerequisite | 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 |

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.</p> |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---------------------|---|
| 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 |

SPRAVATO

Products Affected

- SPRAVATO NASAL SPRAY, NON-AEROSOL 56 MG (28 MG X 2), 84 MG (28 MG X 3)

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Psychiatrist |
| Coverage Duration | MDD with Acute Suicidal Ideation or Behavior: 2 mo. Treatment-Resistant Depression: 6 mo |
| Other Criteria | Major Depressive Disorder with Acute Suicidal Ideation or Behavior-approve if the patient meets the following criteria (A, B and C): A) Patient has major depressive disorder that is considered to be severe, according to the prescriber, AND B) Patient is concomitantly receiving at least one oral antidepressant (Note: Antidepressants may include, but are not limited to, selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), mirtazapine, and bupropion), AND C) Patient has one of the following (i or ii): i. No history of psychosis, OR ii. History of psychosis and the prescriber believes that the benefits of Spravato outweigh the risks. Treatment-Resistant Depression-approve if the patient meets the following criteria (A, B, C and D): A) Patient meets both of the following (i and ii): i. Patient has demonstrated nonresponse (less than or equal to 25 percent improvement in depression symptoms or scores) to at least two different antidepressants, each from a different pharmacologic class, according to the prescriber (Note: Different pharmacologic classes of antidepressants include selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), bupropion, mirtazapine, etc.) AND ii. Each antidepressant was used at therapeutic dosages for at least 6 weeks in the current episode of depression, according |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | to the prescriber, AND C) Patient has one of the following (i or ii): i. No history of psychosis, OR ii. History of psychosis and the prescriber believes that the benefits of Spravato outweigh the risks, AND D) The patient history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), according to the prescriber. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

SPRYCEL

Products Affected

- *dasatinib*
- SPRYCEL

| 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 |

STELARA

Products Affected

- STELARA SUBCUTANEOUS

| 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 | 18 years and older CD/UC (initial therapy). PP/PsA-6 years and older (initial therapy). |
| Prescriber Restrictions | PP-Prescr/consult w/derm (initial therapy).PsA-prescr/consult w/rheum or derm (initial therapy).CD/UC-prescr/consult w/gastro (initial therapy). |
| Coverage Duration | End of the plan year |
| Other Criteria | PsA initial, approve if the patient meets one of the following (i or ii): i. patient is 6 to 17 years of age OR ii. patient is 18 years of age or older and has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor for PsA are not required to step back and try a conventional synthetic DMARD). PP initial, approve if the patient 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: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial, approve. UC initial, approve. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 | Soft tissue Sarcoma, Bone Cancer, CNS tumors (Glioblastoma/H3-mutated high-grade glioma), Appendiceal cancer, Uterine sarcoma |
| Part B Prerequisite | No |

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 to normal isomaltase (palatinase) [normal reference: greater than 5 U/g protein], c) Decreased maltase (normal reference: greater than 100 U/g protein), d) Decreased to 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 |

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 | <p>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 meets (A or B): A) has papillary or follicular thyroid carcinoma and the disease is refractory to radioactive iodine therapy or B) has oncocytic (formerly Hurthle cell) carcinoma. 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.</p> |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), extraskeletal myxoid chondrosarcoma, differentiated (ie, papillary, follicular, and oncocytic carcinoma) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma, pheochromocytoma/paraganglioma, myeloid/lymphoid neoplasms with |

| PA Criteria | Criteria Details |
|------------------------|---|
| | eosinophilia, GIST-unresectable succinate dehydrogenase (SDH)-deficient GIST, or use after avapritinib. |
| Part B Prerequisite | No |

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 |

TADALAFIL

Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| 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 |

TAFAMIDIS

Products Affected

- VYNDAQEL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Concomitant use with Onpattro or Tegsedi or Wainua. 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 the diagnosis was confirmed by one of the following (i, ii or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy),ii. Amyloid deposits are identified on cardiac biopsy OR iii. patient had genetic testing which, according to the prescriber, identified a TTR mutation AND Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum). |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TAFINLAR

