



MedMutual Advantage Signature HMO

2021 Prior Authorization Criteria

ACTEMRA SQ

Products Affected

- Actemra ACTPen
- Actemra subcutaneous

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD. |
| Required Medical Information | Diagnosis, concurrent medications, previous drugs tried. |
| Age Restrictions | Interstitial lung disease-18 years and older (initial and continuation) |
| Prescriber Restrictions | RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy). Interstitial Lung disease-presc/consult-pulmonologist or rheum (initial and cont) |
| Coverage Duration | GCA-6mo initial,3yr cont.PJIA-4mo initial, 3yr cont.Lung dx-1 yr. other dx-3mo initial, 3 yr cont. |
| Other Criteria | <p>RA initial - approve if the patient has tried TWO of the following: Enbrel, Humira, Orencia, Rinvoq or Xeljanz/XR (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the try TWO requirement: Cimzia, infliximab, golimumab SC/IV) OR if, according to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, initial-approve if the patient has tried TWO of the following: Enbrel, Orencia, Xeljanz or Humira. (Note: the patient does not have to have a trial with Enbrel, Orencia or Humira if they have had a trial with infliximab in the past.) OR According to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx - pt must have had a response as determined by the prescriber. Interstitial lung disease associated with systemic sclerosis initial-approve if the patient has elevated acute phase reactants AND the diagnosis is confirmed by high-resolution computed tomography. Continuation-approve if the patient had adequate efficacy, demonstrated by less than or equal to 10 percent decrease in predicted forced vital capacity (FVC) over the past year while on Actemra.</p> |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ACYCLOVIR (TOPICAL)

Products Affected

- acyclovir topical cream
- acyclovir topical ointment

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | N/A |
| Required Medical Information | Medication history |
| Age Restrictions | acyclovir 5% cream, 12 yrs or older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 12 months |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ADEMPAS

Products Affected

- Adempas

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

AFINITOR

Products Affected

- Afinitor Disperz
- Afinitor oral tablet 10 mg
- everolimus (antineoplastic) oral tablet 2.5 mg, 5 mg, 7.5 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Breast Cancer-HER2 status, hormone receptor (HR) status. |
| Age Restrictions | Relapsed or refractory classical Hodgkin lymphoma-18 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | <p>Breast Cancer-approve if the patient meets ALL the following criteria (A, B, C, D, E, and F): A) The patient has recurrent or Stage IV, hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease AND B) The patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND C) The patient has tried at least one prior endocrine therapy (e.g., anastrozole, letrozole, or tamoxifen) AND D) The patient meets ONE of the following conditions (i or ii): i. The patient is a postmenopausal female or a male OR ii. The patient is premenopausal or perimenopausal AND is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin)), or has had surgical bilateral oophorectomy or ovarian irradiation AND E) The patient meets ONE of the following conditions (i or ii): i. If patient is a male AND if everolimus will be used in combination with exemestane, the patient is receiving a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin)) OR ii. everolimus will be used in combination with exemestane, Faslodex (fulvestrant intramuscular), or tamoxifen AND F) The patient has not had disease progression while on everolimus. Tuberous sclerosis complex (TSC) Associated subependymal giant cell astrocytoma (SEGA)-approve if the patient requires therapeutic intervention but cannot</p> |

| PA Criteria | Criteria Details |
|-----------------------|--|
| | <p>be curatively resected. Thymomas and Thymic Carcinomas-approve if the patient has tried one prior chemotherapy (e.g., cisplatin plus doxorubicin, cisplatin plus etoposide, carboplatin plus paclitaxel). TSC associated renal angiomyolipoma-approve. WM/LPL - approve if patient has progressive or relapsed disease or if the patient has not responded to ONE primary therapy (e.g., Velcade with dexamethasone with or without Rituxan, Treanda with Rituxan, Rituxan with cyclophosphamide and dexamethasone, Treanda, Velcade with or without Rituxan, Velcade with dexamethasone, Kyprolis with Rituxan and dexamethasone, Imbruvica Rituxan). Differentiated (i.e. papillary, follicular, and Hurthle cell) Thyroid Carcinoma-approve if the patient is refractory to radioactive iodine therapy. Endometrial Carcinoma-approve if everolimus will be used in combination with letrozole and the patient has recurrent, metastatic or high-risk disease. GIST-approve if the patient has tried TWO of the following drugs: Sutent, Stivarga, or imatinib AND there is confirmation that everolimus will be used in combination with one of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST. Tuberous sclerosis complex (TSC)-associated partial-onset seizures-approve.</p> |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | <p>Advanced, unresectable or metastatic neuroendocrine tumors of the thymus (Carcinoid tumors). Perivascular Epithelioid Cell Tumors (PEComa), Recurrent Angiomyolipoma, Lymphangiomyomatosis, relapsed or refractory classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Thymomas and Thymic carcinomas, Differentiated (i.e. papillary, follicular, and Hurthle cell) Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST) and Recurrent or progressive Meningioma, men with breast cancer</p> |

AJOVY

Products Affected

- Ajoy Autoinjector
- Ajoy Syringe

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | Combination therapy with Aimovig, Vyepti or Emgality |
| Required Medical Information | Diagnosis, number of migraine headaches per month, prior therapies tried |
| 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) Patient has tried at least two standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, beta-blocker), and has had inadequate responses to those therapies or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ALECENSA

Products Affected

- Alecensa

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | metastatic NSCLC - is anaplastic lymphoma kinase (ALK)-positive as detected by an approved test. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ALUNBRIG

Products Affected

- Alunbrig oral tablet 180 mg, 30 mg, 90 mg
- Alunbrig oral tablets,dose pack

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | ALK status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Metastatic NSCLC, must be ALK-positive, as detected by an approved test. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

AMPYRA

Products Affected

- dalfampridine

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | MS. If 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 |

ANABOLIC STEROIDS

Products Affected

- oxandrolone

| 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 | Patients w/Turner's Syndrome or Ullrich-Turner Syndrome (oxandrolone only), management of protein catabolism w/burns or burn injury (oxandrolone only), AIDS wasting and cachexia |

ANTIBIOTICS (IV)

Products Affected

- amikacin injection solution 500 mg/2 mL
- ampicillin sodium injection recon soln 1 gram, 10 gram, 125 mg
- ampicillin-sulbactam injection
- azithromycin intravenous
- aztreonam injection recon soln 1 gram
- Bicillin C-R
- Bicillin L-A
- ceftazidime
- cefuroxime sodium injection recon soln 750 mg
- cefuroxime sodium intravenous recon soln 1.5 gram
- ciprofloxacin in 5 % dextrose intravenous piggyback 200 mg/100 mL
- clindamycin in 5 % dextrose
- clindamycin phosphate injection
- clindamycin phosphate intravenous solution 600 mg/4 mL
- colistin (colistimethate Na)
- Doxy-100
- Erythrocin intravenous recon soln 500 mg
- gentamicin in NaCl (iso-osm) intravenous piggyback 100 mg/100 mL, 60 mg/50 mL, 80 mg/100 mL, 80 mg/50 mL
- gentamicin injection solution 40 mg/mL
- imipenem-cilastatin
- levofloxacin in D5W intravenous piggyback 500 mg/100 mL, 750 mg/150 mL
- levofloxacin intravenous
- linezolid in dextrose 5%
- metronidazole in NaCl (iso-os)
- moxifloxacin-sod.chloride(iso)
- nafcillin injection
- oxacillin in dextrose(iso-osm)
- oxacillin injection
- penicillin G potassium injection recon soln 20 million unit
- penicillin G procaine intramuscular syringe 1.2 million unit/2 mL
- penicillin G sodium
- streptomycin
- Tazicef injection
- Teflaro
- tigecycline
- tobramycin sulfate injection solution

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

| PA Criteria | Criteria Details |
|--------------------------|-------------------------------|
| Coverage Duration | 3 months |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ANTIFUNGALS (IV)

Products Affected

- fluconazole in NaCl (iso-osm) intravenous piggyback 200 mg/100 mL, 400 mg/200 mL
- voriconazole

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 months |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

APOKYN

Products Affected

- APOKYN

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | Concurrent use with a serotonin 5-HT ₃ Antagonist |
| Required Medical Information | Diagnosis, other therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 1 year |
| Other Criteria | Parkinson's disease (PD)-approve if the patient has advanced PD, is experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, is currently receiving carbidopa/levodopa and has previously tried one other treatment for off episodes. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 mo initial, 3 years cont. DIRA-6 mo initial, 3 years cont.Pericard-3 mo initial, 1 yr cont |
| Other Criteria | CAPS renewal - approve if the patient has had a response as determined by the prescriber. DIRA initial-approve if the patient weighs at least 10 kg, genetic test confirms a mutation in the IL1RN gene and the patient has demonstrated a clinical benefit with anakinra subcutaneous injection. DIRA cont-approve if the patient has responded to therapy. Pericarditis initial-approve if the patient has recurrent pericarditis AND for the current episode, the patient is receiving standard treatment or standard treatment is contraindicated. Continuation-approve if the patient has had a clinical response. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ARIKAYCE

Products Affected

- Arikayce

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, previous medication history |
| Age Restrictions | MAC-18 years and older |
| Prescriber Restrictions | MAC-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections. Cystic fibrosis-prescribed by or in consultation with a pulmonologist or physician who specializes in the treatment of cystic fibrosis. |
| Coverage Duration | 1 year |
| Other Criteria | MAC Lung disease-approve if the patient has NOT achieved negative sputum cultures for Mycobacterium avium complex after a background multidrug regimen AND Arikayce will be used in conjunction to a background multidrug regimen. Note-a multidrug regimen typically includes a macrolide (azithromycin or clarithromycin), ethambutol and a rifamycin (rifampin or rifabutin). Cystic fibrosis-patient has pseudomonas aeruginosa in culture of the airway. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Cystic fibrosis pseudomonas aeruginosa infection |

AVONEX

Products Affected

- Avonex intramuscular pen injector kit
- Avonex intramuscular syringe kit

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Concurrent use of other disease-modifying agent used for multiple sclerosis |
| Required Medical Information | Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or after consultation with a neurologist or an MS specialist. |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

AYVAKIT

Products Affected

- Ayvakit

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | GIST-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation. Myeloid/Lymphoid Neoplasms with eosinophilia-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) D842V mutation. Systemic mastocytosis-Approve if the patient has a platelet count greater than or equal to 50,000/mcL and patient has 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 |

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 | 3 years |
| Other Criteria | Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 or fibroblast growth factor receptor 2 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy or checkpoint inhibitor therapy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

BANZEL

Products Affected

- Banzel
- 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 the patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs. 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 |

BENLYSTA

Products Affected

- Benlysta subcutaneous

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concurrent Use with Other Biologics |
| Required Medical Information | Diagnosis, medications that will be used in combination, autoantibody status |
| Age Restrictions | 18 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-3 years. Lupus Nephritis-6 mo initial, 1 year cont |
| Other Criteria | Lupus Nephritis Initial-approve if the patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]). Cont-approve if the patient has responded to the requested medication. SLE-Initial-The patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) 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, as determined by the prescribing physician. 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 be intolerant due to a significant toxicity, as determined by the prescribing physician AND The patient has responded to Benlysta as determined by the prescriber. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

BOSULIF

Products Affected

- Bosulif oral tablet 100 mg, 400 mg, 500 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis. For CML/ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For ALL, prior therapies tried. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 months. |
| Other Criteria | For CML, patient must have Ph-positive CML. For ALL, patient must have Ph-positive ALL and has tried ONE other tyrosine kinase inhibitors that are used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc). |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia |

BRAFTOVI

Products Affected

- Braftovi oral capsule 75 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, BRAF V600 status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| 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, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

BRUKINSA

Products Affected

- Brukinsa

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, prior therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Mantle Cell Lymphoma - approve for 3 years if the patient has tried at least one prior therapy. Chronic lymphocytic leukemia/small lymphocytic lymphoma-approve if the patient has tried at least one prior therapy. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Chronic lymphocytic Leukemia (CLL). Small Lymphocytic Lymphoma (SLL) |

C1 ESTERASE INHIBITORS

Products Affected

- Cinryze
- Haegarda

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

CABLIVI

Products Affected

- Cablivi injection kit

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, concurrent medications |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with a hematologist |
| Coverage Duration | Approve for 12 months |
| Other Criteria | aTTP-approve if the requested medication was initiated in the inpatient setting in combination with plasma exchange therapy AND patient is currently receiving at least one immunosuppressive therapy AND if the patient has previously received Cablivi, he/she has not had more than two recurrences of aTTP while on Cablivi. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

