MEDICAL MUTUAL®

# MedMutual Advantage
# Access PPO
# Signature HMO

2022 Prior Authorization Criteria

Updated 11/2022
Index located on page 343

# ACTEMRA

## Products Affected

- Actemra intravenous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or Targeted Synthetic DMARD. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy). |
| **Coverage Duration** | Initial-RA/SJIA, GCA 3 mos, 4 mos PJIA.Cont-RA, SJIA, PJIA, GCA-1 year. CRS-1 week |
| **Other Criteria** | RA, initial-approve if the patient meets ONE of the following criteria: 1) Patient has had a trial with TWO of the following: Enbrel, Humira, Rinvoq, Orencia or Xeljanz. [Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: Cimzia, infliximab, Simponi (IV/SC)]OR 2) According to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder.Systemic-onset JIA, approve for patients who have tried. one other systemic agent for SJIA (eg, a corticosteroid [oral, IV], a conventional synthetic DMARD [eg, MTX, leflunomide, sulfasalazine], or a biologic DMARD [eg, Kineret, a TNF inhibitor such as Enbrel, Humira or Remicade, or Ilaris (canakinumab for SC injection)], or a 1-month trial of a nonsteroidal anti-inflammatory drug [NSAID]). PJIA, initial-approve if the patient has tried TWO of the following: Enbrel, Orencia, Xeljanz or Humira. [Note: if they have had a trial with infliximab in the past it can count towards meeting the try two requirement.] OR if according to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. Cytokine release syndrome associated with chimeric antigen receptor (CAR) T-Cell therapy-approve. Giant cell arteritis, initial-approve if the patient has tried one systemic corticosteroid. Cont tx for RA, SJIA, PJIA, GCA - pt must have had a response as determined by the prescriber. |

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

# 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 only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont) |
| **Coverage Duration** | GCA-6mo initial, 1yr cont.PJIA-4mo initial, 1yr cont. other dx-3mo initial, 1yr cont. Lung dx-1 yr |
| **Other Criteria** | RA initial tx- approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, Humira, Orencia, Rinvoq or Xeljanz/XR (Note: if the patient does not meet this requirement, previous trial(s) with the following drugs will be counted towards meeting the try TWO requirement: Cimzia, infliximab, golimumab SC/IV), OR B) patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, initial tx-approve if the patient meets one of the following (A or B): patient has tried TWO of the following drugs in the past: Enbrel, Orencia, Xeljanz or Humira. (Note: if the patient does not meet this requirement, previous trial with the drug infliximab will be counted towards meeting the try TWO requirement), OR B) according to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx, RA/PJIA - approve if the pt has had a response as determined by the prescriber. Interstitial lung disease associated with systemic sclerosis, initial tx-approve if the patient has elevated acute phase reactants AND the diagnosis is confirmed by high-resolution computed tomography. Cont tx, interstitial lung disease assoc with systemic sclerosis-approve if the patient had adequate efficacy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# ACYCLOVIR (TOPICAL)

## Products Affected

- acyclovir topical ointment

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

# 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 |

# AJOVY

## Products Affected

- Ajovy Autoinjector
- Ajovy 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 one standard prophylactic pharmacologic therapy (e.g., anticonvulsant, beta-blocker) and has had inadequate response 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 |

# ALDURAZYME

## Products Affected

- Aldurazyme

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, genetic and lab test results |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient has a laboratory test demonstrating deficient alpha-L-iduronidase activity in leukocytes, fibroblasts, plasma, or serum OR has a molecular genetic test demonstrating alpha-L-iduronidase gene mutation |
| **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 |

# ALPHA 1 PROTEINASE INHIBITORS

## Products Affected

- Prolastin-C

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Alpha1-Antitrypsin Deficiency with Emphysema (or Chronic Obstructive Pulmonary Disease)-approve if the patient has a baseline (pretreatment) AAT serum concentration of less than 80 mg/dL or 11 micromol/L |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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 |

# 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 1,000 mg/4 mL, 500 mg/2 mL
- ampicillin sodium
- ampicillin-sulbactam
- azithromycin intravenous
- aztreonam
- Bicillin C-R
- Bicillin L-A
- cefoxitin
- cefoxitin in dextrose, iso-osm
- ceftazidime
- cefuroxime sodium injection recon soln 750 mg
- cefuroxime sodium intravenous
- ciprofloxacin in 5 % dextrose
- clindamycin in 5 % dextrose
- clindamycin phosphate injection
- clindamycin phosphate intravenous
- colistin (colistimethate Na)
- Doxy-100
- doxycycline hyclate intravenous
- ertapenem
- 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
- gentamicin sulfate (ped) (PF)
- imipenem-cilastatin
- levofloxacin in D5W
- levofloxacin intravenous
- lincomycin
- linezolid in dextrose 5%
- linezolid-0.9% sodium chloride
- meropenem intravenous recon soln 1 gram, 500 mg
- Metro I.V.
- metronidazole in NaCl (iso-os)
- moxifloxacin-sod.chloride(iso)
- nafcillin in dextrose iso-osm
- nafcillin injection
- nafcillin intravenous recon soln 2 gram
- oxacillin in dextrose(iso-osm)
- oxacillin injection
- penicillin G potassium
- penicillin G procaine
- penicillin G sodium
- Pfizerpen-G
- streptomycin
- sulfamethoxazole-trimethoprim intravenous
- Tazicef
- Teflaro
- tigecycline
- tobramycin sulfate
- vancomycin in 0.9 % sodium chl intravenous piggyback 1 gram/200 mL, 500 mg/100 mL, 750 mg/150 mL
- vancomycin intravenous recon soln 1,000 mg, 10 gram, 5 gram, 500 mg, 750 mg

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

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

# ANTIFUNGALS (IV)

## Products Affected

- Cresemba
- fluconazole in NaCl (iso-osm)
- 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 |

# 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, derm, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis-cardiologist or rheum |
| **Coverage Duration** | CAPS-3 mos initial, 1 yr cont. DIRA-6 mos initial, 1 yr cont. Pericard-3 mos initial, 1 yr cont |
| **Other Criteria** | 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 within the past 3 months after completion of 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 |

# ASPARLAS

## Products Affected

- Asparlas

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 1 month to 21 years |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# AUBAGIO

## Products Affected

- Aubagio

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

# AVONEX

## Products Affected

- Avonex intramuscular pen injector kit
- Avonex intramuscular syringe kit

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

# AYVAKIT

## Products Affected

- Ayvakit

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

# BENLYSTA

## Products Affected

- Benlysta

| 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-1 year. Lupus Nephritis-6 mo initial, 1 year cont |
| **Other Criteria** | Lupus Nephritis Initial-approve if the patient has autoantibody-positive SLE, defined as 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, defined as 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 |

# BESREMI

## Products Affected

- Besremi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with other interferon products |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# BETASERON/EXTAVIA

## Products Affected

- Betaseron subcutaneous kit

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

# BEXAROTENE (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 |

# BLENREP

## Products Affected

- Blenrep

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Per FDA labeling, approve if the patient has tried at least four prior systemic lines of therapy and has received at least one therapy from each of the following drug classes-proteasome inhibitor, immunomodulatory drug, anti-CD38 monoclonal antibody. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# BONIVA INJECTION

## Products Affected

- ibandronate intravenous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other medications for Osteoporosis |
| **Required Medical Information** | Diagnosis, test results |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | Treatment of postmenopausal osteoporosis, must meet ONE of the following 1. T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, or total hip, 2. has had osteoporotic fracture or fragility fracture, 3. had a T-score (current or at any time in the past) between 1.0 and -2.5 at the lumbar spine, femoral neck, or total hip and the physician determines the patient is at high risk for fracture AND has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of bone mineral density (BMD), lack of BMD increase), had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy, or experienced intolerability to an oral bisphosphonate (e.g., severe GI-related adverse effects) OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid) OR the patient has had an osteoporotic fracture or a fragility fracture. |
| **Indications** | All FDA-approved Indications. |

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

# BOSENTAN/AMBRISENTAN

## 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) |

# 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** | 18 years and older |
| **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 |

# BOTOX

## Products Affected

- Botox

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use in the management of cosmetic uses (eg, facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platsymal bands, rejuvenation of the peri-orbital region) |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Migraine headache prevention-prescribed by, or after consultation with, a neurologist or HA specialist. |
| **Coverage Duration** | Authorization will be for 12 months |
| **Other Criteria** | Blepharospasm Associated with Dystonia or Strabismus-approve, Cervical Dystonia-approve, Hyperhidrosis, primary axillary-approve, Chronic low back pain after trial with at least 2 other pharmacologic therapies (eg, NSAID, antispasmodics, muscle relaxants, opioids, antidepressants) and if being used as part of a multimodal therapeutic pain management program. Essential tremor after a trial with at least 1 other pharmacologic therapy (eg, primidone, propranolol, benzodiazepines, gabapentin, topiramate), Migraine Headache Prevention-must have 15 or more migraine headache days per month with headache lasting 4 hours per day or longer (prior to initiation of Botox therapy) AND have tried at least two standard prophylactic pharmacologic therapies, each from a different pharmacologic class (e.g., beta-blocker, anticonvulsant, tricyclic antidepressant) and patient has had inadequate efficacy or adverse events. Overactive bladder with symptoms of urge urinary incontinence, urgency and frequency Urinary incontinence-approve if the patient has tried at least one other pharmacologic therapy. Spasticity, limb-approve. Urinary incontinence associated with a neurological condition-approve if the patient has tried at least one other pharmacologic therapy.Plantar fasciitis-approve if the patient has tried two other treatment modalities. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | Achalasia, Anal Fissure, Chronic facial pain/pain associated with TMJ dysfunction, Chronic low back pain, Dystonia, other than cervical, Essential tremor, Hyperhidrosis, gustatory, hyperhidrosis, Palmar/Plantar and facial, Myofascial pain, Ophthalmic disorders, other than blepharospasm or Strabismus,Plantar fasciitis, Sialorrhea, chronic, Spasticity, other than limb (i.e., due to cerebral palsy, stroke, brain injury, spinal cord injury, MS, hemifacial spasm) |