Products Affected

- TAFINLAR

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis for which Tafinlar is being used. BRAF V600 mutations |
| Age Restrictions | 1 year and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 1 year. |
| Other Criteria | <p>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. For NSCLC, must have BRAF V600E mutation. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, unless intolerant AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or Hurthle cell) AND the patient has disease that is refractory to radioactive iodine therapy AND the patient has BRAF-positive disease. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Mekinist. Central Nervous System Cancer-approve if the 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) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c, or d): a) glioma OR b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma OR d) Oligodendroglioma OR iii. Melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets).</p> |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | Histiocytic neoplasm-approve if 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 patient has Erdheim Chester disease AND patient has BRAF V600-mutation positive disease. Metastatic or solid tumors-approve if BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets) AND patient has no satisfactory alternative treatment options. 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. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Patients with Differentiated Thyroid Cancer, Biliary tract cancer, central nervous system cancer, histiocytic neoplasm, Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, hairy cell leukemia |
| Part B Prerequisite | No |

TAGRISSO

Products Affected

- TAGRISSO

| 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 |

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 |

TARGRETIN 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 | Adult T-Cell Leukemia/Lymphoma- approve if the patient has chronic/smoldering 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 |

TASIGNA

Products Affected

- TASIGNA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis for which Tasigna is being used. For indication of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and melanoma, cutaneous, prior therapies tried. For melanoma, cutaneous, KIT mutation status. |
| 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. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Part B Prerequisite | No |

TAZAROTENE

Products Affected

- *tazarotene topical cream*
- *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 |

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 |

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 |

TETRABENAZINE

Products Affected

- *tetrabenazine*

| 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 |

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, myelofibrosis, histiocytic neoplasms-18 years and older |
| 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]). Myelofibrosis, approve if according to the prescriber the patient has anemia and has serum erythropoietin levels greater than or equal to 500 mU/mL or if the patient has serum erythropoietin level less than 500 mU/mL and experienced no response or loss of response to erythropoietic stimulating agents. 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's Sarcoma-approve if the patient has tried at least one regimen or therapy and has relapsed or refractory disease. Castleman's disease-approve if the patient has multicentric Castleman's disease and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). Histiocytic neoplasms-approve if pt has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman cutaneous disease. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|--------------------------------|---|
| Off-Label Uses | Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi's Sarcoma, Castleman's Disease, histiocytic neoplasms. |
| Part B Prerequisite | No |

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 . 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 |

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 |

TOPICAL AGENTS FOR ATOPIC DERMATITIS

Products Affected

- *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 |

TOPICAL RETINOID PRODUCTS

Products Affected

- *tretinoin*
- *tretinoin microspheres topical gel 0.1 %*
- *tretinoin microspheres topical gel with pump 0.1 %*

| 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 |

TOPIRAMATE/ZONISAMIDE

Products Affected

- EPRONTIA
- *topiramate oral capsule, sprinkle 15 mg, 25 mg*
- TOPIRAMATE ORAL CAPSULE, SPRINKLE 50 MG
- *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 |

TRANSMUCOSAL FENTANYL DRUGS

Products Affected

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

| 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 | For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate). Clinical criteria incorporated into the quantity limit edits for all transmucosal fentanyl drugs require confirmation that the indication is breakthrough cancer 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 |

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. 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 |

TREMFYA

Products Affected

- TREMFYA INTRAVENOUS
- TREMFYA ONE-PRESS
- TREMFYA PEN
- TREMFYA PEN INDUCTION PK(2PEN)
- TREMFYA SUBCUTANEOUS SYRINGE

| 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- 6 years of age and older (initial therapy), UC/CD- 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 (A and B): A) meets (1 or 2): 1) 18 years of age or older, or 2) 6 to 17 years old and weighs at least 40 kg, and B) 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-approve. CROHN'S DISEASE (CD) initial, approve. PP/PsA/UC/CD continuation of therapy - approve if the pt is responding to therapy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TRIENTINE

Products Affected

- CUVRIOR
- *trientine oral capsule 250 mg*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, medication history, pregnancy status, disease manifestations (all as described in Other Criteria) |
| 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 |

TRIKAFTA

Products Affected

- TRIKAFTA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Patients with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco or Symdeko. |
| Required Medical Information | Diagnosis, specific CFTR gene mutations, concurrent medications |
| Age Restrictions | 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 CFTR gene that is considered to be pathogenic or likely pathogenic, 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 CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR mutations or (iii) abnormal nasal potential difference. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | 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 |