CABOMETYX

Products Affected

- Cabometyx

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, histology, RET gene rearrangement status |
| Age Restrictions | Thyroid carcinoma-12 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Advance Renal Cell Carcinoma (Predominant Clear Cell or Non-Clear Cell Histology)-Approve. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). GIST-approve if the patient has previously tried imatinib or avapritinib and has also tried one of the following: sunitinib, regorafenib or ripretinib. 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. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Patients with Non-Small Cell Lung Cancer with RET Gene Rearrangements, Gastrointestinal stromal tumors (GIST), Bone cancer |

CALQUENCE

Products Affected

- Calquence

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | MCL, CLL and SLL-approve. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried one prior therapy. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma. |

CAPRELSA

Products Affected

- Caprelsa oral tablet 100 mg, 300 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| 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 Hurthle) Thyroid Carcinoma. Non-Small Cell Lung Cancer with RET Gene Rearrangements |

CARBAGLU

Products Affected

- Carbaglu

| 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 for 7 day |
| 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 |

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 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 |

CERDELGA

Products Affected

- Cerdelga

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, 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 Gaucher disease or related disorders |
| Coverage Duration | 1 year |
| Other Criteria | Approve if the patient is a cytochrome P450(CYP) 2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an approved test |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 |

CHENODAL

Products Affected

- Chenodal

| 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 3 years. |
| Other Criteria | For the treatment of gallstones, approve if the patient has tried or is currently using an ursodiol product. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

CHOLBAM

Products Affected

- Cholbam oral capsule 250 mg, 50 mg

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Combination Therapy with Chenodal |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with hepatologist, metabolic specialist, or GI |
| Coverage Duration | 3 mos initial, 12 mos cont |
| Other Criteria | Bile acid synthesis d/o due to SEDs initial - Diagnosis based on an abnormal urinary bile acid as confirmed by Fast Atom Bombardment ionization - Mass Spectrometry (FAB-MS) analysis or molecular genetic testing consistent with the diagnosis. Cont - responded to initial Cholbam tx with an improvement in LFTs AND does not have complete biliary obstruction. Bile-Acid Synthesis Disorders Due to Peroxisomal Disorders (PDs), Including Zellweger Spectrum Disorders initial - PD with an abnormal urinary bile acid analysis by FAB-MS or molecular genetic testing consistent with the diagnosis AND has liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption (e.g., rickets). Cont - responded to initial Cholbam therapy as per the prescribing physician (e.g., improvements in liver enzymes, improvement in steatorrhea) AND does not have complete biliary obstruction. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

CIALIS

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 |

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 one of the following: lamotrigine, topiramate, rufinamide, felbamate, or Epidiolex. 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 |

COMETRIQ

Products Affected

- Cometriq

| 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 3 years. |
| Other Criteria | MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine 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 Hurthle) Thyroid Carcinoma |

COPAXONE

Products Affected

- glatiramer subcutaneous syringe 20 mg/mL, 40 mg/mL
- Glatopa subcutaneous syringe 20 mg/mL, 40 mg/mL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concurrent use with other disease-modifying agent used for multiple sclerosis |
| Required Medical Information | Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or after consultation with a neurologist or an MS specialist. |
| Coverage Duration | Authorization will be for 1 year. |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

COPIKTRA

Products Affected

- Copiktra

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, previous therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | CLL/Follicular Lymphoma/SLL/MALT Lymphoma (gastric and non gastric)/marginal zone lymphoma-approve if the patient has tried two prior therapies |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | MALT Lymphoma (gastric and non gastric), Marginal Zone Lymphoma |

COTELLIC

Products Affected

- Cotellic

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Melanoma initial - must have BRAF V600 mutation. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | 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, OR ii. Recurrent disease for one of the following conditions (a, b, or c): a) Low-grade glioma OR b) Anaplastic glioma OR c) Glioblastoma, OR iii. Melanoma with brain metastases AND medication with be taken in combination with Zelboraf (vemurafenib tablets). Histiocytic Neoplasm-approve if the patient meets one of the following (i, ii, or iii): i. Patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions, OR ii. Patient has Erdheim Chester disease OR iii. Patient has Rosai-Dorfman disease AND patient has BRAF V600 mutation-positive disease. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Central Nervous System Cancer, Histiocytic Neoplasm |

CRESEMBA (ORAL)

Products Affected

- Cresemba oral

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 months |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Candidiasis of the esophagus - HIV infection, sepsis |

CYSTARAN

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 |

CYSTEAMINE (ORAL)

Products Affected

- Cystagon

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Concomitant use of Cystagon and Procysbi |
| Required Medical Information | Diagnosis, genetic tests and lab results |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a nephrologist or a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases) |
| Coverage Duration | 1 year |
| Other Criteria | Cystinosis, nephropathic-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the CTNS gene OR white blood cell cystine concentration above the upper limit of the normal reference range for the reporting laboratory. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

DALIRESP

Products Affected

- Daliresp oral tablet 250 mcg, 500 mcg

| 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 |

DAURISMO

Products Affected

- Daurismo oral tablet 100 mg, 25 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, medications that will be used in combination, comorbidities |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | AML - approve if Daurismo will be used in combination with cytarabine AND the patient meets i. OR ii: i. patient is using Daurismo for treatment induction and is greater than or equal to 75 years old or the patient has comorbidities that preclude the use of intensive induction chemotherapy according to the prescribing physician, OR ii. patient is continuing Daurismo as post-induction therapy. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Patients continuing Daurismo as post-induction therapy |

DOPTELET

Products Affected

- Doptelet (10 tab pack)
- Doptelet (15 tab pack)
- Doptelet (30 tab pack)

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, platelet count, date of procedure |
| Age Restrictions | 18 years and older (for chronic ITP-initial therapy only) |
| Prescriber Restrictions | Chronic ITP-prescribed by or after consultation with a hematologist (initial therapy only) |
| Coverage Duration | Thrombo w/chronic liver disease-5 days, chronic ITP- initial-3 months, cont-1 year |
| Other Criteria | Thrombocytopenia with chronic liver disease-Approve if the patient has a current platelet count less than 50 x 10 ⁹ /L AND the patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. Chronic ITP, initial-approve if the patient has a platelet count less than 30,000 microliters or less than 50,000 microliters and is at an increased risk of bleeding and has tried one other therapy or if the patient has undergone splenectomy. Continuation-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

DUPIXENT

Products Affected

- Dupixent Pen subcutaneous pen injector 200 mg/1.14 mL, 300 mg/2 mL
- Dupixent Syringe subcutaneous syringe 200 mg/1.14 mL, 300 mg/2 mL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concurrent use with Xolair or another Anti-interleukin (IL) Monoclonal Antibody. |
| Required Medical Information | Diagnosis, prescriber specialty, other medications tried and length of trials |
| Age Restrictions | AD-6 years and older, asthma-12 years of age and older. Chronic Rhinosinusitis-18 years of age and older |
| Prescriber Restrictions | Atopic Dermatitis-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist. |
| Coverage Duration | AD-Initial-4 months, Cont-1 year, asthma/Rhinosinusitis-initial-6 months, continuation 1 year |
| Other Criteria | Atopic Dermatitis-Initial-meets both a and b: a.has used at least one medium, medium-high, high, and/or super-high-potency prescription topical corticosteroid OR has atopic dermatitis affecting ONLY the face, eyes/eyelids, skin folds, and/or genitalia and has tried tacrolimus ointment AND b.Inadequate efficacy was demonstrated with these previously tried topical prescription therapies, according to the prescribing physician.Continuation-Approve if the pt has responded to Dupixent therapy as determined by the prescribing physician. Asthma-Initial-approve if pt meets the following criteria (i, ii, and iii):i.Pt meets ONE of the following criteria (a or b):a)has a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin (IL) therapy or Xolair OR b)has oral corticosteroid-dependent asthma, per the prescriber AND ii.has received combination therapy with BOTH of the following (a and b): a)An inhaled corticosteroid (ICS) AND b)At least one additional asthma controller/maintenance medication (NOTE:An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-5 |

| PA Criteria | Criteria Details |
|-----------------------|--|
| | <p>therapy or Xolair used concomitantly with an ICS. Use of a combination inhaler containing both an ICS and a LABA would fulfil the requirement for both criteria a and b) AND iii.asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy or Xolair as defined by ONE of the following (a, b, c, d or e): a)experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b)experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department visit in the previous year OR c)has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d)has an FEV1/forced vital capacity (FVC) less than 0.80 OR e)The patient's asthma worsens upon tapering of oral corticosteroid therapy. Continuation-Approve if meets the following criteria (i and ii): i.continues to receive therapy with one inhaled corticosteroid (ICS) or one ICS-containing combination inhaler AND ii.has responded to Dupixent therapy as determined by the prescribing physician. Chronic rhinosinusitis with Nasal Polyposis-Initial-pt is currently receiving therapy with an intranasal corticosteroid AND is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell according to the prescriber AND meets ONE of the following (a or b): a)has received treatment with a systemic corticosteroid within the previous 2 years or has a contraindication to systemic corticosteroid therapy OR b)has had prior surgery for nasal polyps. Continuation-approve if the pt continues to receive therapy with an intranasal corticosteroid AND pt has responded to Dupixent therapy as determined by the prescriber.</p> |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ENBREL

Products Affected

- Enbrel Mini
- Enbrel subcutaneous recon soln
- 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/ rheumatologist. PsA, prescribed by or in consultation w/ rheumatologist or dermatologist.PP, prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center.Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist. Uveitis, prescribed by or in consultation with an ophthalmologist. |
| Coverage Duration | FDA dx-3 mo init,3 yrs cont, Behcet's/uveitis init-3 mo,cont-12 mo.GVHD-1 mo init/3 mo cont. |
| 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 for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA, approve if the pt has aggressive disease, as determined by the prescriber, or the pt has tried one other agent for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID, biologic DMARD or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide.Plaque psoriasis (PP) initial approve if the patient meets one of the following conditions: 1) patient has tried at least one traditional systemic agent for at least 3 months for plaque psoriasis, unless intolerant (eg, MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA, (note: pts who have already tried a biologic |

| PA Criteria | Criteria Details |
|-----------------------|---|
| | <p>for psoriasis are not required to step back and try a traditional agent first) OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD. Tried or currently is receiving with etanercept 1 conventional GVHD tx (high-dose systemic corticosteroid, CSA, tacrolimus, MM, thalidomide, antithymocyte globulin, etc.). Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Uveitis-tried one of the following: periocular, intraocular, or systemic corticosteroid, immunosuppressives, Humira or an infliximab product. RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Behcet's, GVHD, Uveitis Cont-if the patient has had a response to tx according to the prescriber. Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit, approve additional quantity (to allow for 50 mg twice weekly dosing) if one of the following is met: 1) Patient has plaque psoriasis, OR 2) Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR 3) Patient has RA and the dose is being increased to 50 mg twice weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is contraindicated or intolerant, OR 4) Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months.</p> |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Graft versus host disease (GVHD), Behcet's disease, Uveitis |

EPCLUSA

Products Affected

- Epclusa oral tablet 200-50 mg, 400-100 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | Combination use with other direct acting antivirals, excluding ribavirin. |
| Required Medical Information | Genotype, prescriber specialty, other medications tried or used in combination with requested medication |
| Age Restrictions | 3 years or older |
| Prescriber Restrictions | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician |
| Coverage Duration | 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 |

EPIDIOLEX

Products Affected

- Epidiolex

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, previous therapies |
| Age Restrictions | Patients 1 years and older |
| 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 |

EPOETIN ALFA

Products Affected

- Procrit injection solution 10,000 unit/mL, 2,000 unit/mL, 20,000 unit/mL, 3,000 unit/mL, 4,000 unit/mL, 40,000 unit/mL
- Retacrit

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | CRF anemia in patients not on dialysis.Hemoglobin (Hb) of less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children to start.Hb less than or equal to 11.5 g/dL for adults or 12 g/dL or less for children if previously on epoetin alfa, Mircera or Aranesp. Anemia w/myelosuppressive chemotx.pt must be currently receiving myelosuppressive chemo and Hb 10.0 g/dL or less to start.Hb less than or equal to 12.0 g/dL if previously on epoetin alfa or Aranesp.MDS, approve if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start.Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV with zidovudine, Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 mU/mL or less at tx start.Previously on EA approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Hgb is less than or equal to 13, surgery is elective, nonvascular and non-cardiac and pt is unwilling or unable to donate autologous blood prior to surgery |
| 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(dialysis)-3yrs, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr |
| Other Criteria | Myelofibrosis-Initial-patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 Mu/mL. Cont-patient has a Hgb less than or equal to 12 and according to the prescriber the patient has had a response defined as Hb greater than or equal to 10 or an increase of greater than or equal to 2 g/dL. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Anemia due to myelodysplastic syndrome (MDS), Myelofibrosis |