# 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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II], Prophylaxis, Initial Therapy: approve if the patient has HAE type I or type II confirmed by low levels of functional C1-INH protein (less than 50% of normal) at baseline and lower than normal serum C4 levels at baseline. Patient is currently taking Cinryze for prophylaxis - approve if the patient meets the following criteria (i and ii): i) patient has a diagnosis of HAE type I or II, and ii) according to the prescriber, the patient has had a favorable clinical response since initiating Cinryze as prophylactic therapy compared with baseline. HAE Due to C1-INH Deficiency [Type I or Type II], Treatment of Acute Attacks, Initial Therapy: approve if the patient has HAE type I or type II confirmed by low levels of functional C1-INH protein (less than 50% of normal) at baseline and lower than normal serum C4 levels at baseline. Patient who has treated previous acute HAE attacks with Cinryze: approve if the patient has a diagnosis of HAE Type I or Type II and according to the prescriber, the patient has had a favorable clinical response. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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** | Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). GIST-approve if the patient has previously tried imatinib or avapritinib and has also tried one of the following: sunitinib, regorafinib 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
- Calquence (acalabrutinib mal)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 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
- carglumic acid

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

# 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  Pseudomonas aeruginosa in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture). |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# CEPROTIN

## Products Affected

- Ceprotin (Blue Bar)
- Ceprotin (Green Bar)

| 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 hematologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Protein C Deficiency, Severe-approve if the patient meets the following criteria A, B and C: A) The diagnosis of protein C deficiency is confirmed by at least one of the following (i, ii, or iii): i. Plasma protein C activity below the lower limit of normal based on the age-specific reference range for the reporting laboratory OR ii. Plasma protein C antigen below the lower limit of normal based on the age-specific reference range for the reporting laboratory OR iii. Genetic testing demonstrating biallelic mutations in the PROC gene AND B) Acquired causes of protein C deficiency have been excluded AND C) Patient has a current or prior history of symptoms associated with severe protein C deficiency (e.g., purpura fulminans, thromboembolism). |
| **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 |

# CEREZYME

## Products Affected

- Cerezyme intravenous recon soln 400 unit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, genetic tests and lab results |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Gaucher Disease, Type 1-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation |
| **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 1 year |
| **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 |

# 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 |

# CLOMIPHENE

## Products Affected

- clomiphene citrate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use in patients for infertility |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Woman (a woman 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, Some Medically-accepted Indications. |
| **Off-Label Uses** | Male hypogonadism |

# COMETRIQ

## Products Affected

- Cometriq oral capsule 100 mg/day(80 mg x1-20 mg x1), 140 mg/day(80 mg x1-20 mg x3), 60 mg/day (20 mg x 3/day)

| 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 |

# 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/SLL-approve if the patient has tried two prior therapies |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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 pilocytic astrocytoma or pleomorphic xanthoastrocytoma or ganglioglioma, OR ii) recurrent disease for low-grade glioma or anaplastic glioma or glioblastoma, OR iii) melanoma with brain metastases AND medication will 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: multisystem disease or pulmonary disease or 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, Histocytic Neoplasm |

# CRESEMBA (ORAL)

## Products Affected

- Cresemba

| 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 |

# CRYSVITA

## Products Affected

- Crysvita

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Chronic Kidney Disease (CKD), Severe Renal Impairment or End Stage Renal Disease |
| **Required Medical Information** | Diagnosis, lab values |
| **Age Restrictions** | TIO-2 years and older (initial therapy) |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist or nephrologist (initial therapy) |
| **Coverage Duration** | XLH-1 year (initial/cont), TIO-initial-6 months, cont-1 year |
| **Other Criteria** | XLH-Initial therapy-Approve if the patient has had a baseline (prior to any XLH treatment) serum phosphorus level that was below the normal range for age and patient meets ONE of the following (a or b): a) The patient has had a baseline (i.e., prior to any XLH treatment tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender OR b) The patient has had a genetic test confirming the diagnosis of X-linked hypophosphatemia via identification of a PHEX mutation AND if the patient is greater than or equal to 18 years of age, the patient is currently exhibiting one or more signs or symptoms of XLH. Continuation-approve if the patient is continuing to derive benefit as determined by the prescribing physician. TIO-approve if the patient has a mesenchymal tumor that cannot be curatively resected or identified/localized AND the patient is currently exhibiting one or more signs or symptoms of TIO AND patient has had a baseline (prior to any TIO treatment) serum phosphorus level that was below the normal range for age AND patient has had a baseline (prior to any TIO treatment) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender. Cont-approve if the patient is continuing to derive benefit as determined by the prescribing physician. |
| **Indications** | All FDA-approved Indications. |

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

# CYSTEAMINE (OPHTHALMIC)

## Products Affected

- Cystaran

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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 |

# DALFAMPRIDINE

## Products Affected

- dalfampridine

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older (initial and continuation therapy) |
| **Prescriber Restrictions** | MS. If prescribed by, or in consultation with, a neurologist or MS specialist (initial and continuation). |
| **Coverage Duration** | Initial-4months, Continuation-1 year. |
| **Other Criteria** | Initial-approve if the requested medication is being used to improve or maintain mobility in a patient with MS. Continuation-approve if the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has responded to or is benefiting from therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# DALIRESP

## Products Affected

- Daliresp

| 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 |

# DANYELZA

## Products Affected

- Danyelza

| 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 an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Neuroblastoma-Approve if the requested medication is used as subsequent therapy. |
| **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** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | AML - approve if Daurismo will be used in combination with cytarabine. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Patients continuing Daurismo as post-induction therapy |

# DEFERASIROX

## Products Affected

- deferasirox

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

# DEFERIPRONE

## Products Affected

- deferiprone
- Ferriprox
- Ferriprox (2 times a day)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Serum ferritin level |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias-Initial therapy - approve. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# DIACOMIT

## Products Affected

- Diacomit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Documentation of diagnosis. |
| **Age Restrictions** | 6 months of age 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 weighs at least 7 kg and is concomitantly receiving clobazam. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# DIMETHYL FUMARATE

## Products Affected

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

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

# 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 109/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 100 mg/0.67 mL, 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 months and older, asthma-6 years of age and older, Esophagitis-12 and older, Chronic Rhinosinusitis/Prurigo nodularis-18 and older |
| **Prescriber Restrictions** | Atopic Dermatitis/prurigo nodularis-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist. Esophagitis-presc/consult-allergist or gastro |
| **Coverage Duration** | AD-Init-4mo, Cont-1 yr, asthma/Rhinosinusitis/esophagitis/prurigo nod-init-6 mo, cont 1 yr |
| **Other Criteria** | **Under CMS Review** |

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

# ELAPRASE

## Products Affected

- Elaprase

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, genetic and lab test results |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient has laboratory test demonstrating deficient iduronate-2-sulfatase activity in leukocytes, fibroblasts, serum or plasma OR a molecular genetic test demonstrating iduronate-2-sulfatase gene mutation. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# ELZONRIS

## Products Affected

- Elzonris

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 2 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# EMGALITY

## Products Affected

- Emgality Pen
- EMGALITY SUBCUTANEOUS SYRINGE 120 MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination therapy with Aimovig, Vyepti or Ajovy |
| **Required Medical Information** | Diagnosis, number of migraine or cluster headaches per month, prior therapies tried |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Cluster headache tx-6 months, migraine prevention-1 year |
| **Other Criteria** | Migraine headache prevention-Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least one standard prophylactic pharmacologic therapy (e.g., anticonvulsant, beta-blocker) and has had inadequate response or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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-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-6 mo init, 1 yr cont, Behcet's/uveitis init-6 mo, cont-12 mo.GVHD-3 mo |
| **Other Criteria** | RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic 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 systemic therapy for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID), biologic 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 for psoriasis are not required to step back and try a traditional agent first) |

| PA Criteria | Criteria Details |
|---|---|
| | OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD-approve. 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. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Graft versus host disease (GVHD), Behcet's disease, Uveitis |

# ENTYVIO

## Products Affected

- Entyvio

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with Other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) used for an Inflammatory Condition |
| **Required Medical Information** | N/A |
| **Age Restrictions** | CD/UC - adults (initial therapy) |
| **Prescriber Restrictions** | CD/UC initial - Prescribed by or in consultation with a gastroenterologist. (initial therapy) |
| **Coverage Duration** | CD/UC - initial 14 weeks, cont 1 year |
| **Other Criteria** | CD Initial - the patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient OR the patient has tried one conventional systemic therapy for Crohn's disease (e.g., azathioprine, 6-mercaptopurine, or methotrexate). Note: an exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried a biologic. Cont tx - had a response to Entyvio, as determined by the prescribing physician. UC initial-the patient has had a trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone). NOTE: A trial of a biologic (e.g., an adalimumab product [e.g., Humira], an infliximab product [e.g., Remicade, Inflectra, or Renflexis], or Simponi [golimumab for SC injection]) also counts as a trial of one systemic agent for UC. Cont tx - had a response to Entyvio (for example, decreased stool frequency or rectal bleeding), as determined by the prescribing physician. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# EPCLUSA

## Products Affected

- Epclusa oral pellets in packet 150-37.5 mg, 200-50 mg
- Epclusa oral tablet 200-50 mg, 400-100 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination use with other direct acting antivirals, excluding ribavirin. |
| **Required Medical Information** | 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 year and older (initial therapy) |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist (initial therapy) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Dravet Syndrome-approve if the patient has tried at least two other antiepileptic drugs or if the patient has tried Diacomit, Fintepla or clobazam. Lennox Gastaut Syndrome-approve if the patient has tried at least two other antiepileptics drugs or if the patient has tried one of lamotrigine, topiramate, Banzel, felbamate or clobazam. Tuberous Sclerosis Complex-approve if the patient has tried at least two other antiepileptic drugs. Continuation of therapy-approve if the patient is responding to therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# EPOETIN ALFA

## Products Affected

- Procrit
- 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,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-approve if according to the prescriber the patient has had a response. Anemia in patients with chronic renal failure on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Anemia due to myelodysplastic syndrome (MDS), Myelofibrosis |

# 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 |

# ERLOTINIB

## 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** | Advanced or Metastatic NSCLC, approve if the patient has sensitizing EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note-Examples of sensitizing EGFR mutation-positive non-small cell lung cancer include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. RCC, approve if the patient has recurrent or advanced non-clear cell histology RCC or if the patient had hereditary leiomyomatosis and renal cell carcinoma and erlotinib will be used in combination with bevacizumab. Bone cancer-approve if the patient has chordoma and has tried imatinib, dasatinib or sunitinib. Pancreatic cancer-approve if the medication is used in combination with gemcitabine. Vulvar cancer-approve if the patient has advanced, recurrent or metastatic disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Renal Cell Carcinoma, vulvar cancer and Bone Cancer-Chordoma. |