TUKYSA

Products Affected

- TUKYSA

| 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>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.</p> <p>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.</p> |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Biliary tract cancer |
| Part B Prerequisite | No |

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 |

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 | Postmenopausal Osteoporosis (PMO) Treatment and Osteoporosis Treatment in Men (see Note 1 below) [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, osteoporosis in men- 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. 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. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TZIELD

Products Affected

- TZIELD

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Diagnosis of clinical type 1 diabetes (i.e., Stage 3 type 1 diabetes) or type 2 diabetes |
| Required Medical Information | <p>Patient meets ALL of the following (A, B, C and D): A) has tested positive for at least TWO of the following type 1 diabetes-related autoantibodies on two separate occasions: anti-glutamic acid decarboxylase 65 (anti-GAD65), anti-islet antigen-2 (anti-IA-2), islet-cell autoantibody (ICA), micro insulin, or anti-zinc transporter 8 (anti-ZnT8). B) Patient meets both of the following (i and ii): i. Patient has taken an oral glucose tolerance test within the preceding 2 months AND ii. The results of the oral glucose tolerance test indicated dysglycemia by meeting at least one of the following (a, b, or c): a) Fasting plasma glucose level greater than or equal to 110 to less than 126 mg/dL OR b) 2-hour postprandial plasma glucose level greater than or equal to 140 to less than 200 mg/dL OR c) Intervening postprandial glucose level at 30, 60, or 90 minutes greater than 200 mg/dL. C) At baseline (prior to the initiation of Tzield), patient does NOT have evidence of hematologic compromise, as defined by meeting the following (i, ii, iii, and iv): i. Lymphocyte count greater than or equal to 1,000 lymphocytes/mcL AND ii. Hemoglobin greater than or equal to 10 g/dL AND iii. Platelet count greater than or equal to 150,000 platelets/mcL AND iv. Absolute neutrophil count greater than or equal to 1,500 neutrophils/mcL AND D) At baseline (prior to the initiation of Tzield), patient does NOT have evidence of hepatic compromise, as defined by meeting the following (i, ii, and iii): i. Alanine aminotransferase (ALT) greater than or equal to 2 times the upper limit of normal (ULN) AND ii. Aspartate aminotransferase (AST) greater than or equal to 2 times the ULN AND iii. Bilirubin greater than or equal to 1.5 times the ULN.</p> |
| Age Restrictions | 8 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with an endocrinologist |
| Coverage Duration | 14 days |

| PA Criteria | Criteria Details |
|----------------------------|--|
| Other Criteria | Patient meets all the following (A, B and C): A) has at least one biologicalrelative with a diagnosis of type 1 diabetes B) According to the prescriber,the patient does NOT have any of the following (i, ii, or iii): i. Laboratoryor clinical evidence of acute infection with Epstein-Barr Virus orcytomegalovirus OR ii. Active serious infection OR iii. Chronic activeinfection (other than localized skin infection) AND C) Patient has NOTreceived Tzield in the past |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 chronic/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 |

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 |

VANCOMYCIN

Products Affected

- *vancomycin oral capsule*

| 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 |

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 and this medication is being used for induction, re-induction, consolidation, or maintenance treatment. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

VENCLEXTA

Products Affected

- VENCLEXTA
- 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 |

VENTAVIS

Products Affected

- VENTAVIS INHALATION SOLUTION
FOR NEBULIZATION 10 MCG/ML

| 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 | B vs D coverage determination |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

VERQUVO

Products Affected

- VERQUVO

| 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 | Patient has symptomatic chronic heart failure, an ejection fraction less than 45% and for new starts, has had either a hospitalization for heart failure within the last six months or has needed outpatient IV diuretics within the last three months. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 the 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</p> |

| PA Criteria | Criteria Details |
|----------------------------|---|
| | <p>combo with 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 the metastatic setting and will use this in combo with fulvestrant and trastuzumab.Breast Cancer-Recurrent or Metastatic in Men-pt meets the following criteria (A and B): A)HR+ disease, AND B)either (1 or 2): 1)HER2-negative disease and Pt meets 1 of the 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 the 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 |

VITRAKVI

Products Affected

- VITRAKVI

| 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 |

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 |

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) the patient has a platelet count of less than 50×10^9 /L (less than 50,000/mcL) OR (B) Patient has a platelet count of greater than or equal to 50×10^9 /L (greater than or equal to 50,000/mcL) and has high-risk disease, 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 |