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 | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years |
| Other Criteria | Locally advanced basal cell carcinoma (LABCC), approve if 1. the patient's BCC has recurred following surgery or radiation, OR 2. the patient is not a candidate for surgery and radiation therapy. Central nervous system cancer (this includes brain and spinal cord tumors)-approve if the patient has tried at least one chemotherapy agent and according to the prescriber, the patient has a mutation of the sonic hedgehog pathway. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Central nervous System Cancer |

ERLEADA

Products Affected

- Erleada

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| 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 or if the patient has had a bilateral orchiectomy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ESBRIET

Products Affected

- Esbriet oral capsule
- Esbriet oral tablet 267 mg, 801 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 - 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. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

EXJADE/JADENU

Products Affected

- deferasirox

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Serum ferritin level |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a hematologist |
| Coverage Duration | 1 year |
| Other Criteria | Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve if the patient is benefiting from therapy as confirmed by the prescribing physician. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 | 12 months |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

FASENRA

Products Affected

- Fasenra
- Fasenra Pen

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody |
| Required Medical Information | Diagnosis, severity of disease, peripheral blood eosinophil count, previous therapies tried and current therapies, FEV1/FVC |
| Age Restrictions | 12 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an allergist, immunologist, or pulmonologist |
| Coverage Duration | Authorization will be for 6 months initial, 12 months continuation. |
| Other Criteria | <p>Initial - must have peripheral blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks (prior to treatment with any anti-interleukin (IL)-5 therapy) AND meet both of the following criteria: 1) Patient has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid AND one of the following: inhaled LABA, inhaled long-acting muscarinic antagonist, Leukotriene receptor antagonist, or Theophylline, AND 2) Patient's asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy as defined by ONE of the following: a) patient experienced one or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, OR b) patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year, OR c) patient has a FEV1 less than 80 percent predicted, OR d) Patient has an FEV1/FVC less than 0.80, OR e) Patient's asthma worsens upon tapering of oral corticosteroid therapy. NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-5 therapy (e.g., Cinqair, Fasenra, Nucala) used concomitantly with an ICS for at least 3 consecutive months.</p> <p>Continuation - The patient has responded to Fasenra therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, emergency department</p> |

| PA Criteria | Criteria Details |
|-----------------------|--|
| | (ED)/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy) AND patient continues to receive therapy with an inhaled corticosteroid. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

FERRIPROX

Products Affected

- deferiprone
- Ferriprox

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Serum ferritin level |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a hematologist |
| Coverage Duration | 1 year |
| Other Criteria | Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias-Initial therapy - approve if prior to starting therapy the serum ferritin level was greater than 1,000 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 |

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 or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

FIRAZYR

Products Affected

- icatibant

| 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% 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 |

FIRDAPSE

Products Affected

- Firdapse

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | History of seizures (initial therapy) |
| Required Medical Information | Diagnosis, seizure history, lab and test results |
| Age Restrictions | 18 years and older (initial therapy) |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist or a neuromuscular specialist (initial therapy) |
| Coverage Duration | Initial-3 months, Cont-1 year |
| Other Criteria | Initial therapy-Diagnosis confirmed by at least one electrodiagnostic study (e.g., repetitive nerve stimulation) OR anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing according to the prescribing physician. Continuation-patient continues to derive benefit (e.g., improved muscle strength, improvements in mobility) from Firdapse, according to the prescribing physician. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 3 years |
| Other Criteria | Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or Stage IV disease and has tried at least two other systemic regimens. 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 |

GATTEX

Products Affected

- Gattex 30-Vial

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | 1 year and older |
| Prescriber Restrictions | Prescribed by or in consultation with a gastroenterologist (initial and continuation) |
| Coverage Duration | 1 year |
| Other Criteria | Initial-approve if the patient is currently receiving parenteral nutrition on 3 or more days per week or according to the prescriber, the patient is unable to receive adequate total parenteral nutrition required for caloric needs. Continuation-approve if the patient has experienced at least a 20 percent decrease from baseline in the weekly volume of parenteral nutrition. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

GAVRETO

Products Affected

- Gavreto

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | NSCLC-18 years and older, MTC/thyroid cancer-12 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | NSCLC-approve if the patient has metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an Food and Drug Administration (FDA) approved test. Medullary thyroid cancer (MTC)-approve if the patient has advanced or metastatic rearranged during transfection (RET)-mutant disease and the disease requires treatment with systemic therapy. Thyroid cancer (other than MTC)-approve if the patient has advanced or metastatic rearranged during transfection (RET) fusion-positive disease, the disease is radioactive iodine-refractory AND the disease requires treatment with systemic therapy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

GILENYA

Products Affected

- Gilenya oral capsule 0.5 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Concurrent use of Gilenya with other disease-modifying agents used for multiple sclerosis (MS). |
| Required Medical Information | Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by, or in consultation with, a neurologist or an MS specialist. |
| Coverage Duration | Authorization will be for 1 year. |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | NSCLC EGFR pos - For the treatment of metastatic non small cell lung cancer (NSCLC) must be used in tumors with non-resistant EGFR mutation positive NSCLC as detected by an approved test. NSCLC metastatic squamous cell must have disease progression with first line treatment with platinum based chemotherapy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

GLUCAGON-LIKE PEPTIDE-1 AGONISTS

Products Affected

- Bydureon BCise
- Byetta subcutaneous pen injector 10 mcg/dose(250 mcg/mL) 2.4 mL, 5 mcg/dose (250 mcg/mL) 1.2 mL
- Trulicity

| 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 3 years. |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

Products Affected

- leuprolide subcutaneous kit
- Lupron Depot
- Lupron Depot (3 month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | For the treatment of cancer diagnosis must be prescribed by or in consultation with an oncologist. |
| Coverage Duration | For abnormal uterine bleeding,uterine leiomyomata 6 mo.All other=12 mo |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Ovarian cancer, breast cancer, prophylaxis or treatment of uterine bleeding in patients with hematologic malignancy or undergoing cancer treatment or prior to bone marrow/stem cell transplantation, head and neck cancer-salivary gland tumors |

GROWTH HORMONES

Products Affected

- Omnitrope

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | <p>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 inadequate as defined by a peak GH response which is below the normal reference range of the testing laboratory OR had at least 1 GH test and results show inadequate response 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).</p> <p>2.brain radiation or tumor resection and pt has 1 GH stim test and results is inadequate response 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).</p> <p>3. congenital hypopituitarism and has one GH stim test with inadequate response 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</p> <p>4.pt has panhypopituitarism and has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary bright spot on MRI or CT or pt has 3 or more pituitary hormone deficiencies or pt has had one GH test and results were inadequate</p> <p>5.pt had a hypophysectomy. Cont-pt responding to therapy</p> |
| Age Restrictions | ISS 5 y/o or older, SGA 2 y/o or older, 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 |

| PA Criteria | Criteria Details |
|-----------------------|--|
| Other Criteria | <p>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, AND 3. meets one of the following - A. has known mutations, embryonic lesions, 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 alone 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 | SHOX, Noonan Syndrome, CKD, SBS |

HARVONI

Products Affected

- Harvoni oral pellets in packet 33.75-150 mg, 45-200 mg
- Harvoni oral tablet 90-400 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Combination use with other direct acting antivirals, excluding ribavirin |
| Required Medical Information | N/A |
| Age Restrictions | 3 years or older |
| Prescriber Restrictions | Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD |
| Coverage Duration | Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug |
| Other Criteria | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Indications consistent with current AASLD/IDSA guidance |

HETLIOZ

Products Affected

- HetlioZ

| 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, SMS-16 years and older |
| Prescriber Restrictions | prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders |
| Coverage Duration | 6 mos initial, 12 mos cont |
| Other Criteria | Initial - 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 pt has achieved adequate results with HetlioZ 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 |

HIGH RISK MEDICATIONS - BENZODIAZEPINES

Products Affected

- clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg
- diazepam oral concentrate
- diazepam oral solution 5 mg/5 mL (1 mg/mL)
- diazepam oral tablet
- Lorazepam Intensol
- lorazepam oral tablet 0.5 mg, 1 mg, 2 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply. |
| Prescriber Restrictions | N/A |
| Coverage Duration | Procedure-related sedation = 1mo. All other conditions = 12 months. |
| Other Criteria | All medically accepted indications other than insomnia, authorize use. Insomnia, may approve lorazepam if the patient has had a trial with two of the following: ramelteon, doxepin 3mg or 6 mg, eszopiclone, zolpidem, or zaleplon. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy. |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |

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 |

HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

Products Affected

- cyclobenzaprine oral tablet

| 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 |

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

Products Affected

- hydroxyzine HCl oral tablet
- 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 |

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 |

HIGH RISK MEDICATIONS- ESTROGENS

Products Affected

- Amabelz
- Dotti
- estradiol oral
- estradiol transdermal patch semiweekly
- estradiol transdermal patch weekly
- estradiol-norethindrone acet
- Fyavolv
- Jinteli
- Lyllana
- Menest oral tablet 0.3 mg, 0.625 mg, 1.25 mg
- Mimvey
- norethindrone ac-eth estradiol oral tablet 0.5-2.5 mg-mcg, 1-5 mg-mcg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Previous medication use |
| 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 the treatment of Vulvar Vaginal Atrophy, approve if the patient has had a trial of one of the following for vulvar vaginal atrophy (brand or generic): Estradiol Vaginal Cream or estradiol valerate. For prophylaxis of Postmenopausal Osteoporosis, approve if the patient has had a trial of one of the following (brand or generic): alendronate, ibandronate, risidronate or Raloxifene. 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 |

HUMIRA

Products Affected

- Humira Pen
- Humira Pen Crohns-UC-HS Start
- Humira Pen Psor-Uveits-Adol HS
- Humira subcutaneous syringe kit 40 mg/0.8 mL
- Humira(CF) Pedi Crohns Starter subcutaneous syringe kit 80 mg/0.8 mL, 80 mg/0.8 mL-40 mg/0.4 mL
- Humira(CF) Pen Crohns-UC-HS
- Humira(CF) Pen Pediatric UC
- Humira(CF) Pen Psor-Uv-Adol HS
- Humira(CF) Pen subcutaneous pen injector kit 40 mg/0.4 mL, 80 mg/0.8 mL
- Humira(CF) subcutaneous syringe kit 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concurrent use with another biologic DMARD or targeted synthetic DMARD. |
| Required Medical Information | Diagnosis, concurrent medications, previous therapies tried |
| Age Restrictions | Crohn's disease (CD), 6 or older (initial therapy only). Ulcerative colitis (UC), 5 or older (initial therapy only). |
| Prescriber Restrictions | Initial therapy only for all dx-RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist.UV-ophthalmologist |
| Coverage Duration | initial 3 mo, cont tx 3 years. |
| 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 for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt 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, |

| PA Criteria | Criteria Details |
|-----------------------|---|
| | <p>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. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other agent for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ileocolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone), or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. FDA approve indications cont tx - must respond to tx as determined by prescriber. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). 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. |
| Off-Label Uses | N/A |

IBRANCE

Products Affected

- Ibrance

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Breast cancer - approve advanced (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 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 4. Pt is postmenopausal and Ibrance will be used in combination with fulvestrant |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Liposarcoma |

ICLUSIG

Products Affected

- Iclusig oral tablet 10 mg, 15 mg, 30 mg, 45 mg

| 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 | CML/ALL - Adults |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | CML Ph+, T315I-positive or has tried TWO other TKIs indicated for use in Philadelphia chromosome positive CML (e.g., Gleevec, Sprycel, Tasigna). ALL Ph+, T315I-positive or has tried TWO other TKIs indicated for use in Ph+ ALL (e.g. Gleevec, Sprycel.) |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

IDHIFA

Products Affected

- Idhifa

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | IDH2-mutation status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| 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 |

IMATINIB

Products Affected

- imatinib oral tablet 100 mg, 400 mg

| 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 | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | For ALL/CML, must have Ph-positive for approval of imatinib. AIDS related Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Chordoma, advanced or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, AIDS Related Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor. |