# ESBRIET

## Products Affected

- Esbriet oral capsule
- Esbriet oral tablet 267 mg, 801 mg
- pirfenidone 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 |

# EVEROLIMUS

## Products Affected

- Afinitor Disperz
- Afinitor oral tablet 10 mg
- everolimus (antineoplastic) oral tablet
- everolimus (antineoplastic) oral tablet for suspension

| 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** | 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 |

| PA Criteria | Criteria Details |
|---|---|
| | 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. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Advanced, unresectable or metastatic neuroendocrine tumors of the thymus (Carcinoid tumors). Soft tissue sarcoma-Perivascular Epitheloid Cell Tumors (PEComa), Recurrent Angiomyolipoma, Lymphangioleiomyomatosis, 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 |

# EXKIVITY

## Products Affected

- Exkivity

| 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** | Non-Small Cell Lung Cancer (NSCLC)-approve if the patient meets (A, B and C): A) Patient has locally advanced or metastatic NSCLC AND B) Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutation, as determined by an approved test AND C) Patient has previously tried at least one platinum-based chemotherapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# EYLEA

## Products Affected

- Eylea

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Administered by or under the supervision of an ophthalmologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# FABRAZYME

## Products Affected

- Fabrazyme

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, genetic and lab test results |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient has a laboratory test demonstrating deficient alpha-galactosidase A activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating mutations in the galactosidase alpha gene. |
| **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 |

# FINTEPLA

## Products Affected

- Fintepla

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 2 years and older (initial therapy) |
| **Prescriber Restrictions** | Prescribed by or in consultation with an neurologist (initial therapy) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Dravet Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex, clobazam or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. Lennox-Gastaut Syndrome, initial-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Lennox-Gastaut Syndrome, continuation-approve if the patient is responding to therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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
- Gattex One-Vial

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 1 year and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist (initial and continuation) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Initial-approve if the patient is currently receiving parenteral nutrition on 3 or more days per week or according to the prescriber, the patient is unable to receive adequate total parenteral nutrition required for caloric needs. Continuation-approve if the patient has experienced 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 advanced or metastatic non small cell lung cancer (NSCLC)-approve if the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: examples of sensitizing EGFR mutation-positive NSCLC include the following mutations : exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. NSCLC metastatic squamous cell must have disease progression with first line treatment with platinum based chemotherapy. Head and neck cancer-approve if the patient has non-nasopharyngeal head and neck cancer and the patient has disease progression on or after platinum based chemotherapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Head and neck cancer |

# GLATIRAMER

## Products Affected

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

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

# 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 1 year |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# GNRH AGONIST IMPLANTS

## Products Affected

- Zoladex

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Endometriosis-18 years and older |
| **Prescriber Restrictions** | Prostate cancer/Breast cancer-prescribed by or in consultation with an oncologist. Endometriosis/abnormal uterine bleeding-prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health. |
| **Coverage Duration** | Abnormal uterine bleeding-2 months, Breast/prostate cancer-1 year, Endometriosis-6 months |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast cancer- Zoladex is used in premenopausal or perimenopausal women. Abnormal uterine bleeding-Zoladex is used as an endometrial-thinning agent prior to endometrial ablation |
| **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)
- Lupron Depot-Ped
- Lupron Depot-Ped (3 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** | uterine leiomyomata 3 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** | 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). 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).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 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 5.pt had a hypophysectomy. Cont-pt responding to therapy |
| **Age Restrictions** | ISS 5 y/o or older, SGA 2 y/o or older, SBS 18 y/o or older |
| **Prescriber Restrictions** | GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, Noonan (initial), Prader Willi (initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist. |
| **Coverage Duration** | ISS - 6 mos initial, 12 months cont tx, SBS-1 month, others 12 mos |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | GHD initial in adults and adolescents 1. endocrine must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, 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. |
| **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 45-200 mg, 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 (initial and continuation), 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 (initial and continuation) |
| **Coverage Duration** | 6 mos initial, 12 mos cont |
| **Other Criteria** | Initial - patient is totally blind with no perception of light, dx of Non-24 is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy plus evaluation of sleep logs. Cont - Approve if patient is totally blind with no perception of light and pt has achieved adequate results with 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 injection
- Diazepam Intensol
- diazepam oral concentrate
- diazepam oral solution
- diazepam oral tablet
- lorazepam injection solution
- lorazepam injection syringe 2 mg/mL
- Lorazepam Intensol
- lorazepam oral concentrate
- 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 10 mg, 5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | Patients aged less than 65 years, approve. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | The physician has assessed risk versus benefit in using this High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# 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
- 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 years and older (initial therapy), PP-18 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 6 mo, cont tx 1 year |
| **Other Criteria** | RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried one other systemic therapy for this condition (e.g MTX, sulfasalazine, leflunomide, NSAID) or biologic (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 |

| PA Criteria | Criteria Details |
|---|---|
| | following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ilecolonic 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. |
| **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 with 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 |

# ICATIBANT

## Products Affected

- icatibant
- Sajazir

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders. |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50% 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 |

# ICLUSIG

## Products Affected

- Iclusig

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 3 years. |
| **Other Criteria** | Approve if the patient meets one of the following: 1. Patient has CML or ALL that is Ph+, T315I-positive or, 2. patient has CML, chronic phase with resistance or intolerance to at least two prior TKIs or, 3. patient has accelerated phase or blast phase CML or Philadelphia chromosome positive ALL for whom no other TKIs are indicated. |
| **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 |

# ILARIS

## Products Affected

- Ilaris (PF)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | When used in combination with concurrent biologic therapy (e.g.TNF antagonists, etanercept, adalimumab, certolizumab pegol, golimumab, infliximab), anakinra, or rilonacept. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | CAPS-4 years of age and older. SJIA-2 years of age and older. Still's disease-18 years and older (Note-patients less than 18 should be referred to criteria for systemic juvenile idiopathic arthritis) |
| **Prescriber Restrictions** | CAPS/MWS/FCAS initial- Prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist. SJIA/Still's disease initial- prescribed by or in consultation with a rheumatologist. FMF initial - rheumatologist, nephrologist, geneticist, gastroenterologist, oncologist, hematologist. HIDS/MKD/TRAPS initial - rheumatologist, nephrologist, geneticist, oncologist, hematologist. |
| **Coverage Duration** | CAPS/SJIA-3 mos ini, 1 yr cont.FMF/HIDS/MKD/TRAPS-4 mos ini, 1yr cont. Still's-3 mo ini, 1 yrcont |
| **Other Criteria** | For renewal of CAPS/MWS/FCAS/SJIA/FMF/HIDS/MKD/TRAPS/Still's - After pt had been started on Ilaris, approve if the pt had a response to therapy as determined by prescribing physician. SJIA, initial therapy - approve if the pt meets one of the following: 1. has tried at least 2 other biologics for SJIA (tocilizumab, abatacet, TNF antagonists (e.g. etanercept, adalimumab, infliximab) OR 2. pt has features of poor prognosis (e.g. arthritis of the hip, radiographic damage, 6-month duration of significant active systemic disease, defined by fever, elevated inflammatory markers, or requirement for treatment with systemic glucocorticoids AND tried Actemra or Kineret OR 3. Pt has features of SJIA with active systemic features with concerns of progression to macrophage activation syndrome (MAS) [as determined by the prescribing physician] AND has tried Kineret. Still's Disease-Initial-approve if the patient has tried at least TWO other biologics or patient has features of poor prognosis and has tried Actemra or Kineret or patient has active systemic features with concerns of |

| PA Criteria | Criteria Details |
|---|---|
| | progression to macrophage activation syndrome (MAS) and has tried Kineret. |
| **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** | ASM, DFSP, HES, MDS/MPD-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | For ALL/CML, must have Ph-positive for approval of imatinib. Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease. Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT)-patient has tried Turalio or according to the prescriber, the patient cannot take Turalio. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Chordoma, advanced, agressive or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor. |

# IMBRUVICA

## Products Affected

- Imbruvica oral capsule 140 mg, 70 mg
- Imbruvica oral suspension
- 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 |

# INFLECTRA

## Products Affected

- Inflectra

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with Biologic DMARD or Targeted Synthetic DMARD. |
| **Required Medical Information** | Diagnosis, concurrent medication, medications previously tried |
| **Age Restrictions** | CD/UC - Pts aged 6 years or more (initial therapy). PP - Pts aged 18 years or more (initial therapy) |
| **Prescriber Restrictions** | All dx initial therapy only-Presc/consult with: RA/AS/Still's disease/JIA/JRA-rheum, Plaque Psoriasis/Pyoderma gangrenosum/Hidradenitis suppurativa-derm, Psoriatic Arthritis-rheum or derm, Crohn's Disease/UC-gastroenterologist, Uveitis ophthalmologist, GVHD-a physician affiliated with a transplant center, oncologist, or hematologist, Behcet's Disease- rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist, Sarcoidosis-pulmonol, ophthalmol, or dermatol. |
| **Coverage Duration** | FDAind ini-3 mo,cont1yr,GVHD ini-1 mo,cont-3 mo,Pyo Gang-ini4 mo,cont1 yr,others-ini 3mo,cont-12 mo |
| **Other Criteria** | RA initial, patient has tried ONE conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). CD approve if the pt has tried corticosteroid (CS) or if CSs contraindicated or if currently on CS or if the patient has tried one other agent for CD OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR the patient has had ileocolonic resection. Ulcerative colitis (UC).Tried one systemic agent or was intolerant to one of these agents OR the patient has pouchitis AND has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Note-a previous trial of a biologic also counts as a trial of one systemic agent for UC. Behcet's.Pt has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa). NOTE: An exception to the requirement for a trial of one |

| PA Criteria | Criteria Details |
|---|---|
| | conventional therapy can be made if the patient has already had a trial of at least one tumor necrosis factor for Behcet's disease. These patients who have already tried a tumor necrosis factor for Behcet's disease are not required to "step back" and try a conventional therapy) OR has ophthalmic manifestations. SD.Tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant.UV.Tried periocular/intraocular CS, systemic CS, immunosuppressant (eg, MTX, MM, CSA, AZA, CPM), etanercept, adalimumab. Sarcoidosis.Tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG).Tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to one of these agents. Hidradenitis suppurativa (HS).Tried 1 tx (eg, intralesional/oral CS, systemic antibiotic, isotretinoin).GVHD.Tried 1 tx (eg, high-dose CS, antithymocyte globulin, CSA, thalidomide, tacrolimus, MM, etc.) or receiving IFX concurrently. JIA (regardless of type of onset) approve if pt has tried 1 other agent for this condition (eg, MTX, sulfasalazine, or leflunomide, an NSAID, or one biologic DMARD [eg, Humira, Orencia, Enbrel, Kineret, Actemra]) or the pt has aggressive disease. PP- approve if the patient has tried at least 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 prescriber. FDA approved indications cont tx - approve if patient has had a response, as determined by the prescriber.Cont tx - approve if patient has had a response, as determined by the prescriber. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Behcet's disease (BD). Still's disease (SD). Uveitis (UV). Pyoderma gangrenosum (PG). Hidradenitis suppurativa (HS). Graft-versus-host disease (GVHD). Juvenile Idiopathic Arthritis (JIA). Sarcoidosis |