VORANIGO

Products Affected

- VORANIGO

| 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 |

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 |

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 |

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 (or will start a bowel prep the day before and at least 8 hours prior to taking the first dose), 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 |

VYLOY

Products Affected

- VYLOY

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with an 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. GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA (all of A, B, C, D and E): A. Unresectable locally advanced, recurrent or metastatic disease, AND B. Tumor is claudin 18.2 positive as determined by an approved test, Note: Claudin 18.2 positivity is defined as greater than or equal to 75 percent of tumor cells demonstrating moderate to strong membranous claudin 18.2 immunohistochemical staining. AND C. Tumor is human epidermal growth factor receptor 2 (HER2)-negative, AND D. Used for first-line treatment, AND E. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy. Note: Examples of fluoropyrimidines include 5-fluorouracil and capecitabine. Examples of platinum chemotherapy agents include oxaliplatin. Esophageal adenocarcinoma- all of (A, B, C, D and E): A. unresectable locally advanced, recurrent, or metastatic disease, AND B. tumor is is claudin 18.2 positive as determined by an approved test, AND C. tumor is human epidermal growth factor receptor 2 (HER2)-negative, and D. used for first-line treatment, AND E. used in combination with fluoropyrimidine- and platinum-containing chemotherapy. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Esophageal adenocarcinoma |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Part B Prerequisite | No |

VYVGART HYTRULO

Products Affected

- VYVGART HYTRULO

| 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 (CIDP: initial only, GMG: initial and continuation) |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist (CIDP: initial only, GMG: initial and continuation) |
| Coverage Duration | Initial-6 months, Continuation-1 year |
| Other Criteria | <p>CIDP, 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. CIDP, 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, 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. Generalized myasthenia gravis, Continuation Therapy-Approve if patient is continuing to derive benefit from Vyvgart. All treatment cycles should be no more frequent than every 50 days from the start of the previous treatment cycle.</p> |
| Indications | All FDA-approved Indications. |

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

WELIREG

Products Affected

- WELIREG

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | Pheochromocytoma/paraganglioma-12 years and older, Other indications-18 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 1 year |
| Other Criteria | Pheochromocytoma/paraganglioma- approve if pt has locally advanced, unresectable, or metastatic disease. Renal Cell Carcinoma- approve if pt has advanced disease AND has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor AND 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.] 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. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Part B Prerequisite | No |

XALKORI

Products Affected

- XALKORI

| 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 |

XATMEP

Products Affected

- XATMEP

| 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 | N/A |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

XCOPRI

Products Affected

- XCOPRI
- XCOPRI TITRATION PACK
- XCOPRI MAINTENANCE PACK

| 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 patient has tried one other anticonvulsant therapy (eg, carbamazepine, divalproex sodium, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, topiramate, valproic acid). |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

XDEMVY

Products Affected

- XDEMVY

| 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 |

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 | Initial therapy - approve if the patient meets ALL of the following criteria: 1) patient has been on long-acting somatostatin analog (SSA) therapy (eg, Somatuline Depot [lanreotide for injection]) AND 2) while on long-acting SSA therapy (prior to starting Xermelo), the patient continues to have at least four bowel movements per day, AND 3) Xermelo will be used concomitantly with a long-acting SSA therapy. Continuation therapy - approve if the patient is continuing to take Xermelo concomitantly with a long-acting SSA therapy for carcinoid syndrome diarrhea. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

XGEVA

Products Affected

- XGEVA

| 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 | N/A |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

XIAFLEX

Products Affected

- XIAFLEX

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Retreatment (i.e., treatment beyond eight injections for Peyronie's Disease). |
| Required Medical Information | Diagnosis |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Dupuytren's Contracture-administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture. Peyronie's Disease -administered by a healthcare provider experienced in the treatment of male urological diseases. |
| Coverage Duration | Dupuytren's Contracture-3 months, Peyronie's Disease-6 months |
| Other Criteria | Dupuytren's Contracture-at baseline (prior to initial injection of Xiaflex), the patient had contracture of a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint of at least 20 degrees AND the patient will not be treated with more than a total of three injections (maximum) per affected cord as part of the current treatment course. Peyronie's Disease-the patient meets ONE of the following (i or ii): i. at baseline (prior to use of Xiaflex), the patient has a penile curvature deformity of at least 30 degrees OR in a patient who has received prior treatment with Xiaflex, the patient has a penile curvature deformity of at least 15 degrees AND the patient has not previously been treated with a complete course (8 injections) of Xiaflex for Peyronie's disease. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