IMBRUVICA

Products Affected

- Imbruvica oral capsule 140 mg, 70 mg
- Imbruvica oral tablet

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | GVHD-1 year, all others-3 years |
| Other Criteria | Marginal Zone Lymphoma - Approve. GVHD-Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, imatinib, Jakafi). B-cell lymphoma-approve if the patient is using Imbruvica as second-line or subsequent therapy according to the prescribing physician. Central nervous system Lymphoma (primary)/Hairy Cell Leukemia-approve if relapsed or refractory. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma (e.g., follicular lymphoma, gastric MALT lymphoma, nongastric MALT lymphoma, AIDS related, post-transplant lymphoproliferative disorders). |

IMPAVIDO

Products Affected

- Impavido

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with an infectious diseases specialist |
| Coverage Duration | 1 month |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- testosterone cypionate intramuscular oil 100 mg/mL, 200 mg/mL, 200 mg/mL (1 ML)
- testosterone enanthate

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

INLYTA

Products Affected

- Inlyta oral tablet 1 mg, 5 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | Advanced Renal cell carcinoma-approve. Differentiated thyroid cancer, approve if patient is refractory to radioactive iodine therapy. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma |

INQOVI

Products Affected

- Inqovi

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 1 year |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

INREBIC

Products Affected

- Inrebic

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| 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. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

IRESSA

Products Affected

- Iressa

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Metastatic NSCLC - The patient has epidermal growth factor receptor (EGFR) exon 19 deletions OR has exon 21 (L858R) substitution mutations as detected by an FDA-approved test. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

IVIG

Products Affected

- Privigen

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 months. |
| Other Criteria | Part B versus D determination per CMS guidance to establish if drug used for PID in pt's home. |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |

JAKAFI

Products Affected

- Jakafi

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | ALL-less than 21 years of age |
| Prescriber Restrictions | N/A |
| Coverage Duration | GVHD/ALL-1 year, all others-Authorization will be for 3 years. |
| Other Criteria | For polycythemia vera patients must have tried hydroxyurea. 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. 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 mutation. Chronic monomyelocytic leukemia-2 (CMML-2)-approve if the patient is also receiving a hypomethylating agent. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Acute lymphoblastic leukemia, graft versus host disease, chronic, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2) |

JUXTAPID

Products Affected

- Juxtapid oral capsule 10 mg, 20 mg, 30 mg, 5 mg

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Combination use with Kynamro, Praluent, or Repatha. |
| Required Medical Information | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a cardiologist, an endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders. |
| Coverage Duration | 12 months |
| Other Criteria | Patient must meet ALL of the following criteria: 1) Patient has had genetic confirmation of two mutant alleles at the LDL receptor, apolipoprotein B APOB, PCSK9, or LDLRAP1 gene locus OR the patient has an untreated LDL-C level greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents) OR the patient has a treated LDL-C level greater than or equal to 300 mg/dL (after treatment with antihyperlipidemic agents but prior to agents such as Repatha) OR the patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) Patient has tried Repatha and had an inadequate response according to the prescribing physician OR the patient is known to have two LDL-receptor negative alleles, AND 3) Patient has tried one high-intensity statin therapy (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than 20 mg daily [as a single-entity or as a combination product]) for greater than or equal to 8 continuous weeks and the LDL-C level remains greater than or equal to 70 mg/dL OR the patient has been determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or patient experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. |

| PA Criteria | Criteria Details |
|-----------------------|-------------------------------|
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

KALYDECO

Products Affected

- Kalydeco oral granules in packet
- Kalydeco oral tablet

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | Combination use with Orkambi, Trikafta or Symdeko |
| Required Medical Information | N/A |
| Age Restrictions | 4 months 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 have one mutation in the CFTR gene that is responsive to the requested medication. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

KISQALI

Products Affected

- Kisqali
- Kisqali Femara Co-Pack

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | <p>Breast cancer - approve advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer when the pt meets ONE of the following</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 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. Patients must have a trial of Ibrance prior to approval of Kisqali/Kisqali Femara Co-Pack unless the patient meets one of the following-a) Patient has been taking Kisqali or Kisqali Femara Co-Pack and is continuing therapy OR b) Patient is pre/perimenopausal and will be using Kisqali or Kisqali Femara Co-Pack in combination with an aromatase inhibitor as initial endocrine-based therapy OR c) Kisqali will be used in |

| PA Criteria | Criteria Details |
|-----------------------|---|
| | combination with fulvestrant in postmenopausal female or male patients as initial endocrine-based therapy |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Men with breast cancer |

KORLYM

Products Affected

- Korlym

| 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 | Cushing's-1 year. Patients 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 Korlym 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 |

KUVAN

Products Affected

- Kuvan
- sapropterin

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Concurrent use with Palynziq (continuation only) |
| 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 - approve if the patient has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescribing physician OR patient had a 20% or greater reduction in blood Phe concentration from baseline OR treatment with sapropterin has resulted in an increase in dietary phenylalanine tolerance. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

KYNMOBI

Products Affected

- Kynmobi sublingual film 10 mg, 15 mg, 20 mg, 25 mg, 30 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 1 year |
| Other Criteria | Parkinson's Disease-Approve if the patient is experiencing off episodes, such as muscle stiffness, slow movements or difficulty starting movements, is currently receiving carbidopa/levodopa and has previously tried one other treatment for off episodes. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

LENVIMA

Products Affected

- Lenvima

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| 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 Keytruda OR ii. Lenvima is used in combination with Afinitor/Afinitor Disperz and the patient meets a or b: a. Patient has clear cell histology and patient has tried one antiangiogenic therapy OR b. patient has non-clear cell histology. MTC-approve if the patient has tried Caprelsa or Cometriq. Anaplastic thyroid cancer-approve if the disease does not have a curative option. Endometrial Carcinoma- Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has advanced endometrial carcinoma that 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.</p> |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Patients with Medullary Thyroid Carcinoma (MTC) and anaplastic thyroid carcinoma. |

LETAIRIS/TRACLEER

Products Affected

- ambrisentan
- bosentan

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Pulmonary arterial hypertension (PAH) WHO Group 1, results of right heart cath |
| Age Restrictions | N/A |
| Prescriber Restrictions | For treatment of pulmonary arterial hypertension, ambrisentan or bosentan must be prescribed by or in consultation with a cardiologist or a pulmonologist. CTEPH - prescribed by or in consultation with a cardiologist or pulmonologist |
| Coverage Duration | Authorization will be for 1 year. |
| Other Criteria | CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving bosentan for CTEPH. Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Chronic thromboembolic pulmonary hypertension (CTEPH) (bosentan) |

LEUKINE

Products Affected

- Leukine injection recon soln

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | Neuroblastoma-less than 18 years of age |
| Prescriber Restrictions | AML if prescribed by or in consultation with an oncologist or hematologist, PBPC/BMT - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation, Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome. Neuroblastoma-prescribed by or in consultation with an oncologist. |
| Coverage Duration | Radiation Syndrome/BMT - 1 mo, AML/Neuroblastoma-6 months, PBPC-14 days |
| Other Criteria | Neuroblastoma-approve if the patient is receiving Leukine in a regimen with dinutuximab. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Neuroblastoma |

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 |

LONG ACTING OPIOIDS

Products Affected

- buprenorphine
- hydrocodone bitartrate oral capsule, oral only, ER 12hr
- hydromorphone oral tablet extended release 24 hr
- methadone oral solution 10 mg/5 mL, 5 mg/5 mL
- methadone oral tablet 10 mg, 5 mg
- morphine oral capsule, ER multiphase 24 hr
- morphine oral capsule, extend. release pellets
- morphine oral tablet extended release

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Acute (ie, non-chronic) pain |
| Required Medical Information | Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 months. |
| Other Criteria | For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, sickle cell disease, in hospice or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|-----------------------|-------------------------|
| Off-Label Uses | N/A |

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 3 years. |
| 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. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

LORBRENA

Products Affected

- Lorbrena oral tablet 100 mg, 25 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, ALK status, ROS1 status, previous therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | NSCLC - Approve if the patient has ALK-positive metastatic NSCLC. NSCLC-ROS1 Rearrangement-Positive-approve if the patient has tried one of crizotinib, entrectinib or ceritinib. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Non-small cell lung cancer (NSCLC)-ROS1 Rearrangement-Positive |

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 3 years |
| 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. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

LYNPARZA

Products Affected

- Lynparza

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | <p>Ovarian Cancer - Treatment-initial-Approve if the patient meets the following criteria (i and ii): i. patient has a germline BRCA-mutation as confirmed by an approved test AND per product labeling the patient has progressed on three or more prior lines of chemotherapy. Continuation-approve if the patient has a BRCA mutation (germline) as confirmed by an approved test. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient meets one of the following criteria (A or B): A) patient meets both of the following criteria for first-line maintenance therapy (i and ii): i. patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND ii. The patient is in complete or partial response to first-line platinum-based chemotherapy regimen (e.g., carboplatin with paclitaxel, carboplatin with doxorubicin, docetaxel with carboplatin) OR B)The patient is in complete or partial response after at least two platinum-based chemotherapy regimens (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combo tx-approve if Lynparza is used in combo with bevacizumab, pt has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and pt is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast Cancer-Approve if the patient meets the following criteria (A, B, and C)-A. The patient has metastatic, germline BRCA mutation-</p> |

| PA Criteria | Criteria Details |
|-----------------------|---|
| | <p>positive breast cancer AND B. The patient meets ONE of the following criteria (i or ii)- i. The patient meets BOTH of the following criteria (a and b)-a) The patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive ER+ and/or progesterone receptor positive PR+] disease AND b) The patient meets ONE of the following criteria (1 or 2)-1-The patient has been treated with prior endocrine therapy OR-2 The patient is considered inappropriate for endocrine therapy OR ii. Patient has triple negative disease (i.e., ER-negative, PR-negative, and HER2-negative) AND C. The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. 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 pt has metastatic disease, Lynparza is used concurrently with a GnRH analog or pt has had a bilateral orchiectomy, pt has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test, pt does not have a PPP2R2A mutation and pt has been previously treated with abiraterone or Xtandi.</p> |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

MEGACE

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | Coverage is not provided for weight gain for cosmetic reasons. |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 12 months |
| Other Criteria | N/A |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |

MEKINIST

Products Affected

- Mekinist oral tablet 0.5 mg, 2 mg

| 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 | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| 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. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation postive 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 disease for one of the following conditions (a, b, or c): a) Low-grade glioma OR b) Anaplastic glioma OR c) Glioblastoma, OR iii. Melanoma with brain 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 |

| PA Criteria | Criteria Details |
|-----------------------|--|
| | 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 AND patient has BRAF V600-mutation positive disease. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Biliary Tract Cancer, Central Nervous System Cancer, Histiocytic Neoplasm. |

MEKTOVI

Products Affected

- Mektovi

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, BRAF V600 status, concomitant medications |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| 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. Colon or Rectal cancer-approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Colon or rectal cancer |

MEMANTINE

Products Affected

- memantine oral capsule, sprinkle, ER 24hr
- memantine oral solution
- memantine oral tablet
- Namzaric

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Indication for which memantine is being prescribed. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 months. |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Patients with mild to moderate vascular dementia. |

MIGLUSTAT

Products Affected

- miglustat

| 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 geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of Gaucher disease or related disorders |
| Coverage Duration | 1 year |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

MULPLETA

Products Affected

- Mulpleta

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, platelet count, date of procedure |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 7 days |
| Other Criteria | Approve if the patient has a current platelet count less than $50 \times 10^9/L$ AND the patient is scheduled to undergo a procedure within 8 to 14 days after starting Mulpleta therapy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

MYALEPT

Products Affected

- Myalept

| 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 endocrinologist or a geneticist physician specialist |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

NATPARA

Products Affected

- Natpara

| 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 endocrinologist. |
| Coverage Duration | 1 year |
| Other Criteria | Chronic hypoparathyroidism, initial therapy - approve if before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL and 25-hydroxyvitamin D stores are sufficient per the prescribing physician. Chronic hypoparathyroidism, continuing therapy - approve if during Natpara therapy, the patient's 25-hydroxyvitamin D stores are sufficient per the prescribing physician, AND the patient is responding to Natpara therapy, as determined by the prescriber. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 |

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 | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Adjuvant tx-Approve for 1 year (total), advanced or metastatic disease-3yrs |
| Other Criteria | Breast cancer adjuvant therapy - approve if the patient meets all of the following criteria: 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, advanced 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 in the metastatic setting. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