# 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. Myeloid/Lymphoid Neoplasms with Eosinophilia-approve if the tumor has a JAK2 rearrangement. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Myeloid/Lymphoid Neoplasms with Eosinophilia |

# 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** | NSCLC-approve if the patient has advanced or metastatic disease and the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. |
| **Indications** | All FDA-approved Indications. |
| **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, GVHD-12 and older, MF/PV/CMML-2/essential thrombo/myeloid/lymphoid neoplasm-18 and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | GVHD-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. Polycythemia vera-approve if the patient has tried hydroxyurea. 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. Essential thrombocythemia-approve if the patient has tried hydroxyurea, peginterferon alfa-2a or anagrelide. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the tumor has a janus associated kinase 2 (JAK2) rearrangement. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms |

# JEMPERLI

## Products Affected

- Jemperli

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Endometrial cancer-approve if the patient has mismatch repair deficient (dMMR) disease and has tried a platinum-containing regimen. Mismatch repair deficient (dMMR) or microsatellite instability high (MSI-H) Solid tumors-approve if the patient has progressed on or after prior treatment and according to the prescriber, the patient does not have any satisfactory alternative treatment options. Small Bowel Adenocarcinoma-approve if the patient has dMMR or MSI-H disease and has advanced or metastatic disease and Jemperli will be used as initial therapy when the patient has received adjuvant oxaliplatin or has a contraindication to oxaliplatin OR Jemperli is used as subsequent therapy and the patient has NOT received oxaliplatin in the adjuvant setting and the patient does NOT have a contraindication to oxaliplatin. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Small Bowel Adenocarcinoma |

# JUXTAPID

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history. |
| **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) and had clinical manifestation of HoFH before the age of 10 years OR both parents of the patient had untreated LDL-C levels or total cholesterol levels consistent with HeFH OR the patient has a treated LDL-C level greater than or equal to 300 mg/dL and had clinical manifestation of HoFH before the age of 10 years OR both parents of the patient had untreated LDL-C levels or total cholesterol levels consistent with HeFH), AND 2) Patient has tried at least one PCSK9 inhibitor for greater than or equal to 8 continuous weeks and the LDL-C level after this PCSK9 inhibitor therapy remains greater than or equal to 70 mg/dL 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 after these treatment regimens remains greater than or equal to 70 mg/dL OR the patient has been determined to be statin intolerant defined by experiencing statin related |

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

# KADCYLA

## Products Affected

- Kadcyla

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist. |
| **Coverage Duration** | Breast Cancer-Recurrent/metastatic-1 yr, Breast Cancer-Adjuvant tx-approve 1 yr total, other-1yr |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast Cancer-approve if the patient has human epidermal growth factor receptor 2 (HER2)-positive disease and the patient is using for recurrent or metastatic breast cancer OR if using for adjuvant therapy. NSCLC-approve if the patient has human epidermal growth factor receptor 2 (HER2) mutation-positive NSCLC. Salivary gland tumor-approve if the patient has recurrent, unresectable, or metastatic disease and the patient has human epidermal growth factor receptor 2 (HER2)-positive disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Non-small cell lung cancer (NSCLC), Salivary gland tumor |

# 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 |

# KANUMA

## Products Affected

- Kanuma

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, genetic and lab test results |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient has a laboratory test demonstrating deficient lysosomal acid lipase activity in leukocytes, fibroblasts, or liver tissue OR a molecular genetic test demonstrating lysosomal acid lipase gene mutation. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# KERENDIA

## Products Affected

- Kerendia

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with spironolactone or eplerenone |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older (initial and continuation therapy) |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Diabetic kidney disease, initial-approve if the patient meets the following criteria (i, ii, and iii): i. Patient has a diagnosis of type 2 diabetes, AND ii. Patient meets one of the following (a or b): a)Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b)According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy, AND iii.At baseline (prior to the initiation of Kerendia), patient meets all of the following (a, b, and c): a)Estimated glomerular filtration rate greater than or equal to 25 mL/min/1.73 m2 AND b)Urine albumin-to-creatinine ratio greater than or equal to 30 mg/g AND c)Serum potassium level less than or equal to 5.0 mEq/L. Diabetic kidney disease, continuation-approve if the patient meets the following criteria (i and ii): i.Patient has a diagnosis of type 2 diabetes, AND ii. Patient meets one of the following (a or b): a.Patient is currently receiving a maximally tolerated labeled doseage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b.According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# KEYTRUDA

## Products Affected

- Keytruda

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist. |
| **Coverage Duration** | Adjuvant treatment of melanoma-approve up to 1 year total, all other dx-1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | adrenal gland tumor, anal carcinoma, extranodal NK/T-Cell Lymphoma, nasal type, Gestational trophoblastic neoplasia, malignant pleural mesothelioma, mycosis fungoides/Sezary syndrome, soft tissue sarcoma, squamous cell skin cancer, thymic carcinoma, vulvar cancer |

# KIMMTRAK

## Products Affected

- Kimmtrak

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Uveal melanoma-approve if the patient has unresectable or metastatic disease and if the tumor is HLA-A*02:01 positive. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# KISQALI

## Products Affected

- Kisqali Femara Co-Pack oral tablet 200 mg/day(200 mg x 1)-2.5 mg, 400 mg/day(200 mg x 2)-2.5 mg, 600 mg/day(200 mg x 3)-2.5 mg
- Kisqali oral tablet 200 mg/day (200 mg x 1), 400 mg/day (200 mg x 2), 600 mg/day (200 mg x 3)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | 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 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 with be used in combination with anastrozole, exemestane or letrozole. 4. Patient is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and Kisqali (not Co-Pack) will be used in combination with fulvestrant. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane or letrozole. Patients must have a trial of Ibrance or Verzenio prior to approval of Kisqali/Kisqali Femara Co-Pack unless the patient meets one |

| PA Criteria | Criteria Details |
|---|---|
| | 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 combination with fulvestrant in postmenopausal female or male patients as initial endocrine-based therapy |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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** | Endogenous Cushing's Syndrome-1 yr. Patients awaiting surgery or response after radiotherapy-4 mo |
| **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 |

# 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 and experienced intolerance or inadequate efficacy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# LAPATINIB

## Products Affected

- lapatinib

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis for which lapatinib is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status. |
| **Age Restrictions** | 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 |

# LEMTRADA

## Products Affected

- Lemtrada

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Current Use of Lemtrada with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS). Patients with HIV infection. |
| **Required Medical Information** | Diagnosis, Previous medication use |
| **Age Restrictions** | MS - 17 years of age and older (initial and continuation) |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS (initial and continuation) |
| **Coverage Duration** | MS, has not completed 1 course of Lemtrada-5 days.MS, has completed prior course Lemtrada-3 days |
| **Other Criteria** | MS pts who have not completed a course of Lemtrada tx (including pt who started but not completed Lemtrada tx) - patient must have had an inadequate response or was unable to tolerate according to the prescribing physician TWO disease modifying agents used for MS or according to the prescribing physician the patient has a highly-active or aggressive multiple sclerosis by meeting one of the following-the patient has demonstrated rapidly-advancing deterioration(s) in physical functioning (e.g., loss of mobility/or lower levels of ambulation, severe changes in strength or coordination OR disabling relapse(s) with suboptimal response to systemic corticosteroids OR magnetic resonance imaging (MRI) findings suggest highly-active or aggressive multiple sclerosis (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium lesions) OR manifestation of multiple sclerosis-related cognitive impairment. MS patients who already completed a prior course of Lemtrada tx - Approve if at least 12 months has elapsed from the last dose of any prior Lemtrada treatment course for relapsing MS. |
| **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** | DTC - must be refractory to radioactive iodine treatment for approval. RCC, advanced disease - approve if the pt meets i or ii:i. Lenvima is is being used in combination with pembrolizumab OR ii. Lenvima is used in combination with everolimus and the patient meets a or b - a. Patient has clear cell histology and patient has tried one antiangiogenic therapy or b. patient has non-clear cell histology. 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. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Patients with Medullary Thyroid Carcinoma (MTC) and anaplastic thyroid carcinoma. |

# 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 |

# LIBTAYO

## Products Affected

- Libtayo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, previous surgeries or radiation |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Locally advanced or metastatic CSCC-approve if the patient is not a candidate for curative surgery or curative radiation. Basal Cell Carcinoma-approve if the patient has locally advanced or metastatic disease and has received previous treatment with at least one hedgehog pathway inhibitor or a hedgehog pathway inhibitor is not an appropriate therapy for the patient. NSCLC-approve if the patient has locally advanced disease and is not eligible for surgical resection or chemoradiation or if the patient has metastatic disease, the tumor proportion score (TPS) for programmed death ligand-1 (PD-L1) as determined by an approved test is greater than or equal to 50 percent AND the tumor is negative for actionable mutations. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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

- hydromorphone oral tablet extended release 24 hr
- Methadone Intensol
- methadone oral concentrate
- methadone oral solution 10 mg/5 mL, 5 mg/5 mL
- methadone oral tablet 10 mg, 5 mg
- Methadose oral concentrate
- 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** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | NSCLC - Approve if the patient has ALK-positive metastatic NSCLC, as detected by an approved test. NSCLC-ROS1 Rearrangement-Positive- approve if the patient has tried at least 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 |

# LOTRONEX

## Products Affected

- alosetron

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# LUCENTIS

## Products Affected

- Lucentis intravitreal solution 0.3 mg/0.05 mL
- Lucentis intravitreal syringe

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Administered by or under the supervision of an ophthalmologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Retinopathy of prematurity |