XIFAXAN

Products Affected

- XIFAXAN

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | Hepatic encephalopathy, irritable bowel syndrome - 18 years of age or older. Traveler's diarrhea - 12 years of age or older. |
| Prescriber Restrictions | Pouchitis - prescribed by or in consultation with a gastroenterologist |
| Coverage Duration | HepEnceph-6mo,IBS/diarr-14days,Traveler's diarr-3days,Sm intest bact overgrowth-14days,Pouchitis-1yr |
| 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. (For IBS with diarrhea - customers are limited to 3 courses) 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 |

XOLAIR

Products Affected

- XOLAIR

| 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 | asthma/CIU-Initial tx 4 months, Polyps-initial-6 months, continued tx 12 months, Food allergy-1 yr |
| Other Criteria | MODERATE TO SEVERE PERSISTENT ASTHMA (A, B, C and D): A) baseline IgE greater than or equal to 30 IU/mL, and B) baseline positive skin test or in vitro test for 1 or more perennial or seasonal aeroallergens C) received at least 3 months of combination therapy with an inhaled corticosteroid (ICS) and additional asthma controller/maintenance medication (e.g., LABA, LAMA, leukotriene receptor antagonist, monoclonal antibody) [see Exception 1 below] and D) asthma is uncontrolled or was uncontrolled prior to receiving Xolair or another monoclonal antibody and meets one of the following (a, b, c, d, or e): a) experienced two or more asthma exacerbations requiring systemic CSs in the past year, b) experienced one or more asthma exacerbation requiring hospitalization/urgent care visit/emergency department visit in the past year, c) forced expiratory volume in 1 second (FEV1) less than 80% predicted, d) FEV1/forced vital capacity (FVC) less than 0.80, or e) asthma worsens upon tapering of oral CS. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRwNP) [all of A, B, C, D, and E]: A) diagnosis by direct exam, endoscopy, or sinus CT scan, B) baseline (prior to Xolair or another monoclonal antibody that may lower IgE) IgE at least 30 IU/ml, C) |

| PA Criteria | Criteria Details |
|----------------------------|--|
| | <p>at least two of the following symptoms for 6 months: nasal congestion, obstruction, discharge, reduction/loss of smell, D) tried intranasal CS and will continue in combination with Xolair, and E) one of the following (a, b, or c): a) had systemic CS at least 5 days in past 2 years, b) contraindication to systemic CS, or c) had nasal polyp surgery. CHRONIC IDIOPATHIC URTICARIA (CIU): urticaria more than 6 weeks prior to treatment with Xolair with symptoms present more than 3 days per week despite daily non-sedating H1-antihistamine therapy. IgE-MEDIATED FOOD ALLERGY (all of A, B, C and D): A) baseline IgE greater than or equal to 30 IU/mL, B) positive skin prick test or positive in vitro test for IgE to one or more foods, C) history of allergic reaction that met all of the following (a, b, and c): a) signs and symptoms of a significant systemic allergic reaction, b) reaction occurred within a short period of time following a known ingestion of the food, and c) prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector, and D) patient has been prescribed an epinephrine auto-injector.</p> <p>CONTINUATION THERAPY: ASTHMA: patient responded to therapy and continues to receive an ICS. CRwNP: patient responded after 6 months of therapy and continues intranasal CS. CIU: patient responded to therapy.</p> <p>Exception 1: an exception to the requirement of a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS.</p> |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | 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 |

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 | Multiple Myeloma-Approve if the patient meets the following (A and B): A) The medication will be taken in combination with dexamethasone AND 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 one prior regimen for multiple myeloma AND b) The medication will be taken in combination with bortezomib 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 Darzalex (daratumumab infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules). Note: Examples include bortezomib/Revlimid (lenalidomide capsules)/dexamethasone, Kyprolis (carfilzomib infusion)/Revlimid/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 been treated with at least two prior systemic therapies. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|----------------------------|--|
| Off-Label Uses | Treatment of multiple myeloma in combination with daratumumb or pomalidomide |
| Part B Prerequisite | No |