NEXAVAR

Products Affected

- Nexavar

| 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 3 years. |
| Other Criteria | Osteosarcoma, approve if the patient has tried standard chemotherapy and have relapsed/refractory or metastatic disease. GIST, approve if the patient has tried TWO of the following: imatinib mesylate (Gleevec), sunitinib (Sutent), or regorafenib (Stivarga). Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test. Renal cell carcinoma (RCC)-approve if the patient has relapsed or Stage IV clear cell histology and the patient has tried at least one prior systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and Nexavar is used in combination with topotecan. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Osteosarcoma, angiosarcoma, desmoids tumors (aggressive fibromatosis), gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, Chordoma with recurrent disease, solitary fibrous tumor and hemangiopericytoma, ovarian, fallopian tube, primary peritoneal cancer |

NILUTAMIDE

Products Affected

- nilutamide

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Prostate cancer-approve if nilutamide is used concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

NINLARO

Products Affected

- Ninlaro

| 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 3 years. |
| Other Criteria | MM - be used in combination with Revlimid and dexamethasone OR pt had received at least ONE previous therapy for multiple myeloma (e.g., Thalomid, Revlimid, Pomalyst, Alkeran, dexamethasone, prednisone) 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 (applies only to beneficiaries enrolled in an MA-PD plan). |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Patients with systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma |

NITYR/ORFADIN

Products Affected

- nitisinone
- Orfadin oral capsule 20 mg
- Orfadin oral suspension

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concomitant use of therapy with nitisinone products |
| Required Medical Information | Diagnosis, genetic tests and lab results |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases) |
| Coverage Duration | 1 year |
| Other Criteria | Hereditary Tyrosinemia, Type 1-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the FAH gene OR elevated serum levels of alpha-fetoprotein (AFP) and succinylacetone. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

NIVESTYM

Products Affected

- Nivestym

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| 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, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. |
| Coverage Duration | chem/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS/BMT-3 mo.PBPC,Drug induce A/N,AA,ALL-3 mo.Radi-1 mo,other=12mo. |
| Other Criteria | Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia |

| PA Criteria | Criteria Details |
|-----------------------|--|
| | [absolute neutrophil account 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. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL). Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome). |

NON-INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| 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 | N/A |
| 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.] |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|----------------|------------------|
| Off-Label Uses | N/A |

NORTHERA

Products Affected

- droxidopa
- Northera

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Medication history |
| 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 |

NUBEQA

Products Affected

- Nubeqa

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog or if the patient has had a bilateral orchiectomy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

NUEDEXTA

Products Affected

- Nuedexta

| 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 |

NUPLAZID

Products Affected

- Nuplazid oral capsule
- Nuplazid oral tablet 10 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 1 year |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

NUVIGIL/PROVIGIL

Products Affected

- armodafinil
- modafinil oral tablet 100 mg, 200 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | N/A |
| 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 - modafinil only. Adjunctive/augmentation for treatment of depression in adults - modafinil only. |

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, if 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 is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia 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 the patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Patients undergoing PBPC collection and therapy |

OCALIVA

Products Affected

- Ocaliva

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Prescriber specialty, lab values, prior medications used for diagnosis and length of trials |
| Age Restrictions | 18 years and older (initial) |
| Prescriber Restrictions | Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial) |
| Coverage Duration | 6 months initial, 1 year cont. |
| Other Criteria | Initial treatment of PBC-Patient must meet both 1 and 2-1. Patient has a diagnosis of PBC as defined by TWO of the following:a)Alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values b)Positive anti-mitochondrial antibodies (AMAs) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative c)Histologic evidence of primary biliary cholangitis (PBC) from a liver biopsy 2. Patient meets ONE of the following: a) Patient has been receiving ursodiol therapy for greater than or equal to 1 year and has had an inadequate response. b) Patient is unable to tolerate ursodiol therapy. Cont tx - approve if the patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT] levels)). |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ODACTRA

Products Affected

- Odactra

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | The patient is NOT currently receiving SC or SL allergen immunotherapy |
| Required Medical Information | Diagnosis |
| Age Restrictions | Greater than or equal to 18 years of age |
| Prescriber Restrictions | N/A |
| Coverage Duration | 12 months |
| Other Criteria | House Dust Mite (HDM)-Induced Allergic Rhinitis (AR)-approve if the diagnosis is confirmed by meeting ONE of the following conditions (i or ii): i. The patient has a positive skin test response to house dust mite allergen extracts OR ii. The patient has a positive in vitro test (i.e., a blood test for allergen-specific IgE antibodies) for house dust mite (HDM). |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| 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. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Metastatic BCC |

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 | IPF - 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. Interstitial lung disease associated with systemic sclerosis-approve if the FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by high-resolution computed tomography. Chronic fibrosing interstitial lung disease-approve if the forced vital capacity is greater than or equal to 45% of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10% of lung volume on high-resolution computed tomography AND according to the prescriber the patient has clinical signs of progression. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 | 3 years |
| Other Criteria | AML - Approve if the patient meets the following criteria (both A and B): A)Following intensive induction chemotherapy, the patient achieves one of the following according to the prescriber (i or ii): i. First complete remission OR ii. First complete remission with incomplete blood count recovery AND B) Patient is not able to complete intensive curative therapy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

OPSUMIT

Products Affected

- Opsumit

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | PAH WHO group, right heart catheterization |
| Age Restrictions | N/A |
| Prescriber Restrictions | PAH - must be prescribed by or in consultation with a cardiologist or a pulmonologist. |
| Coverage Duration | Authorization will be for 3 years |
| Other Criteria | Pulmonary arterial hypertension (PAH) WHO Group 1 patients are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ORENCIA

Products Affected

- Orenzia ClickJect
- Orenzia subcutaneous syringe 125 mg/mL, 50 mg/0.4 mL, 87.5 mg/0.7 mL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD. |
| Required Medical Information | Diagnosis, concurrent medications, previous drugs tried. |
| Age Restrictions | 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 | SC-3 mos initial, 3 years cont |
| 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 for RA are not required to step back and try a conventional synthetic DMARD). Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)], approve if the patient has tried one other agent for this condition or the patient will be starting on Orenzia concurrently with methotrexate, sulfasalazine or leflunomide or the patient has an absolute contraindication to methotrexate, sulfasalazine or leflunomide or the patient has aggressive disease as determined by the prescribing physician. Cont tx - responded to therapy as per the prescriber. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 | 3 years |
| Other Criteria | Prostate Cancer-approve. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ORKAMBI

Products Affected

- Orkambi oral granules in packet
- Orkambi oral tablet

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | Combination use with Kalydeco, Trikafta or Symdeko. |
| Required Medical Information | N/A |
| 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 | 3 years |
| Other Criteria | CF - homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation) |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ORLADEYO

Products Affected

- Orladeyo

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concomitant Use with Other HAE Prophylactic Therapies (e.g., Cinryze, Haegarda, Takhzyro). |
| Required Medical Information | Diagnosis |
| Age Restrictions | 12 years and older (initial and continuation) |
| Prescriber Restrictions | Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders. (initial and continuation) |
| Coverage Duration | Authorization will be for 1 year. |
| Other Criteria | Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Prophylaxis, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein at baseline, as defined by the laboratory reference values [documentation required] AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values [documentation required]. Continuation-According to the prescriber the patient has had a favorable clinical response since initiating Orladeyo prophylactic therapy compared with baseline [documentation required to confirm diagnosis of HAE type I or II for continuation]. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

OTEZLA

Products Affected

- Otezla
- Otezla Starter oral tablets,dose pack 10 mg (4)-20 mg (4)-30 mg (47)

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, previous drugs tried |
| Age Restrictions | 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 | 4 months initial, 3 years cont |
| 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 if the patient has tried at least one conventional synthetic DMARD (eg, MTX, leflunomide, sulfasalazine) for at least 3 months, unless intolerant (note: pts who have already tried a biologic DMARD are not required to step back and try a conventional DMARD first). Behcet's-patient has oral ulcers or other mucocutaneous involvement AND patient has tried at least ONE other systemic therapy. 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 |

OXERVATE

Products Affected

- Oxervate

| 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 an optometrist. |
| Coverage Duration | 2 months |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

PALYNZIQ

Products Affected

- Palynziq subcutaneous syringe 10 mg/0.5 mL, 2.5 mg/0.5 mL, 20 mg/mL

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, phenylalanine concentrations |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases |
| Coverage Duration | 1 year (initial and continuation) |
| Other Criteria | Initial therapy - approve if the patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., prior treatment with Kuvan). Maintenance therapy - approve if the patient's blood phenylalanine concentration is less than or equal to 600 micromol/L OR the patient has achieved at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

PANRETIN

Products Affected

- Panretin

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a dermatologist, oncologist, or infectious disease specialist |
| Coverage Duration | 1 year |
| Other Criteria | Kaposi Sarcoma related to Acquired Immunodeficiency Syndrome (AIDS) (Note: Kaposi sarcoma related to AIDS may also be referred to as epidemic Kaposi sarcoma.)-approve if the patient is not receiving systemic therapy for Kaposi Sarcoma. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

PEMAZYRE

Products Affected

- Pemazyre

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, prior therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years |
| Other Criteria | Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test AND the patient has been previously treated with at least one systemic therapy regimen |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

PENICILLAMINE

Products Affected

- penicillamine

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | Wilson's Disease-Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant physician |
| Coverage Duration | 3 years |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

PHENYL BUTYRATE

Products Affected

- Ravicti
- sodium phenylbutyrate

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Concomitant use of Ravicti and Buphenyl |
| Required Medical Information | Diagnosis, genetic tests and lab results |
| 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 testing confirmed a mutation resulting in a urea cycle disorder or if the patient has hyperammonemia. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

PHEOCHROMOCYTOMA

Products Affected

- Demser
- metyrosine
- phenoxybenzamine

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, prior medication trials |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial therapy for phenoxybenzamine, initial and continuation therapy for metyrosine) |
| Coverage Duration | Authorization will be for 1 year |
| Other Criteria | If the requested drug is metyrosine for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin) AND the patient has tried phenoxybenzamine (brand or generic). 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 |

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Products Affected

- Alyq
- sildenafil (Pulmonary Arterial Hypertension) oral suspension for reconstitution 10 mg/mL
- sildenafil (Pulmonary Arterial Hypertension) oral tablet 20 mg
- tadalafil (pulmonary arterial hypertension) oral tablet 20 mg

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

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 | 3 years |
| 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 or a male or premenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) analog 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, Faslodex, tamoxifen, toremifene) AND F) Piqray will be used in combination with fulvestrant injection. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Treatment of breast cancer in premenopausal women |

PLEGRIDY

Products Affected

- Plegridy subcutaneous pen injector 125 mcg/0.5 mL
- Plegridy subcutaneous syringe 125 mcg/0.5 mL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concurrent use of with other disease-modifying agents used for multiple sclerosis (MS). |
| Required Medical Information | Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by, or in consultation with, a neurologist or an MS specialist. |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

POMALYST

Products Affected

- Pomalyst

| 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 3 years |
| Other Criteria | 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). CNS Lymphoma-approve if the patient has relapsed or refractory disease |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Systemic Light Chain Amyloidosis, Central Nervous System (CNS) Lymphoma |

POSACONAZOLE (ORAL)

Products Affected

- Noxafil oral suspension
- posaconazole oral tablet, delayed release (DR/EC)

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Aspergillus/Candida prophylaxis, mucormycosis-6 mo, all others-3 months |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Aspergillus infections - treatment, mouth and esophageal infections (refractory to other azole antifungals) - treatment, mucormycosis - maintenance, fusariosis, invasive - treatment fungal infections (systemic) in patients with human immunodeficiency virus (HIV) infections (e.g., histoplasmosis, coccidioidomycosis) - treatment |

PRALUENT

Products Affected

- Praluent Pen

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concurrent use of Juxtapid or Repatha. |
| Required Medical Information | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history |
| Age Restrictions | 18 years of age and older. |
| Prescriber Restrictions | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | <p>Hyperlipidemia in patients with HeFH-approve if meets all of the following</p> <p>1. Pt has been diagnosed with HeFH AND 2. tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or Crestor greater than or equal to 20 mg daily) AND 3. LDL-C remains greater than or equal to 70 mg/dL unless is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c.</p> <p>Hyperlipidemia Pt with Clinical ASCVD -approve if meets all of the following: has one of the following conditions prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND tried ONE high intensity statin (as defined above) AND LDL-C remains greater than or equal to 70 mg/dL unless the pt is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c.</p> <p>Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if the patient has tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above).</p> |

| PA Criteria | Criteria Details |
|-----------------------|-------------------------------|
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