# LUMAKRAS

## Products Affected

- Lumakras

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 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 |

# LUMIZYME

## Products Affected

- Lumizyme

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, genetic and lab test results |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a geneticist, neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient has a laboratory test demonstrating deficient acid alpha-glucosidase activity in blood, fibroblasts, or muscle tissue OR patient has a molecular genetic test demonstrating acid alpha-glucosidase gene mutation. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# LUMOXITI

## Products Affected

- Lumoxiti

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Creatinine clearance less than 30 ml/min |
| **Required Medical Information** | Diagnosis, previous therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. HCL-approve if the patient has tried at least two prior systemic therapies including therapy with a purine analog (cladribine and/or pentostatin). |
| **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** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Ovarian Cancer-Treatment-initial-Approve if pt meets the following criteria (i and ii): i.pt 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. Cont-approve if pt has a BRCA mutation (germline) as confirmed by an approved test. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if pt meets one of the following criteria (A or B): A)pt meets both of the following criteria for first-line maintenance therapy (i and ii): i.pt has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND ii.pt 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)pt 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, combination therapy-approve if the medication is used in combination with bevacizumab, the patient has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and the patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast Cancer-Approve if the pt meets the following criteria (A, B and C)-A.pt has metastatic, germline BRCA mutation-positive breast cancer AND B.pt |

| PA Criteria | Criteria Details |
|---|---|
| | meets ONE of the following criteria (i or ii)- i. pt meets BOTH of the following criteria (a and b)-a)pt has hormone receptor positive (HR+) [i.e., estrogen receptor positive ER+ and/or progesterone receptor positive PR+] disease AND b)pt meets ONE of the following criteria (1 or 2)-1-pt has been treated with prior endocrine therapy OR-2 pt is considered inappropriate for endocrine therapy OR ii. Pt has triple negative disease (i.e., ER-negative, PR-negative, and HER2-negative) AND C.pt 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 the pt has metastatic disease, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or the pateint has had a bilateral orchiectomy, the patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test, the pt does not have a PPP2R2A mutation and the patient has been previously treated with at least one androgen receptor directed therapy. Uterine Leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Uterine Leiomyosarcoma |

# MARGENZA

## Products Affected

- Margenza

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast Cancer-approve if the patient meets A, B, C and D: A) Patient has metastatic human epidermal growth factor receptor 2 (HER2)-positive disease AND B) Patient has tried at least two prior anti-HER2 regimens AND C) At least one of the prior anti-HER2 regimen was used for metastatic disease AND D) The medication is used in combination with chemotherapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# MEGACE

## Products Affected

- megestrol oral suspension 400 mg/10 mL (10 mL), 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 Tafinlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafinlar, 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 positive disease and the medication will be taken in combination with Tafinlar. 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: pilocytic astrocytoma or pleomorphic xanthoastrocytoma or ganglioglioma, OR ii) recurrent disease for one of the following conditions: low-grade glioma OR anaplastic glioma OR glioblastoma, OR iii) melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Tafinlar (dabrafenib). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the |

| PA Criteria | Criteria Details |
|---|---|
| | following: multisystem disease or pulmonary disease or central nervous system lesions or patient has Erdheim Chester disease or Rosai-Dorfman disease AND patient has BRAF V600-mutation positive disease. Metastatic or Solid Tumors-Approve if the patient meets the following (A, B, and C): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafinlar (dabrafenib capsules), AND C) Patient has no satisfactory alternative treatment options. |
| **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. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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. |

# MEPSEVII

## Products Affected

- Mepsevii

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

# METHYLERGONOVINE

## Products Affected

- Methergine
- methylergonovine oral

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 7 days |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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 |

# MODAFINIL/ARMODAFINIL

## Products Affected

- armodafinil
- modafinil

| 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. |

# MONJUVI

## Products Affected

- Monjuvi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-Cell Lymphoma - Approve if the patient meets one of the following criteria (A or B): A) Patient has been treated with at least one prior chemotherapy regimen AND the patient is not eligible for autologous stem cell transplant AND Monjuvi will be used in combination with Revlimid (lenalidomide) OR B) Patient has already received 12 cycles of Monjuvi |
| **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 x 109/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 1 year |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# NAGLAZYME

## Products Affected

- Naglazyme

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, genetic and lab test results |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient has a laboratory test demonstrating deficient N-acetylgalactosamine 4-sulfatase (arylsulfatase B) activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating arylsulfatase B gene mutation. |
| **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, recurrent or metastatic disease-approve if the patient has HER-2 positive breast cancer, Nerlynx will be used in combination with capecitabine and the patient has tried at least two prior anti-HER2 based regimens. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# NEXAVAR

## Products Affected

- Nexavar
- sorafenib

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 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 sorafenib 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** | 18 years and older |
| **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 |

# NITISINONE

## Products Affected

- nitisinone

| 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** | chemo/SCN/AML-6mo.HIV/AIDS-4mo.MDS-3mo.PBPC,Drug induce A/N,AA,ALL,BMT-3 mo.Radi-1mo, 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/mm3], 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
- 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

| 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. Prostate cancer-metastatic, castration sensitive-approve if the medication is used in combination with docetaxel and the medication will be used in combination with a GnRH agonist or in combination with Firmagon or if the patient 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

| 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 |

# 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 |

# OCREVUS

## Products Affected

- Ocrevus

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other Disease-Modifying Agents used for MS |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with, a physician who specializes in the treatment of MS and/or a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# OCTREOTIDE INJECTABLE

## Products Affected

- octreotide acetate

| 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 Medically-accepted 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 |

# OPDIVO

## Products Affected

- Opdivo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | cHL, mesothelioma, NSCLC- 18 years of age or older, colon/rectal-12 years and older, pediatric hodgkin lymphoma-less than 18 years old |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist. |
| **Coverage Duration** | Adjuvant treatment of melanoma-approve up to 1 year total, all other dx-1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | anal carcinoma, endometrial carcinoma, extranodal NK/T-Cell Lymphoma, nasal type, gestational trophoblastic neoplasia, merkel cell carcinoma, pediatric hodgkin lymphoma, small bowel adenocarcinoma, vulvar cancer |

# OPDUALAG

## Products Affected

- Opdualag

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 12 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Melanoma-approve if the patient is greater than or equal to 40 kg and if the patient has unresectable or metastatic disease. |
| **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

- Orencia (with maltose)
- Orencia ClickJect
- Orencia subcutaneous syringe 125 mg/mL, 50 mg/0.4 mL, 87.5 mg/0.7 mL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried. |
| **Age Restrictions** | 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-6 mos initial, 1 year 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)], initial - approve if the patient has tried one other agent for this condition or the patient will be starting on Orencia 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. PsA, initial - approve. 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** | 1 year of age and older |
| **Prescriber Restrictions** | prescribed by or in consultation with a pulmonologist or a physician who specializes in CF |
| **Coverage Duration** | 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** | 6 months initial, 1 year 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 |

# PADCEV

## Products Affected

- Padcev

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Urothelial carcinoma-approve if the patient has locally advanced or metastatic disease and has tried at least one other systemic therapy. |
| **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** | Combination use with sapropterin (continuation therapy) |
| **Required Medical Information** | Diagnosis, phenylalanine concentrations |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases |
| **Coverage Duration** | 1 year (initial and continuation) |
| **Other Criteria** | Initial therapy - approve if the patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., prior treatment with Kuvan). Maintenance therapy - approve if the patient has had a response to therapy. |
| **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-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. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia, the cancer has fibroblast growth factor receptor 1 (FGFR1) rearrangement, as detected by an approved test, and the cancer is in chronic phase or blast phase. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# PENICILLAMINE

## Products Affected

- penicillamine oral tablet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Wilson's Disease-Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant physician |
| **Coverage Duration** | 1 year |
| **Other Criteria** | N/A |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# PHENYLBUTYRATE

## 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

- metyrosine

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

# PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

## Products Affected

- Alyq
- sildenafil (Pulmonary Arterial Hypertension) intravenous solution 10 mg/12.5 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 or has had surgical bilateral oophorectomy or ovarian irradiation AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene) 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 intramuscular
- Plegridy subcutaneous pen injector 125 mcg/0.5 mL, 63 mcg/0.5 mL- 94 mcg/0.5 mL
- Plegridy subcutaneous syringe 125 mcg/0.5 mL, 63 mcg/0.5 mL- 94 mcg/0.5 mL

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

# POLIVY

## Products Affected

- Polivy

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-cell lymphoma/B-Cell Lymphoma-Approve if the patient has been treated with at least one prior chemotherapy regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | B-Cell Lymphoma |

# POMALYST

## Products Affected

- Pomalyst

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Kaposi Sarcoma/MM-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 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. MM-approve if the patient has received at least one other Revlimid (lenalidomide tablets)-containing regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Systemic Light Chain Amyloidosis, Central Nervous System (CNS) Lymphoma |

# POSACONAZOLE (ORAL)

## Products Affected

- Noxafil oral suspension
- posaconazole

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

# POTELIGEO

## Products Affected

- Poteligeo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Mycosis fungoides/Sezary-prescribed by, or in consultation with an oncologist or dermatologist. ATLL-prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Mycosis Fungoides/Sezary Syndrome-Approve. ATLL-patient has relapsed or refractory disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Adults with T-cell leukemia/lymphoma (ATLL) |

# PROLIA

## Products Affected

- Prolia

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with other medications for osteoporosis |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 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 and in receiving concurrent AI therapy (eg, anastrozole, letrozole, |

| PA Criteria | Criteria Details |
|---|---|
| | 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. |
| **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** | Immune Thrombocytopenia 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** | Immune thrombo/MDS initial-3 mo, cont 1yr, AA-initial-4 mo, cont-1 yr, Thrombo/Hep C-1 yr |
| **Other Criteria** | Thrombocytopenia in patients with immune thrombocytopenia, initial-approve if the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and the patient is at an increased risk for bleeding AND the patient has tried ONE other therapy 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 moefetil, 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 and is at an increased risk |