XTANDI

Products Affected

- XTANDI

| 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 |

XYREM

Products Affected

- SODIUM OXYBATE

| 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, 18 years and older - approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). For EDS in patients with narcolepsy, less than 18 years old-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine) or modafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). 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 |

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 in complete or partial response to first-line primary treatment or if the patient has recurrent disease and a BRCA mutation. 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, Ovarian, fallopian tube or primary peritoneal cancer-treatment |
| Part B Prerequisite | No |

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 | <p>Melanoma, patient new to therapy must have BRAFV600 mutation for approval AND have unresectable, advanced or metastatic melanoma. HCL - must have tried at least one other systemic therapy for hairy cell leukemia OR is unable to tolerate purine analogs and Zelboraf will be used in combination with Gazyva (obinutuzumab intravenous infusion) as initial therapy. Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy. Erdheim-Chester disease, in patients with BRAF V600 mutation-approve. Central Nervous System 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, c or d): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma/neuroglioma/glioneuronal tumor OR d) pediatric diffuse high-grade glioma OR ii. Recurrent or progressive disease for one of the following conditions (a or b): a) glioma/circumscribed glioma OR b) Glioblastoma OR iii. Melanoma with brain metastases AND the medication will be taken in combination with Cotellic (cobimetinib tablets). 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 AND the patient has BRAF V600-mutation positive disease.</p> |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---------------------|--|
| 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 |

ZIIHERA

Products Affected

- ZIIHERA

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 1 year |
| Other Criteria | Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. BILIARY TRACT CANCER - (all of A, B, C, D and E): A. Patient has ONE of the following (i, ii, or iii): i. Gallbladder cancer, OR ii. Intrahepatic cholangiocarcinoma, OR iii. Extrahepatic cholangiocarcinoma, AND B. Patient has unresectable, resected gross residual, or metastatic disease, AND C. The tumor is human epidermal growth factor receptor 2 (HER2) positive with immunohistochemistry score of 3+ (IHC3+) as determined by an approved test, AND D. The medication is used for subsequent therapy, AND E. The medication is used as a single agent. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 |

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 | Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder-approve if the patient has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene and patient has tried or is concomitantly receiving two other antiepileptic drugs. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ZTLIDO

Products Affected

- 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 |

ZURZUVAE

Products Affected

- ZURZUVAE

| 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 | Postpartum depression-approve if the patient meets the following (A, B and C): A.Patient meets BOTH of the following (i and ii): i. Patient has been diagnosed with severe depression, AND ii. Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery, AND B. Patient is less than or equal to 12 months postpartum, AND C. Patient is not currently pregnant. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | 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 1 year |
| Other Criteria | CLL/SLL-approve if the patient has tried at least one systemic regimen. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | small lymphocytic lymphoma |
| Part B Prerequisite | No |

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 | Erdheim-Chester Disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. NSCLC, ALK positive-approve if the patient has advanced or metastatic disease that is ALK positive as detected by an approved test and for patients new to therapy must have a trial of Alecensa or Lorbrena prior to approval of Zykadia. NSCLC, ROS1 Rearrangement-approve if the patient has advanced or metastatic disease. 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 | Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement. Erdheim-Chester disease. Peripheral T-Cell Lymphoma. |
| Part B Prerequisite | No |

ZYPREXA RELPREVV

Products Affected

- ZYPREXA RELPREVV

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | Dementia-related psychosis |
| 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 | 1 year |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ZYTIGA