PROLIA

Products Affected

- Prolia

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, Evenity, calcitonin nasal spray [Fortical], abaloparatide), except calcium and Vitamin D. |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 1 year. |
| Other Criteria | Treatment of postmenopausal osteoporosis/Treatment of osteoporosis in men (to increase bone mass) [a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression], approve if the patient meets one of the following: 1. has had inadequate response after 12 months of therapy with an oral bisphosphonate, had osteoporotic fracture or fragility fracture while receiving an oral bisphosphonate, or intolerability to an oral bisphosphonate, OR 2. the patient cannot take an oral bisphosphonate because they cannot swallow or have difficulty swallowing, they cannot remain in an upright position, or they have a pre-existing GI medical condition, OR 3. pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR 4. the patient has severe renal impairment (eg, creatinine clearance less than 35 mL/min) or chronic kidney disease, or if the patient has an osteoporotic fracture or fragility fracture. Treatment of bone loss in patient at high risk for fracture receiving ADT for nonmetastatic prostate cancer, approve if the patient has prostate cancer that is not metastatic to the bone and the patient is receiving ADT (eg, leuprolide, triptorelin, goserelin) or the patient has undergone a bilateral orchiectomy. Treatment of bone loss (to increase bone mass) in patients at high risk for fracture receiving adjuvant AI therapy for breast cancer, approve if the patient has breast cancer that is not metastatic to the bone |

| PA Criteria | Criteria Details |
|-----------------------|--|
| | <p>and in receiving concurrent AI therapy (eg, anastrozole, letrozole, exemestane). 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.</p> |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 | Thrombocytopenia due to chronic ITP or Aplastic Anemia, approve if prescribed by, or after consultation with, a hematologist (initial therapy). Thrombocytopenia in pt with chronic Hep C, approve if 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). |
| Coverage Duration | Chronic ITP/MDS initial-3 mo, cont 1yr, AA-initial-4 mo, cont-1 yr, Thrombo/Hep C-1 yr |
| Other Criteria | Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura, 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 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 to allow for initiation of antiviral therapy 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 microliters) AND tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate mofetil, sirolimus) 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 patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters |

| PA Criteria | Criteria Details |
|-----------------------|---|
| | 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. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Thrombocytopenia in Myelodysplastic Syndrome (MDS) |

PYRIMETHAMINE

Products Affected

- pyrimethamine

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Patient's immune status |
| 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 |

QINLOCK

Products Affected

- Qinlock

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, other therapies tried |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years |
| Other Criteria | Gastrointestinal stromal tumor (GIST), advanced-approve if, according to labeling, the patient has been previously treated with imatinib and at least two other kinase inhibitors, in addition to imatinib. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

REBIF

Products Affected

- Rebif (with albumin)
- Rebif Titration Pack
- Rebif Rebidose subcutaneous pen injector
22 mcg/0.5 mL, 44 mcg/0.5 mL,
8.8mcg/0.2mL-22 mcg/0.5mL (6)

| 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 |

REPATHA

Products Affected

- Repatha
- Repatha Pushtronex
- Repatha SureClick

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Concurrent use of Juxtapid or Praluent. |
| Required Medical Information | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history |
| Age Restrictions | ASCVD/Primary Hyperlipidemia - 18 yo and older, HoFH/HeFH - 10 yo and older. |
| Prescriber Restrictions | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders |
| Coverage Duration | Approve for 3 years for ASCVD/HeFH/HoFH/primary hyperlipidemia. |
| Other Criteria | 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 Crestor 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 Crestor and during both trials the symptoms resolved upon discontinuation. 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, PAD, undergone a coronary or other arterial revascularization procedure, AND 2) tried ONE high intensity statin (defined above) and LDL remains 70 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 500 mg/dL (prior to treatment), OR c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha, Kynamro or Juxtapid), OR d) 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 |

| PA Criteria | Criteria Details |
|-----------------------|---|
| | higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if the patient has tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above). |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

RETEVMO

Products Affected

- Retevmo oral capsule 40 mg, 80 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | Medullary Thyroid Cancer/Thyroid Cancer-12 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years |
| Other Criteria | Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has metastatic disease AND the tumor is RET fusion-positive. Medullary Thyroid Cancer-approve if the patient has advanced or metastatic RET-mutant disease and the disease requires treatment with systemic therapy. Thyroid Cancer-approve if the patient has advanced or metastatic RET fusion positive disease, the disease is radioactive iodine-refractory (if radioactive iodine is appropriate) and the disease requires treatment with systemic therapy. Anaplastic thyroid cancer-approve if the patient has RET fusion-positive anaplastic thyroid carcinoma. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Anaplastic thyroid carcinoma |

REVLIMID

Products Affected

- Revlimid

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis and previous therapies or drug regimens tried. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | Follicular lymphoma-approve if the patient is using Revlimid in combination with rituximab or has tried at least on prior therapy. MCL-approve. MZL-approve. 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]). Diffuse, Large B Cell Lymphoma (Non-Hodgkin's Lymphoma)-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia and the pt has serum erythropoietin levels greater than or equal to 500 mU/ml. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve if the pt has tried at least one other therapy or regimen. CNS cancers (primary)-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical-approve if the patient has relapsed or refractory disease. Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. AIDS Related Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|----------------|---|
| 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 cancer (primary), Acquired immune deficiency syndrome (AIDS)-related Kaposi's sarcoma. |

RILUZOLE

Products Affected

- riluzole

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS. |
| Coverage Duration | 1 year |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

RINVOQ

Products Affected

- Rinvoq

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Concurrent use with a biologic or with a targeted synthetic DMARD. Concurrent use with other potent immunosuppressants. |
| Required Medical Information | Diagnosis, concurrent medications, previous drugs tried. |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | RA, prescribed by or in consultation with a rheumatologist. |
| Coverage Duration | Authorization will be for 3 months initial, 3 years cont. |
| Other Criteria | RA initial-approve if the 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 for RA are not required to step back and try a conventional synthetic DMARD). Continuation Therapy - Patient must have responded, as determined by the prescriber |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ROZLYTREK

Products Affected

- Rozlytrek oral capsule 100 mg, 200 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | Solid Tumors-12 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | <p>Solid Tumors-Approve if the patient meets the following criteria (A, B, and C): A) The patient has locally advanced or metastatic solid tumor AND B) The patient's tumor has neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND C) The patient meets one of the following criteria (i or ii): i. The patient has progressed on prior therapies OR ii. There are no acceptable standard therapies and the medication is used as initial therapy.</p> <p>Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease.</p> |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3years |
| Other Criteria | Ovarian, Fallopian Tube or Primary Peritoneal Cancer-treatment-Approve if the patient meets the following criteria (i and ii): i.The patient has a BRCA-mutation (germline or somatic) as confirmed by an approved test, AND ii.The patient has progressed on two or more prior lines of chemotherapy. Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if the patient is in complete or partial response after at least two platinum-based chemotherapy regimens. Castration-Resistant Prostate Cancer - Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND B) The patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy AND C) The patient has been previously treated with at least one androgen receptor-directed therapy AND D) The patient meets one of the following criteria (i or ii): i. The patient has been previously treated with at least one taxane-based chemotherapy OR ii. The patient is not a candidate or is intolerant to taxane-based chemotherapy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

RYDAPT

Products Affected

- Rydapt

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | For AML, FLT3 status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | AML (for PDP enrollees) -approve if the patient is FLT3-mutation positive as detected by an approved test. AML (for MAPD enrollees) - approve if the patient is FLT3-mutation positive as detected by an approved test AND the patient is receiving Rydapt in one of the following settings (i, ii, iii, or iv)-i. Induction therapy in combination with cytarabine and daunorubicin OR ii. After standard-dose cytarabine induction/reinduction, along with cytarabine and daunorubicin OR iii. Post remission or consolidation therapy in combination with cytarabine OR iv. Maintenance therapy. 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 |

SAMSCA

Products Affected

- Samsca oral tablet 15 mg
- tolvaptan oral tablet 30 mg

| 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 | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 30 days |
| Other Criteria | Hyponatremia - 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 Samsca and has received less than 30 days of therapy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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-Initial-4mo, Cont therapy-1 yr. Pt awaiting surgery or response after radiotherapy-4 mo |
| 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 |

SIRTURO

Products Affected

- Sirturo

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Patients weighing less than 15 kg |
| Required Medical Information | Diagnosis, concomitant therapy |
| Age Restrictions | Patients 5 years of age or older |
| Prescriber Restrictions | Prescribed by, or in consultation with an infectious diseases specialist |
| Coverage Duration | 9 months |
| Other Criteria | Tuberculosis, Pulmonary Multidrug-resistant or extensively drug resistant-prescribed as part of a combination regimen with other anti-tuberculosis agents |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

SKYRIZI

Products Affected

- Skyrizi subcutaneous pen injector
- Skyrizi subcutaneous syringe 150 mg/mL
- Skyrizi subcutaneous syringe kit

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) |
| Required Medical Information | Diagnosis, Previous medication use |
| Age Restrictions | 18 years of age and older (initial therapy) |
| Prescriber Restrictions | PP-Prescribed by or in consultation with a dermatologist (initial therapy) |
| Coverage Duration | 3 mos initial, 3 years cont |
| Other Criteria | Initial Therapy-The patient meets ONE of the following conditions (a or b): a) The patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant. NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (e.g., an adalimumab product [Humira], a certolizumab pegol product [Cimzia], an etanercept product [Enbrel, Erelzi], an infliximab product [e.g., Remicade, Inflectra, Renflexis], Cosentyx [secukinumab SC injection], Ilumya [tildrakizumab SC injection], Siliq [brodalumab SC injection], Stelara [ustekinumab SC injection], Taltz [ixekizumab SC injection], or Tremfya [guselkumab SC injection]). These patients who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional systemic agent for psoriasis)b) The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician.Continuation Therapy - Patient must have responded, as determined by the prescriber. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

SOLARAZE

Products Affected

- diclofenac sodium topical gel 3 %

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 6 months. |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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-approve if patient meets ONE of the following (i, ii, or iii): i. patient has had an inadequate response to surgery and/or radiotherapy OR ii. The patient 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) AND patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal (ULN) based on age and gender for the reporting laboratory. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

SPRYCEL

Products Affected

- Sprycel oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis for which Sprycel is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | For CML, new patient must have Ph-positive CML for approval of Sprycel. For ALL, new patient must have Ph-positive ALL for approval of Sprycel. GIST - has D842V mutation AND previously tried Sutent and Gleevec. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | GIST, chondrosarcoma, chordoma |

STELARA

Products Affected

- Stelara subcutaneous solution
- Stelara subcutaneous syringe 45 mg/0.5 mL, 90 mg/mL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD |
| Required Medical Information | Diagnosis, concurrent medications, previous drugs tried. |
| Age Restrictions | 18 years and older-UC/CD (initial therapy). PP-6 years and older (initial therapy). |
| Prescriber Restrictions | Plaque psoriasis.Prescribed by or in consultation with a dermatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy). |
| Coverage Duration | PP/PsA Init-3mo,CD/UC load-approve 1 dose IV,CD/UC post IV load-SC 3 mo,cont tx-SC 3 yr |
| Other Criteria | PP initial - Approve Stelara SC. CD, induction therapy - approve single dose of IV formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD (eg, azathioprine, 6-MP, MTX, certolizumab, vedolizumab, adalimumab, infliximab). UC, initial therapy-approve SC if the patient received a single IV loading dose within 2 months of initiating therapy with Stelara SC. CD, initial therapy (only after receiving single IV loading dose within 2 months of initiating therapy with Stelara SC) - approve 3 months of the SC formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD. PP/PsA/CD/UC cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | For GIST, patient must have previously been treated with imatinib (Gleevec) and sunitinib (Sutent). For HCC, patient must have previously been treated with at least one tyrosine kinase inhibitor (e.g., Nexavar, Lenvima). Soft tissue sarcoma-approve if the patient has non-adipocytic extremity/superficial trunk, head/neck or retroperitoneal/intra-abdominal sarcoma OR pleomorphic rhabdomyosarcoma. Osteosarcoma-approve if the patient has relapsed/refractory or metastatic disease and the requested medication is being used as subsequent therapy. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Soft tissue Sarcoma, Osteosarcoma |

SUCRAID

Products Affected

- Sucraid

| 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, 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 has a laboratory test demonstrating deficient sucrase or isomaltase activity in duodenal or jejunal biopsy specimens OR patient has a sucrose hydrogen breath test OR has a molecular genetic test demonstrating sucrose-isomaltase mutation in saliva or blood. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