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

# RADICAVA

## Products Affected

- Radicava

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | ALSFRS-R score, FVC %, time elapsed since 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 (initial and continuation). |
| **Coverage Duration** | Initial, 6 months. Continuation, 6 months |
| **Other Criteria** | ALS, initial therapy - approve if the patient meets ALL of the following criteria: 1. According to the prescribing physician, the patient has a definite or probable diagnosis of ALS, AND 2. Patient has a score of two points or more on each item of the ALS Functional Rating Scale - Revised (ALSFRS-R) [ie, has retained most or all activities of daily living], AND 3. Patient has a FVC greater than or equal to 80% (ie, normal respiratory function), AND 4. Patient has been diagnosed with ALS for less than or equal to 2 years. ALS, continuation therapy - approve if, according to the prescribing physician, the patient continues to benefit from therapy AND the patient is not requiring invasive ventilation. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# RECLAST

## Products Affected

- zoledronic acid-mannitol-water intravenous piggyback 5 mg/100 mL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with Other Medications for Osteoporosis (e.g., other bisphosphonates, Evenity, Prolia, Forteo/Bonsity, Tymlos, calcitonin nasal spray) |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Paget's 1 month. Others 12 months. |
| **Other Criteria** | Tx of osteo in post menopausal pt or osteo in men (a man defined as an individual with biological traits of man, regardless of the individual's gender identity/gender expression), must meet ONE of the following: pt had inadequate response after 12 mo (eg,ongoing and sign loss of BMD, lack of BMD increase) or pt had osteo fracture or fragility fracture while receiving therapy or pt experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because pt cannot swallow or has difficulty swallowing or pt cannot remain in upright position post oral bisphos admin or pt has pre-existing GI condition (eg, pt with esophageal lesions/ulcers, or abnormal of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt had an osteo fracture or a fragility fracture OR pt has tried IV Reclast (zoledronic acid). Tx of PMO may have also tried IV Boniva (ibandronate) for approval. Prevent or tx of GIO, approve if: pt is initiating or cont therapy with systemic glucocorticoids, AND had an inadequate response after 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had an osteo fracture or fragility fracture while on therapy or pt experienced intol (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because pt cannot |

| PA Criteria | Criteria Details |
|---|---|
| | swallow or has difficulty swallowing or pt cannot remain in an upright position post oral bisphos 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 has tried Reclast OR patient had an osteo fracture or a fragility fracture. Tx of Paget's disease, approve if pt has elevations in serum alkaline phos of two times higher than the upper limit of the age-specific normal reference range, OR pt is symptomatic (eg,bone pain, hearing loss, osteoarthritis), OR pt is at risk for complications from their disease (eg,immobilization, bone deformity, fractures, nerve compression syndrome). Prevent of PMO - meets 1 of the following had inadequate response after trial duration of 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had osteo fracture or fragility fracture while receiving therapy or patient experienced intol (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphos admin or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions/ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried Reclast or the patient has had an osteo fracture or fragility fracture. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# REMICADE

## Products Affected

- Remicade

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with Biologic DMARD or Targeted Synthetic DMARD |
| **Required Medical Information** | Diagnosis, concurrent medication, previous medications tried |
| **Age Restrictions** | CD and UC, Pts aged 6 years or more (initial therapy). PP-18 years and older (initial therapy) |
| **Prescriber Restrictions** | All dx-initial therapy only-Prescribed by or in consult w/RA/AS/Still's/JIA-rheumatol.Plaque Psor/Pyoderma gangrenosum/HS-dermatol.Psoriatic Arthritis-rheumatol or dermatol.CD/UC-gastroenterol.Uveitis-ophthalmol.GVHD-transplant center, oncol, or hematol.Behcet's-rheumatol, dermatol,ophthalmol, gastroenterol, or neurol.Sarcoidosis-pulmonol, ophthalmol, or dermatol. |
| **Coverage Duration** | FDAind ini-3 mo,cont1yr,GVHD ini-1 mo,cont-3 mo,Pyo Gang-ini4 mo,cont1 yr,others-ini 3mo,cont-12 mo |
| **Other Criteria** | RA initial, patient has tried ONE conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). CD approve if the pt has tried corticosteroid (CS) or if CSs contraindicated or if currently on CS or if the patient has tried one other agent for CD OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR the patient has had ileocolonic resection. Ulcerative colitis (UC).Tried one systemic agent or was intolerant to one of these agents OR the patient has pouchitis AND has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Note-a previous trial of a biologic also counts as a trial of one systemic agent for UC. Behcet's.Pt has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa). NOTE: An exception to the requirement for a trial of one conventional therapy can be made if the patient has already had a trial of at least one tumor necrosis factor for Behcet's disease. These patients who |

| PA Criteria | Criteria Details |
|---|---|
| | have already tried a biologic for Behcet's disease are not required to "step back" and try a conventional therapy) OR has ophthalmic manifestations. SD.Tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant.UV.Tried periocular/intraocular CS, systemic CS, immunosuppressant (eg, MTX, MM, CSA, AZA, CPM), etanercept, adalimumab. Sarcoidosis.Tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG).Tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to one of these agents. Hidradenitis suppurativa (HS).Tried 1 tx (eg, intralesional/oral CS, systemic antibiotic, isotretinoin).GVHD.Tried one conventional systemic treatment (eg, high-dose CS, antithymocyte globulin, CSA, thalidomide, tacrolimus, MM, etc.). JIA (regardless of type of onset) approve if pt has tried 1 other agent for this condition (eg, MTX, sulfasalazine, or leflunomide, an NSAID, or one biologic DMARD [eg, Humira, Orencia, Enbrel, Kineret, Actemra]) or the pt has aggressive disease. PP- approve if the patient has tried at least 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 prescriber. FDA approved indications cont tx - approve if patient has had a response, as determined by the prescriber. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Behcet's disease (BD). Still's disease (SD). Uveitis (UV). Pyoderma gangrenosum (PG). Hidradenitis suppurativa (HS). Graft-versus-host disease (GVHD). Juvenile Idiopathic Arthritis (JIA). Sarcoidosis |

# REMODULIN

## Products Affected

- treprostinil sodium

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | PAH WHO group, right heart catheterization results, WHO functional status, previous drugs tried |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH WHO Group 1, prescribed by or in consultation with a cardiologist or a pulmonologist. |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. PAH WHO Group 1, initial-pt required to have had a right-heart catheterization to confirm the diagnosis of WHO Group 1 PAH AND have Class III or IV functional status or if functional class II must have tried or is currently receiving one oral agent for PAH or patient has tried one inhaled or parenteral prostacyclin product for PAH.If pt has idiopathic PAH, they must have one of the following: 1. had an acute response to vasodilator testing that occurred during the right heart cath AND has tried an oral CCB or 2. pt did not have an acute response to vasodilator testing or 3. cannot undergo vasodilator test or cannot take CCB or 4. has tried a CCB. Continuation-pt required to have had a right heart catheterization to confirm the diagnosis of WHO Group 1PAH. |
| **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 1 year |
| **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 rosuvastatin greater than or equal to 20 mg daily) and LDL remains 70 mg/dL or higher unless pt is statin intolerant defined by experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the symptoms resolved upon discontinuation. 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, all others 18 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. Solid tumors-approve if the patient has recurrent, advanced or metastatic disease and the tumor is rearranged during transfection (RET) fusion-positive. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Anaplastic thyroid carcinome |

# REVCOVI

## Products Affected

- Revcovi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, lab values, genetic tests |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with, an immunologist, hematologist/oncologist, or physician that specializes in ADA-SCID or related disorders. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | ADA-SCID - approve if the patient had absent or very low (less than 1% of normal) ADA catalytic activity at baseline (i.e., prior to initiating enzyme replacement therapy) OR if the patient had molecular genetic testing confirming bi-allelic mutations in the ADA gene |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# REVLIMID

## Products Affected

- lenalidomide
- Revlimid

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis and previous therapies or drug regimens tried. |
| **Age Restrictions** | 18 years and older (except Kaposi's Sarcoma, Castleman's Disease, CNS Lymphoma) |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 3 years. |
| **Other Criteria** | Follicular lymphoma-approve if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least on prior therapy. MCL-approve -if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least two other therapies or therapeutic regimens. MZL-approve if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least one other therapy or therapeutic regimen. Multiple myeloma-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). B-cell-lymphoma (other)-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia and the pt has serum erythropoietin levels greater than or equal to 500 mU/mL or according to the prescriber the patient has anemia, has serum erythropoietin levels less than 500 mU/mL and patient has experienced no response or loss of response to erythropoietic stimulating agents. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve if the pt has tried at least one other therapy or regimen. CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical- |

| PA Criteria | Criteria Details |
|---|---|
| | approve if the patient has tried at least one other therapy or therapeutic regimen. Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. Systemic light chain amyloidosis-approve if lenalidomide (brand or generic) is used in combination with dexamethasone. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma, Central nervous system lymphoma, Kaposi's sarcoma. |

# 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 oral tablet extended release 24 hr
  15 mg, 30 mg, 45 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with a biologic or with a targeted synthetic DMARD. Concurrent use with other potent immunosuppressants. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried. |
| **Age Restrictions** | PsA/RA/UC/AS-18 years and older (initial therapy), AD-12 years and older (Initial therapy) |
| **Prescriber Restrictions** | RA/AS, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescr/consult with allergist, immunologist or derm. UC-prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | Authorization will be for 6 months initial, 1 year cont. |
| **Other Criteria** | RA/PsA/UC/AS initial-approve if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AD-approve if the patient has had a 3 month trial of at least one traditional systemic therapy or has tried at least one traditional systemic therapy but was unable to tolerate a 3 month trial. Note: Examples of traditional systemic therapies include methotrexate, azathioprine, cyclosporine, and mycophenolate mofetil. A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to step back and try a traditional systemic agent for atopic dermatitis. 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** | 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. Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease. |
| **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** | 18 years and older |
| **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 |

# RUFINAMIDE

## Products Affected

- rufinamide

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patients 1 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Initial therapy-approve if rufinamide is being used for adjunctive treatment. Continuation-approve if the patient is responding to therapy |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Treatment-Refractory Seizures/Epilepsy |

# RUXIENCE

## Products Affected

- Ruxience

| 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** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# RYBREVANT

## Products Affected

- Rybrevant

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Non-Small Cell Lung Cancer (NSCLC) - approve if the has epidermal growth factor receptor exon 20 insertion mutations, as detected by an approved test AND has progressed on or following treatment with platinum-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** | 18 years and older |
| **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 Neopasms 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 |

# RYLAZE

## Products Affected

- Rylaze

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Acute lymphoblastic leukemia/lymphoblastic lymphoma - approve if the patient has a systemic allergic reaction or anaphylaxis to a pegylated asparaginase product. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# SANDOSTATIN LAR