Products Affected

- *abiraterone*

| 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 |

PART B VERSUS PART D

Products Affected

- *acetylcysteine*
- *acyclovir sodium intravenous solution*
- *albuterol sulfate inhalation solution for nebulization*
- *amiodarone intravenous solution*
- *aprepitant*
- *arformoterol*
- *arsenic trioxide*
- ATGAM
- *azacitidine*
- *azathioprine oral tablet 50 mg*
- *azathioprine sodium*
- BELEODAQ
- *bendamustine intravenous recon soln*
- BENDAMUSTINE INTRAVENOUS SOLUTION
- BENDEKA
- *bleomycin*
- BLINCYTO INTRAVENOUS KIT
- *budesonide inhalation*
- *busulfan*
- *carboplatin intravenous solution*
- *carmustine intravenous recon soln 100 mg*
- *cisplatin intravenous solution*
- *cladribine*
- CLINIMIX 5%/D15W SULFITE FREE
- CLINIMIX 4.25%/D10W SULF FREE
- CLINIMIX 4.25%/D5W SULFITE FREE
- CLINIMIX 5%-D20W(SULFITE-FREE)
- CLINIMIX 6%-D5W (SULFITE-FREE)
- CLINIMIX 8%-D10W(SULFITE-FREE)
- CLINIMIX 8%-D14W(SULFITE-FREE)
- CLINISOL SF 15 %
- *clofarabine*
- *cromolyn inhalation*
- *cyclophosphamide intravenous recon soln*
- CYCLOPHOSPHAMIDE INTRAVENOUS SOLUTION
- *cyclophosphamide oral capsule*
- CYCLOPHOSPHAMIDE ORAL TABLET
- *cyclosporine modified*
- *cyclosporine oral capsule*
- *cytarabine*
- *cytarabine (pf)*
- *dacarbazine*
- *dactinomycin*
- *daunorubicin*
- *decitabine*
- *docetaxel*
- DOCIVYX
- *doxorubicin intravenous recon soln 50 mg*
- *doxorubicin intravenous solution*
- *doxorubicin, peg-liposomal*
- *dronabinol*
- ENGERIX-B (PF)
- ENGERIX-B PEDIATRIC (PF)
- ENVARSUS XR
- *epirubicin intravenous solution*
- ERBITUX
- ETOPOPHOS
- *etoposide intravenous*
- *everolimus (immunosuppressive)*
- FIRMAGON KIT W DILUENT SYRINGE
- *floxuridine*
- *fludarabine*
- *fluorouracil intravenous*
- FOLOTYN
- *fulvestrant*
- *gemcitabine intravenous recon soln*
- *gemcitabine intravenous solution 1 gram/26.3 ml (38 mg/ml), 2 gram/52.6 ml (38 mg/ml), 200 mg/5.26 ml (38 mg/ml)*
- GEMCITABINE INTRAVENOUS SOLUTION 100 MG/ML
- *gengraf*
- GRAFAPEX
- *granisetron hcl oral*
- HEPLISAV-B (PF)
- *idarubicin*
- *ifosfamide*
- INFUMORPH P/F
- *intralipid intravenous emulsion 20 %*
- INTRALIPID INTRAVENOUS EMULSION 30 %

- *ipratropium bromide inhalation*
- *ipratropium-albuterol*
- *irinotecan*
- IXEMPRA
- JEVTANA
- KABIVEN
- KYPROLIS
- *melphalan hcl*
- *mesna intravenous*
- *methotrexate sodium (pf)*
- *methotrexate sodium injection*
- *mitomycin intravenous*
- *mitoxantrone*
- *mycophenolate mofetil*
- *mycophenolate mofetil (hcl)*
- *mycophenolate sodium*
- *nelarabine*
- NIPENT
- *nitroglycerin intravenous*
- NULOJIX
- ONCASPAR
- *ondansetron hcl oral solution*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet, disintegrating 4 mg, 8 mg*
- *oxaliplatin*
- *paclitaxel*
- PANZYGA
- *pentamidine inhalation*
- PERIKABIVEN
- PLENAMINE
- *plerixafor*
- PRALATREXATE
- *premasol 10 %*
- PROGRAF INTRAVENOUS
- PROGRAF ORAL GRANULES IN PACKET
- PROSOL 20 %
- PULMOZYME
- RECOMBIVAX HB (PF)
- RYLAZE
- SIMULECT
- *sirolimus*
- SYLVANT
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- TEMODAR INTRAVENOUS
- *temsirolimus*
- TICE BCG
- *tobramycin in 0.225 % nacl*
- *topotecan*
- *travasol 10 %*
- TROPHAMINE 10 %
- TYVASO
- TYVASO INSTITUTIONAL START KIT
- TYVASO REFILL KIT
- TYVASO STARTER KIT
- *valrubicin*
- *vinblastine*
- *vincristine*
- *vinorelbine*
- VYXEOS
- XEMBIFY
- ZALTRAP
- ZANOSAR
- ZOLADEX
- *zoledronic acid intravenous solution*
- *zoledronic acid-mannitol-water intravenous piggyback 5 mg/100 ml*
- ZOLEDRONIC AC-MANNITOL-0.9NACL

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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