SUTENT

Products Affected

- sunitinib
- Sutent

| 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 3 years. |
| Other Criteria | Gastrointestinal stromal tumors (GIST), approve if the patient has previously tried imatinib (Gleevec). Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried chemotherapy or radiation therapy. Renal Cell Carcinoma (RCC), clear cell or non-clear cell histology-approve if the patient is at high risk of recurrent clear cell RCC following nephrectomy and Sutent is used for adjuvant therapy or if the patient has relapsed or Stage IV disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), differentiated (ie, papillary, follicular, and Hurthle) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma. |

SYMDEKO

Products Affected

- Symdeko

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Patients with unknown CFTR gene mutations, Combination therapy with Orkambi, Kalydeco or Trikafta |
| Required Medical Information | Diagnosis, specific CFTR gene mutations |
| Age Restrictions | Six years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF |
| Coverage Duration | 3 years |
| Other Criteria | CF - must be homozygous for the F508del mutation or have at least one mutation in the CFTR gene that is responsive to the requested medication. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TABRECTA

Products Affected

- Tabrecta

| 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 3 years. |
| Other Criteria | Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has metastatic disease AND the tumor is positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping, as detected by an approved test. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TAFAMIDIS

Products Affected

- Vyndamax
- Vyndaqel

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Concomitant use with Onpattro or Tegsedi. Concurrent use of Vyndaqel and Vyndamax. |
| Required Medical Information | Diagnosis, genetic tests and lab results |
| 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 |

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 | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | 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 disease for one of the following conditions (a, b, or c): a) Low-grade glioma OR b) Anaplastic glioma OR c) Glioblastoma, 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). Histiocytic neoplasm-approve if patient has |

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

TAGRISSO

Products Affected

- Tagrisso

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | NSCLC - prior therapies and EGFR T790M mutation or EGFR exon 19 deletion or exon 21 (L858R) substitution |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | NSCLC - Must have metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC as detected by an approved test AND has progressed on one of the EGFR tyrosine kinase inhibitors (e.g., Tarceva, Iressa, Vizimpro or Gilotrif) therapy OR Advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who have EGFR exon 19 deletion or exon 21 (L858R) substitution as detected by an approved test. NSCLC, EGFR Mutation positive-approve if the medication is used as adjuvant therapy after tumor resection and the tumor is positive for EGFR exon 19 deletions or exon 21 L858R mutations as detected by an approved test. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TALTZ

Products Affected

- Taltz Autoinjector
- Taltz Syringe

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Concurrent use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) |
| Required Medical Information | Diagnosis, Previous medication use |
| Age Restrictions | PP-6 years and older (initial therapy), all other dx-18 years of age and older (initial therapy) |
| Prescriber Restrictions | All dx initial therapy only-PP-Prescribed by or in consultation with a dermatologist. PsA prescribed by or in consultation with a rheumatologist or a dermatologist. AS/spondylo-prescribed by or in consultation with a rheum. |
| Coverage Duration | Initial authorization will be for 3 months, 3 years continuation. |
| Other Criteria | Initial Therapy - Plaque Psoriasis-approve if the patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant OR the patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic. PsA-Approve. AS initial-approve. Non-Radiographic Axial Spondyloarthritis-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory or sacroiliitis reported on magnetic resonance imaging. Continuation Therapy - approve if the patient has responded, as determined by the prescriber. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TALZENNA

Products Affected

- Talzenna oral capsule 0.25 mg, 1 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, BRCA mutation status, HER2 status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Locally-advanced or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive AND human epidermal growth factor receptor 2 (HER2) negative disease |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TARCEVA

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Advanced, recurrent, or metastatic non small cell lung cancer (NSCLC), EGFR mutation or gene amplification status, pancreatic cancer. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | Metastatic NSCLC, approve if the patient meets both of the following: 1. patient is EGFR mutation positive, AND 2. patient has EGFR exon 19 deletions OR exon 21 (L858R) substitution mutations as detected by an FDA-approved test. Advanced RCC, approve if the patient has non-clear cell histology. Bone cancer-chordoma-approve if the patient has tried imatinib, dasatinib or sunitinib. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Renal Cell Carcinoma and Bone Cancer-Chordoma. |

TARGRETIN ORAL

Products Affected

- bexarotene

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, previous therapies tried |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation) |
| Coverage Duration | 3 years |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TARGRETIN TOPICAL

Products Affected

- Targretin topical

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, previous therapies tried |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation) |
| Coverage Duration | 3 years |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TASIGNA

Products Affected

- Tasigna oral capsule 150 mg, 200 mg, 50 mg

| 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 ALL, prior therapies tried. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 months. |
| Other Criteria | For CML, new patient must have Ph-positive CML for approval of Tasigna. For GIST, patient must have tried TWO of the following - sunitinib (Sutent), imatinib (Gleevec), or regorafenib (Stivarga). For ALL, Approve if the patient has tried one other tyrosine kinase inhibitor that is used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc). |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST). |

TAZAROTENE

Products Affected

- tazarotene topical cream
- Tazorac topical gel
- Tazorac topical cream 0.05 %

| 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 | Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene). |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |

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 | 3 years |
| 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 according to the prescriber, there are no appropriate alternative therapies or the patient's tumor is positive for an EZH2 mutation and the patient has tried at least two prior systemic therapies. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TECFIDERA

Products Affected

- dimethyl fumarate oral capsule, delayed release (DR/EC) 120 mg, 120 mg (14)- 240 mg (46), 240 mg
- Tecfidera oral capsule, delayed release (DR/EC) 120 mg, 120 mg (14)- 240 mg (46), 240 mg

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concurrent use with other disease-modifying agents used for multiple sclerosis (MS). |
| Required Medical Information | Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist or MS specialist. |
| Coverage Duration | Authorization will be for 1 year. |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 | 3 years |
| Other Criteria | NSCLC-approve if the patient has metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping alterations. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TERIPARATIDE

Products Affected

- teriparatide

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, calcitonin nasal spray [Fortical], abaloparatide), except calcium and Vitamin D. |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 2 years |
| 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 |

THALOMID

Products Affected

- Thalomid

| 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 3 years. |
| 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). AIDS Related 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, is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8) and has hyaline vascular histology. |
| 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, AIDS related Kaposi's Sarcoma, Castleman's Disease. |

TIBSOVO

Products Affected

- Tibsovo

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, IDH1 Status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| 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 (chemotherapy requirement only applies to beneficiaries enrolled in an MA-PD plan). Chondrosarcoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Cholangiocarcinoma, Chondrosarcoma |

TOLCAPONE

Products Affected

- tolcapone

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, current medications and medication history |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 1 year |
| Other Criteria | Parkinson's disease-approve if the patient is currently receiving carbidopa/levodopa therapy and the patient has tried entacapone and according to the prescriber, experienced unacceptable tolerability or could not achieve adequate benefit |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 |

TOPICAL RETINOID PRODUCTS

Products Affected

- Avita topical cream
- tretinoin topical

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | Coverage is not provided for cosmetic use. |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 months |
| Other Criteria | N/A |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |

TOPIRAMATE/ZONISAMIDE

Products Affected

- topiramate oral capsule, sprinkle
- topiramate oral tablet
- 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 |

TRANSDERMAL FENTANYL

Products Affected

- fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Acute (i.e., non-chronic) pain. |
| Required Medical Information | Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 1 year |
| Other Criteria | For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, sickle cell disease, in hospice or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids (including transdermal fentanyl products) require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TRANSMUCOSAL FENTANYL DRUGS

Products Affected

- fentanyl citrate buccal lozenge on a handle

| 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 |

TRIENTINE

Products Affected

- trientine

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, medication history, pregnancy status, disease manifestations |
| 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 3 years. |
| Other Criteria | For Wilson's Disease, approve if the 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. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

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 | Six years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF |
| Coverage Duration | 3 years |
| Other Criteria | CF - must have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to the requested medication. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TRUSELTIQ

Products Affected

- Truseltiq oral capsule 100 mg/day (100 mg x 1), 50 mg/day (25 mg x 2), 75 mg/day (25 mg x 3), 125 mg/day (100 mg x 1-25mg)

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease, has fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test and Truseltiq will be used as subsequent therapy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TUKYSA

Products Affected

- Tukysa oral tablet 150 mg, 50 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, prior therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | Breast Cancer-approve if the patient has advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

TURALIO

Products Affected

- Turalio

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| 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 |

TYKERB

Products Affected

- lapatinib
- Tykerb

| 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 | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | HER2-positive advanced or metastatic breast cancer, approve if the patient has received prior therapy with trastuzumab and lapatinib will be used in combination with capecitabine OR lapatinib will be used in combination with trastuzumab. HER2-positive HR positive metastatic breast cancer, approve if the patient is a man receiving a GnRH agonist, a premenopausal or perimenopausal woman receiving ovarian suppression/ablation with a GnRH agonist, surgical bilateral oophorectomy or ovarian radiation or a postmenopausal woman and lapatinib will be used in combination with an aromatase inhibitor, that is letrozole (Femara), anastrozole, or exemestane. In this criteria, man/woman is defined as an individual with the biological traits of a man/woman, regardless of the individual's gender identity or expression. 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 the medication is used as subsequent therapy in combination with trastuzumab (the requirement of use in combination with trastuzumab only applies to beneficiaries enrolled in an MA-PD plan) and the patient has not been previously treated with a HER2-inhibitor. Bone Cancer-chordoma-approve if the patient has epidermal growth-factor receptor (EGFR)-positive recurrent disease. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Bone cancer-chordoma, colon or rectal cancer |

UKONIQ

Products Affected

- Ukoniq

| 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 the patient has received at least three prior lines of systemic therapy. Marginal Zone Lymphoma-approve if the patient has received at least one prior anti-CD20-based regimen. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

UPTRAVI

Products Affected

- Uptravi oral

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Confirmation of right heart catheterization, medication history. |
| Age Restrictions | N/A |
| Prescriber Restrictions | PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist. |
| Coverage Duration | 1 year |
| Other Criteria | Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Patient new to therapy must meet a) OR b): a) tried one or is currently taking one oral therapy for PAH for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, or epoprostenol injection). |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

VALCHLOR

Products Affected

- Valchlor

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Cutaneous Lymphomas (Note-includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders)-approve. Adult T-Cell Leukemia/Lymphoma-approve if the patient has chronic/smoldering subtype of adult T-cell leukemia/lymphoma. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Adults with T-cell leukemia/lymphoma |

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 antiepileptic medication(s). |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

VANCOMYCIN

Products Affected

- vancomycin oral capsule 125 mg, 250 mg

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 2 weeks |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

VENCLEXTA

Products Affected

- Venclexta
- Venclexta Starting Pack

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, prior therapy |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | CLL with or without 17p deletion - approve. SLL-approve. Mantle Cell Lymphoma-approve if the patient has tried one prior therapy. AML-approve if the patient is using Venclexta in combination with either azacitidine, decitabine, or cytarabine. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Mantle Cell Lymphoma |

VERZENIO

Products Affected

- Verzenio

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | <p>Breast cancer - approve advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative breast cancer when the pt meets ONE of the following</p> <ol style="list-style-type: none"> 1. Pt is postmenopausal and Verzenio 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 Verzenio will be used in combination with anastrozole, exemestane, or letrozole 3. Patient is postmenopausal and meets the following conditions: Verzenio will be used in combination with fulvestrant. 4. patient is premenopausal or perimenopausal and meets the following conditions: The patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND Verzenio will be used in combination with fulvestrant 5. patient is postmenopausal, premenopausal, /perimenopausal (patient is receiving ovarian suppression/ablation with GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or 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) and meets the following conditions: Verzenio will be used as monotherapy AND patient's breast cancer has progressed on at least one prior endocrine |

| PA Criteria | Criteria Details |
|-----------------------|--|
| | therapy (e.g., anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus everolimus, fulvestrant, everolimus plus fulvestrant or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol) AND patient has tried chemotherapy for metastatic breast cancer. 6. pt is a man who is receiving GnRH analog AND Verzenio with be used in combination with anastrozole, exemestane or letrozole 7. Patient is a man and Verzenio will be used in combination with fulvestrant. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Men with breast cancer |

VITRAKVI

Products Affected

- Vitrakvi oral capsule 100 mg, 25 mg
- Vitrakvi oral solution

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, NTRK gene fusion status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Solid tumors - approve if the tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity AND there are no satisfactory alternative treatments or the patient has disease progression following treatment. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