## Products Affected

- Sandostatin LAR Depot intramuscular suspension,extended rel recon

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

# SAPROPTERIN

## Products Affected

- 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 |

# SARCLISA

## Products Affected

- Sarclisa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, other therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Multiple myeloma-approve if the requested medication will be used in combination with Pomalyst and dexamethasone and the patient has tried at least TWO prior regimens for multiple myeloma and a proteasome inhibitor was a component of at least one previous regimen and Revlimid was a component of at least one previous regimen. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# SCEMBLIX

## Products Affected

- Scemblix oral tablet 20 mg, 40 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Chronic Myeloid Leukemia (CML)-approve if the patient meets the following (A and B): A) Patient has Philadelphia chromosome-positive chronic myeloid leukemia, AND B) Patient meets one of the following (i or ii): i. The chronic myeloid leukemia is T315I-positive, OR ii. Patient has tried at least two other tyrosine kinase inhibitors indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia. Note: Examples of tyrosine kinase inhibitors include imatinib tablets, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), Sprycel (dasatinib tablets), and Tasigna (nilotinib capsules). |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# SENSIPAR

## Products Affected

- cinacalcet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Hypercalcemia d/t parathyroid CA-prescr/consult w/onco or endo.Hypercalcemia w/primary hyperparathyroidism-prescr/consult w/nephro or endo. Hyperparathyroidism in post-renal transplant-prescr/consult w/transplant physician/nephro/endo. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Hypercalcemia due to parathyroid carcinoma-approve. Hypercalcemia in patients with primary hyperparathyroidism-approve if the patient has failed or is unable to undergo a parathyroidectomy due to a contraindication. Secondary Hyperparathyroidism in patients with chronic kidney disease on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundles payment benefit). Hyperparathyroidism in Post-Renal Transplant Patients-approve if the baseline (prior to starting cinacalcet therapy) calcium and intact parathyroid hormone (iPTH) levels are above the normal range, as defined by the laboratory reference values. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | hyperparathyroidism in post-renal transplant patients |

# SIGNIFOR

## Products Affected

- Signifor

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older (initial therapy) |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist or a physician or specializes in the treatment of Cushing's syndrome (initial therapy) |
| **Coverage Duration** | Cushing's disease/synd-Initial-4 mo, Cont-1 yr. Pt awaiting surgery or response after radio-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 intravenous
- Skyrizi subcutaneous pen injector
- Skyrizi subcutaneous syringe 150 mg/mL
- Skyrizi subcutaneous syringe kit
- Skyrizi subcutaneous wearable injector

| 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), PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy), CD-presc/consult-gastro |
| **Coverage Duration** | 6 mos initial, 1 year cont |
| **Other Criteria** | PP-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. Psoriatic arthritis (initial)-approve. Continuation-patient must have responded as determined by the prescriber. CD, initial-approve if the patient has tried or is currently taking |

| PA Criteria | Criteria Details |
|---|---|
| | corticosteroids, or corticosteroids are contraindicated or if the patient has tried one other conventional systemic therapy for CD (Please note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. A trial of mesalamine does not count as a systemic agent for Crohn's disease.) or if the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas or if the patient had ileocolonic resection (to reduce the chance of CD recurrence). Patients must be receiving an inducation dosing with Skyrizi IV within 3 month of initiating therapy with Skyrizi subcutaneous. Continuation-patient must have responded as determined by the prescriber. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# SOMATULINE

## Products Affected

- Somatuline Depot

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

# 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** | GIST-18 years and older |
| **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 - approve if the patient has tried at least two other therapies. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | GIST, chondrosarcoma, chordoma |

# STELARA

## Products Affected

- Stelara intravenous
- 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-6mo,CD/UC load-approve 1 dose IV,CD/UC post IV load-SC 6 mo,cont tx-SC 1 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 conventional systemic therapy for CD (eg, azathioprine, 6-MP, MTX, certolizumab, vedolizumab, adalimumab, infliximab) OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). 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.PP initial - approve Stelara SC. CD, initial therapy - approve 3 months of the SC formulation if the |

| PA Criteria | Criteria Details |
|---|---|
| | 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 conventional systemic therapy for CD OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). UC, initial therapy-approve SC if the patient received a single IV loading dose within 2 months of initiating therapy with Stelara SC. 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 |

# STRENSIQ

## Products Affected

- Strensiq

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, genetic and lab test results |
| **Age Restrictions** | Disease onset-less than or equal to 18 |
| **Prescriber Restrictions** | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of hypophosphatasia or related disorders. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Hypophosphatasia - Perinatal/Infantile- and Juvenile-Onset-Patient must meet both A and B for approval. A) Diagnosis is supported by one of the following (i, ii, or iii): i. Molecular genetic testing documenting tissue non-specific alkaline phosphatase (ALPL) gene mutation OR ii. Low baseline serum alkaline phosphatase activity OR iii. An elevated level of a tissue non-specific alkaline phosphatase substrate (i.e., serum pyridoxal 5'-phosphate, serum or urinary inorganic pyrophosphate, urinary phosphoethanolamine) AND B) Patient meets one of the following (i or ii): i. Patient currently has, or has a history of clinical manifestations consistent with hypophosphatasia (e.g., skeletal abnormalities, premature tooth loss, muscle weakness, poor feeding, failure to thrive, respiratory problems, Vitamin B6-dependent seizures) OR ii. Patient has a family history (parent or sibling) of hypophosphatasia without current clinical manifestations of hypophosphatasia |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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

| 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 |

# SYNAREL

## Products Affected

- Synarel

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Endometriosis-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Central Precocious Puberty-12 months, Endometriosis-6 months |
| **Other Criteria** | Central precocious puberty-approve. Endometriosis-approve if the patient has tried one of the following, unless contraindicated, a contraceptive, an oral progesterone or a depo-medroxyprogesterone injection. Note: An exception to the requirement for a trial of the above therapies can be made if the patient has previously used a gonadotropin-releasing hormone (GnRH) agonist or antagonist for endometriosis. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# TABRECTA

## Products Affected

- Tabrecta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 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 or high-level MET amplification, as detected by an approved test. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Non-small cell lung cancer with high-level MET amplification. |

# 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 pilocytic astrocytoma OR pleomorphic xanthoastrocytoma OR ganglioglioma, OR ii) recurrent disease for one of the following: low-grade glioma OR anaplastic glioma OR 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 Langerhans cell histiocytosis and one of the following: multisystem disease OR pulmonary disease OR |

| PA Criteria | Criteria Details |
|---|---|
| | central nervous system lesions OR patient has Erdheim Chester disease AND patient has BRAF V600-mutation positive disease. Metastatic or solid tumors-approve if BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets) AND patient has no satisfactory alternative treatment options. |
| **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** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | NSCLC-EGFR Mutation Positive (other than EGFR T790M-Positive Mutation)- approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note-examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. NSCLC-EGFR T790M mutation positive-approve if the patient has metastatic EGFR T790M mutation-positive NSCLC as detected by an approved test and has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors. NSCLC-Post resection-approve if the patient has received previous adjuvant chemotherapy or if the patient is inegligible to receive platinum based chemotherapy and the patient has EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# TALTZ

## Products Affected

- Taltz Autoinjector
- Taltz Autoinjector (2 Pack)
- Taltz Autoinjector (3 Pack)
- 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 6 months, 1 year 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, 0.5 mg, 0.75 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 |

# TARGRETIN TOPICAL

## Products Affected

- bexarotene
- 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** | ALL/GIST-18 years and older |
| **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 or more therapies. 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 cream 0.05 %
- Tazorac topical gel

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Cosmetic uses |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 1 year |
| **Other Criteria** | 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** | Epitheliod Sarcoma-approve if the patient has metastatic or locally advanced disease and the patient is not eligible for complete resection. Follicular Lymphoma-approve if 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 |

# 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 mutations or patient has high-level MET amplification, as detected by an approved test. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Non-small cell lung cancer with high-level MET amplification. |

# TERIPARATIDE

## Products Affected

- teriparatide

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with other medications for osteoporosis |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 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 |

# TETRABENAZINE

## Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist. |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism. |

# THALOMID

## Products Affected

- Thalomid

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | MM, myelofibrosis-18 years and older |
| **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). Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and has relapsed or refractory disease. Castleman's disease-approve if the patient has multicentric Castleman's disease and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off-Label Uses** | Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi's Sarcoma, Castleman's Disease. |

# TIBSOVO

## Products Affected

- Tibsovo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, IDH1 Status |
| **Age Restrictions** | All diagnoses (except chondrosarcoma)-18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 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** | Chondrosarcoma |

# TIVDAK

## Products Affected

- Tivdak

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Cervical cancer-approve if the patient has tried at least one chemotherapy agent. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# TOLVAPTAN

## Products Affected

- Samsca oral tablet 15 mg
- tolvaptan

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with Jynarque. |
| **Required Medical Information** | Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion). |
| **Age Restrictions** | 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 tolvaptan and has received less than 30 days of therapy. |
| **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

- Eprontia
- topiramate oral capsule, sprinkle
- topiramate oral tablet
- Zonisade
- zonisamide

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Coverage is not provided for weight loss or smoking cessation. |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | N/A |
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |

# 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 1 year |
| **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, OR 6) the patient has been started on therapy with trientine. |
| **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 |

# TRODELVY

## Products Affected

- Trodelvy

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast Cancer-approve if the patient has metastatic triple-negative breast cancer and has been previously treated with at least two systemic therapy regimens for metastatic disease. Urothelial Cancer-approve if the patient has locally advanced or metastatic urothelial cancer AND has tried at least one systemic chemotherapy AND has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# TRUSELTIQ