VIZIMPRO

Products Affected

- Vizimpro

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, EGFR status, exon deletions or substitutions |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Metastatic-NSCLC-Epidermal Growth Factor Receptor (EGFR) mutation positive AND has epidermal growth factor receptor (EGFR) exon 19 deletion as detected by an approved test OR exon 21 (L858R) substitution mutations as detected by an approved test. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

VORICONAZOLE (ORAL)

Products Affected

- voriconazole

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Aspergillus-Prophy, systemic w/risk neutropenia-Prophy, systemic w/HIV-Prophy/Tx-6 mo, others-3 mo |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Aspergillus Infections - prophylaxis, oropharyngeal candidiasis (fluconazole-refractory) - treatment, candidia endophthalmitis - treatment, blastomycosis - treatment, fungal infections (systemic) in patients at risk of neutropenia - prophylaxis, fungal infections (systemic) in patients with human immunodeficiency virus (HIV) - prophylaxis or treatment |

VOTRIENT

Products Affected

- Votrient

| 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 3 years. |
| Other Criteria | Soft tissue sarcoma other than GIST [angiosarcoma, Pleomorphic rhabdomyosarcoma, retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive, soft tissue sarcoma of the extremity/superficial trunk or head/neck, including synovial sarcoma, or solitary fibrous tumor/hemangiopericytoma or alveolar soft part sarcoma], approve. 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, advanced or metastatic disease. Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or stage IV 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 tried TWO of the following: Gleevec, Sutent, or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Differentiated (ie, papillary, follicular, Hurthle cell) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma. |

WELIREG

Products Affected

- Welireg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | 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, and 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 |

XALKORI

Products Affected

- Xalkori

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | ALK status, high level MET amplification status, MET Exon 14 skipping mutation, and ROS1. For soft tissue sarcoma IMT, ALK translocation. |
| Age Restrictions | Anaplastic large cell lymphoma-patients greater than or equal to 1 year of age and less than 21 years of age |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | NSCLC, must be ALK-positive as detected by an approved test, have high level MET amplification, have MET Exon 14 skipping mutation, or have ROS1 rearrangement. Anaplastic Large Cell Lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease AND has received at least one prior systemic treatment . |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Soft tissue sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation, NSCLC with high level MET amplification or MET Exon 14 skipping mutation. |

XELJANZ

Products Affected

- Xeljanz oral solution
- Xeljanz oral tablet
- Xeljanz XR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Concurrent use with a biologic or with a Targeted Synthetic DMARD for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil]. |
| Required Medical Information | Diagnosis, concurrent medications, previous drugs tried. |
| Age Restrictions | N/A |
| Prescriber Restrictions | RA, JIA/JRA prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist. |
| Coverage Duration | PsA/RA/JIA/JRA-3 months initial, UC-16 weeks initial, All diagnoses-3 years cont. |
| Other Criteria | RA/PsA initial, approve Xeljanz/XR if the 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 for RA are not required to step back and try a conventional synthetic DMARD). UC-Approve Xeljanz/XR if the patient has had a trial of at least ONE tumor necrosis factor inhibitor for ulcerative colitis. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthritis/active sacroiliac arthritis]-initial-approve Xeljanz tablets (not the XR formulation) or oral solution if the patient meets ONE of the following: patient has tried one other medication (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID). A previous trial of a biologic also counts as a trial of one medication.) for this condition OR Patient has aggressive disease. Continuation Therapy - Patient must have responded, as determined by the prescriber. |
| Indications | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|----------------|------------------|
| Off-Label Uses | N/A |

XENAZINE

Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| 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 | N/A |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism. |

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 |

XOLAIR

Products Affected

- Xolair subcutaneous recon soln
- Xolair subcutaneous syringe 150 mg/mL, 75 mg/0.5 mL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Concurrent use with an Interleukin (IL) Antagonist Monoclonal Antibody |
| Required Medical Information | Moderate to severe persistent asthma, baseline IgE level of at least 30 IU/mL. For asthma, patient has a baseline positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as an enzyme-linked immunoabsorbant assay (eg, immunoCAP, ELISA) or the RAST) for 1 or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores) and/or for 1 or more seasonal aeroallergens (grass, pollen, weeds). CIU - must have urticaria for more than 6 weeks (prior to treatment with Xolair), with symptoms present more than 3 days/wk despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine). |
| Age Restrictions | Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Polyps-18 years 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 |
| Coverage Duration | asthma/CIU-Initial tx 4 months, Polyps-initial-6 months, continued tx 12 months |
| Other Criteria | Moderate to severe persistent asthma approve if pt meets criteria 1 and 2: 1) pt has received at least 3 months of combination therapy with an inhaled corticosteroid and at least one the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2)patient's asthma is uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy as defined by ONE of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) The patient experienced one or more asthma exacerbation requiring |

| PA Criteria | Criteria Details |
|-----------------------|--|
| | <p>hospitalization or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy NOTE: An exception to the requirement for 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 for at least 3 consecutive months. For continued Tx for asthma - patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For CIU cont tx - must have responded to therapy as determined by the prescribing physician. Nasal Polyps Initial-Approve if the patient has a baseline IgE level greater than or equal to 30 IU/ml, patient is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell and patient is currently receiving therapy with an intranasal corticosteroid. Nasal polyps continuation-approve if the patient continues to receive therapy with an intranasal corticosteroid and has responded to therapy.</p> |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

XOSPATA

Products Affected

- Xospata

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, FLT3-mutation status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | AML - approve if the patient has relapsed or refractory disease AND the disease is FLT3-mutation positive as detected by an approved test. Lymphoid, Myeloid, or Mixed Lineage 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, or Mixed Lineage Neoplasms |

XPOVIO

Products Affected

- Xpovio oral tablet 100 mg/week (50 mg x 1), 60mg twice week (120 mg/week), 80 mg/week (40 mg x 2), 40 mg/week (40 mg x 1), 40mg twice week (40 mg x 2), 60 mg/week (60 mg x 1), 80mg twice week (160 mg/week)

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, prior therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| 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-approve if the patient has been treated with at least two prior systemic therapies. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

XTANDI

Products Affected

- Xtandi oral capsule
- Xtandi oral tablet 40 mg, 80 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis for which Xtandi is being used. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | Prostate cancer-castration-resistant (CRPC) [Metastatic or Non-metastatic] and Prostate cancer-metastatic, castration sensitive-approve if Xtandi will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog or if the patient has had a bilateral orchiectomy. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

XURIDEN

Products Affected

- Xuriden

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, lab results |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a metabolic specialist, geneticist or physician specializing in the condition being treated |
| Coverage Duration | 1 year |
| Other Criteria | Hereditary orotic aciduria (Orotic aciduria Type 1)-Approve if the patient has molecular genetic testing confirming mutation in the UMPS gene or clinical diagnosis supported by first degree family relative (i.e., parent or sibling) with hereditary orotic aciduria and urinary orotic acid level above the normal reference range for the reporting laboratory. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

XYREM

Products Affected

- Xyrem

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Medication history |
| Age Restrictions | N/A |
| 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 - approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dexamethylphenidate, dextroamphetamine), modafinil, or armodafinil 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 |

YONSA

Products Affected

- Yonsa

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, concomitant medications |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Metastatic castration-resistant prostate cancer (mCRPC) - approve if the patient will be using Yonsa in combination with methylprednisolone. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ZEJULA

Products Affected

- Zejula

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| 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. Ovarian, fallopian tube, or primary peritoneal cancer, treatment-approve per label if the patient has tried at least three prior chemotherapy regimens and has homologous recombination deficiency (HRD)-positive disease as confirmed by an approved test. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ZELBORAF

Products Affected

- Zelboraf

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | BRAFV600 mutation status required. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | Melanoma, patient new to therapy must have BRAFV600 mutation for approval AND have unresectable, advanced or metastatic melanoma. HCL - must have relapsed or refractory disease AND tried at least one other therapy for hairy cell leukemia. Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy. Erdheim-Chester disease, in patients with the 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, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma, OR ii. Recurrent disease for one of the following conditions (a, b, or c): a) Low-grade glioma OR b) Anaplastic glioma OR c) 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. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e., |

| PA Criteria | Criteria Details |
|-------------|---|
| | papillary, follicular, or Hurthle cell) with BRAF-positive disease, Central Nervous System Cancer, Histiocytic Neoplasm |

ZIEXTENZO

Products Affected

- Ziextenzo

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | Cancer patients receiving chemotherapy, if 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 is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia 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 the patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Patients undergoing PBPC collection and therapy |

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 | 3 years |
| Other Criteria | Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve. |
| Indications | All FDA-approved Indications. |
| Off-Label Uses | N/A |

ZYDELIG

Products Affected

- Zydelig

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | CLL-approve if the patient has tried two prior therapies. Marginal Zone Lymphoma/Follicular Lymphoma/SLL - approve if the patient has tried two prior therapies. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Marginal Zone Lymphoma |

ZYKADIA

Products Affected

- Zykadia oral tablet

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | Must have metastatic NSCLC that is anaplastic lymphoma kinase (ALK)-positive as detected by an approved test or ROS1 Rearrangement. IMT - ALK Translocation status. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | N/A |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Soft Tissue Sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement-First-line therapy. |

ZYTIGA

Products Affected

- abiraterone oral tablet 250 mg, 500 mg
- Zytiga oral tablet 500 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | Prostate Cancer-Metastatic, Castration-Resistant (mCRPC) and Metastatic, Castration-Sensitive (mCSPC), high risk-Approve if abiraterone is being used in combination with prednisone and the medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog 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 gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron [leuprolide acetate for injection], Lupron Depot [leuprolide acetate for depot suspension], Trelstar [triptorelin pamoate for injectable suspension], Zoladex [goserelin acetate implant], Vantas [histrelin acetate subcutaneous implant], Firmagon) OR ii. Patient has had an orchiectomy. |
| Indications | All FDA-approved Indications, Some Medically-accepted Indications. |
| Off-Label Uses | Prostate Cancer-Regional Risk Group |

PART B VERSUS PART D

Products Affected

- Abelcet
- acetylcysteine
- Actimmune
- acyclovir sodium intravenous solution
- albuterol sulfate inhalation solution for nebulization 0.63 mg/3 mL, 1.25 mg/3 mL, 2.5 mg /3 mL (0.083 %), 2.5 mg/0.5 mL
- AmBisome
- Aminosyn II 15 %
- Aminosyn-PF 7 % (sulfite-free)
- amphotericin B
- aprepitant
- arformoterol
- azathioprine oral tablet 50 mg
- Bethkis
- budesonide inhalation suspension for nebulization 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL
- caspofungin
- Clinimix 5%/D15W Sulfite Free
- Clinimix 4.25%/D10W Sulf Free
- Clinimix 4.25%/D5W Sulfite Free
- Clinimix 5%-D20W(sulfite-free)
- cromolyn inhalation
- cyclophosphamide oral capsule
- cyclophosphamide oral tablet
- cyclosporine modified
- cyclosporine oral capsule
- dronabinol
- Emend oral suspension for reconstitution
- Engerix-B (PF) intramuscular syringe
- Engerix-B Pediatric (PF)
- everolimus (immunosuppressive)
- Firmagon kit w diluent syringe
- formoterol fumarate
- Gengraf
- granisetron HCl oral
- Intralipid intravenous emulsion 20 %
- Intron A injection
- ipratropium bromide inhalation
- ipratropium-albuterol
- levalbuterol HCl
- methotrexate sodium
- methotrexate sodium (PF) injection solution
- methylprednisolone oral tablet
- Millipred oral tablet
- mycophenolate mofetil
- mycophenolate sodium
- ondansetron
- ondansetron HCl oral solution
- ondansetron HCl oral tablet 4 mg, 8 mg
- pentamidine inhalation
- Perforomist
- Plenamine
- Prednisone Intensol
- prednisone oral tablet
- Premasol 10 %
- Prograf oral granules in packet
- Pulmozyme
- Recombivax HB (PF) intramuscular suspension 10 mcg/mL, 40 mcg/mL
- Recombivax HB (PF) intramuscular syringe
- Sandimmune oral solution
- sirolimus
- Synribo
- tacrolimus oral
- tobramycin in 0.225 % NaCl
- tobramycin inhalation
- Travasol 10 %
- Trelstar intramuscular suspension for reconstitution
- TrophAmine 10 %
- Varubi oral
- Xatmep
- Xgeva
- Zortress oral tablet 1 mg

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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