## Products Affected

- Truseltiq oral capsule 100 mg/day (100 mg x 1), 125 mg/day(100 mg x1-25mg x1), 50 mg/day (25 mg x 2), 75 mg/day (25 mg x 3)

| 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 |

# TYSABRI

## Products Affected

- Tysabri

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use of other disease-modifying agents used for MS. Concurrent use with immunosuppressants (eg, 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) in Crohn's disease (CD) patients. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Adults (initial and continuation) |
| **Prescriber Restrictions** | MS. Prescribed by, or in consultation with, a neurologist or physician who specializes in the treatment of MS (initial and continuation). CD. Prescribed by or in consultation with a gastroenterologist (initial and continuation). |
| **Coverage Duration** | MS-Authorization will be for 1 year .CD, initial-3 mo. CD, cont therapy-1 year. |
| **Other Criteria** | Adults with a relapsing form of MS. Patient has had an inadequate response to, or is unable to tolerate, one disease modifying agent used for MS (eg, interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia), glatiramer acetate (Copaxone/Glatopa), Plegridy, fingolimod (Gilenya), Tecfidera, Lemtrada, daclizumab (Zinbryta), Aubagio) OR the patient has highly active or aggressive disease according to the prescribing physician by meeting one of the following-the patient has demonstrated rapidly-advancing deterioration(s) in physical functioning (e.g., loss of mobility/or lower levels of ambulation, severe changes in strength or coordination OR disabling relapse(s) with suboptimal response to systemic corticosteroids OR magnetic resonance imaging (MRI) findings suggest highly-active or aggressive multiple sclerosis (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium lesions) OR manifestation of multiple sclerosis-related cognitive impairment. Adults with CD, initial. Patient has moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein) and patient has tried two of the following agents for CD for at least 2 months each: adalimumab, certolizumab pegol, infliximab, vedolizumab, ustekinzumab, OR pt has had an inadequate response or was intolerant to these agents. CD, continuation |

| PA Criteria | Criteria Details |
|---|---|
| | therapy. Patient has had a response to Tysabri, as determined by the prescribing physician. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# ULTOMIRIS

## Products Affected

- Ultomiris intravenous solution 100 mg/mL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, test results |
| **Age Restrictions** | PNH, MG-18 years and older |
| **Prescriber Restrictions** | PNH-Prescribed by or in consultation with a hematologist, aHUS-prescribed by or in consultation with a nephrologist, MG-presc/consult neurologist |
| **Coverage Duration** | PNH/MG-Initial 6 months, cont-1 year, aHUS-1 year |
| **Other Criteria** | PNH-Initial therapy-Approve if diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least two cell lineages.Continuation-approve if the patient is continuing to derive benefit (e.g., stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis) from Ultomiris, according to the prescribing physician. aHUS-approve if the patient does not have Shiga toxin E. coli related hemolytic uremic syndrome. Generalized Myasthenia Gravis (gMG)-Initial therapy-approve if the patient meets the following criteria (A, B, C and D):A) Patient has confirmed anti-acetylcholine receptor (AchR) antibody positive generalized Myasthenia Gravis (gMG) AND B) Patient is currently receiving or has tried and has contraindications, intolerance, or failed pyridostigmine, AND C) Patient has evidence of unresolved symptoms of generalized Myasthenia Gravis (gMG), such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility) AND D) patient has myasthenia gravis foundation of America classification of II to IV and myasthenia gravis activities of daily living (MG-ADL) score of greater than or equal to 5.Continuation-approve if the patient is continuing to derive benefit (e.g., reductions in exacerbations of |

| PA Criteria | Criteria Details |
|---|---|
| | myasthenia gravis, improvements in speech, swallowing, mobility, and respiratory function) from Soliris, according to the prescribing physician. |
| **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. Langerhans cell histiocytosis-approve if the patient has unifocal Langerhans cell histiocytosis with isolated skin disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Adults with T-cell leukemia/lymphoma, Langerhans Cell Histiocytosis |

# 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 oral tablet 10 mg, 100 mg, 50 mg
- Venclexta Starting Pack

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, prior therapy |
| **Age Restrictions** | 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** | Breast cancer, early-approve for 2 years, all other-3 years |
| **Other Criteria** | Breast Cancer, Early-Approve if pt meets (A,B,C and D): A)Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets the following:Pt has node-positive disease at high risk of recurrence (Note-High risk includes patients with greater than or equal to 4 positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: Grade 3 disease, tumor size greater than or equal to 5 cm, or a Ki-67 score of greater than or equal to 20%) AND D)Pt meets ONE of the following (i or ii): i.Verzenio will be used in combo w/anastrozole, exemestane, or letrozole AND pt meets one of the following (a,b, or c): a)Pt is a postmenopausal woman, OR b)Pt is a pre/perimenopausual woman and meets one of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, OR 2-Pt has had surgical bilateral oophorectomy or ovarian irradiation, OR c)Pt is a man and pt is receiving a GnRH analog, OR ii.Verzenio will be used in combo with tamoxifen AND pt meets one of the following (a or b): a)Pt is a postmenopausal woman or man OR b)Pt is a pre/perimenopausual woman and meets one of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Patient has had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer-Advanced or Metastatic in Women-Approve if pt meets (A, B, C and D): A) Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets ONE of the following criteria (i or ii): i.Pt is a |

| PA Criteria | Criteria Details |
|---|---|
| | postmenopausal woman, OR ii.Pt is a pre/perimenopausal woman and meets one of the following (a or b): a)Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR b)Pt has had surgical bilateral oophorectomy or ovarian irradiation, AND D)Pt meets ONE of the following criteria (i, ii, or iii): i.Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least one prior endocrine therapy, AND c)Pt has tried chemotherapy for metastatic breast cancer.Breast Cancer-Advanced or Metastatic in Men-Approve if pt meets the following criteria (A,B and C): A)Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets ONE of the following criteria (i, ii, or iii): i.Pt meets BOTH of the following conditions (a and b): a)Pt is receiving a GnRH analog, AND b)Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.Pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least one prior endocrine therapy, AND c)Pt has tried chemotherapy for metastatic breast cancer. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# VIMIZIM

## Products Affected

- Vimizim

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis, genetic and lab test results |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient has a laboratory test demonstrating deficient N-acetylgalactosamine-6-sulfatase activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating N-acetylgalactosamine-6-sulfatase gene mutation. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# VISTOGARD

## Products Affected

- Vistogard

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 7 days |
| **Other Criteria** | Capecitabine or fluorouracil overdose-approve. Capecitabine or fluorouracil toxicity, severe or life threatening-approve. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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** | NSCLC-approve if the patient has advanced or metastatic disease and has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# VONJO

## Products Affected

- Vonjo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 years |
| **Other Criteria** | Myelofibrosis (MF), including primary MF, post-polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has intermediate risk or high risk disease and the patient has a platelet count of less than 50 X 10 9/L (less than 50,000/mcL) |
| **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. |

# VOSEVI

## Products Affected

- Vosevi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Genotype, prescriber specialty, other medications tried or used in combination with requested medication |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician |
| **Coverage Duration** | 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 |

# 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, 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 |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Authorization will be for 3 years. |
| **Other Criteria** | NSCLC, recurrent or metastatic disease-approve if the patient meets one of the following: must be ALK-positive as detected by an approved test or have high level MET amplification or have MET Exon 14 skipping mutation or have ROS1 rearrangement as detected by an approved test. Anaplastic Large Cell Lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease AND has received at least one prior systemic treatment. Histiocytic neoplasm-approve if the patient has ALK rearrangement/fusion-positive disease and meets one of the following criteria (i, ii, or iii): (i. Patient has Langerhans cell histiocytosis, OR ii. Patient has Erdheim-Chester disease OR iii. Patient has Rosai-Dorfman disease. Soft Tissue Sarcoma - Inflammatory Myofibroblastic Tumor with Anaplastic Lymphoma Kinase (ALK) Translocation-approve. |
| **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, Histiocytic neoplasms. |

# 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/AS prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | PsA/RA/JIA/JRA/AS/UC-6 months initial, All diagnoses-1 year cont. |
| **Other Criteria** | RA initial-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. PsA initial, approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial and the requested medication will be used in combination with methotrexate or another conventional synthetic disease modifying antirheumatic drug (DMARD), unless contraindicated. UC-Approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least ONE tumor necrosis factor inhibitor for ulcerative colitis or was unable to tolerate a 3-month trial. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthropathy/active sacroiliac arthritis]-initial-approve Xeljanz immediate release tablets or solution if the patient meets the following: patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AS-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least |

| PA Criteria | Criteria Details |
|---|---|
| | one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. Continuation Therapy - Patient must have responded, as determined by the prescriber. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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 |

# XIAFLEX

## Products Affected

- Xiaflex

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Retreatment (i.e., treatment beyond three injections per affected cord for those with Dupuytren's Contracture or beyond eight injections for Peyronie's Disease). |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Dupuytren's Contracture-administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture. Peyronie's Disease -administered by a healthcare provider experienced in the treatment of male urological diseases. |
| **Coverage Duration** | Dupuytren's Contracture-3 months, Peyronie's Disease-6 months |
| **Other Criteria** | Dupuytren's Contracture-at baseline (prior to initial injection of Xiaflex), the patient had contracture of a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint of at least 20 degrees AND the patient will not be treated with more than a total of three injections (maximum) per affected cord. Peyronie's Disease-the patient meets ONE of the following (i or ii): i. at baseline (prior to use of Xiaflex), the patient has a penile curvature deformity of at least 30 degrees OR in a patient who has received prior treatment with Xiaflex, the patient has a penile curvature deformity of at least 15 degrees AND the patient has not previously been treated with a complete course (8 injections) of Xiaflex for Peyronie's disease. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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 |
|---|---|
| | 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 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. |
| **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** | 18 years and older |
| **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 2), 40 mg/week (40 mg x 1), 40mg twice week (40 mg x 2), 60 mg/week (60 mg x 1), 60mg twice week (120 mg/week), 80 mg/week (40 mg x 2), 80mg twice week (160 mg/week)

| 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** | 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 (daratumumb infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules). Note: Examples of regimens for multiple myeloma 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, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
| --- | --- |
| **Off-Label Uses** | Treatment of multiple myeloma in combination with daratumumb or pomalidomide |

# 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, dexmethylphenidate, 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 and the patient meets ONE of the following criteria (i or ii): i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy. |
| **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** | 18 years and older |
| **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. Uterine leiomyosarcoma-approve if the patient has BRCA2 mutation and has tried one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Uterine Leiomyosarcoma |

# 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 tried at least one other systemic 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 pilocytic astrocytoma OR pleomorphic xanthoastrocytoma OR ganglioglioma, OR ii) recurrent disease for one of the following conditions: low-grade glioma OR anaplastic glioma OR glioblastoma, OR iii) melanoma with brain metastases AND the medication with be taken in combination with Cotellic (cobimetinib tablets). Histiocytic Neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following: multisystem disease OR pulmonary disease OR 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., papillary, follicular, or Hurthle cell) with BRAF-positive disease, Central Nervous System Cancer, Histiocytic Neoplasm |

# ZEPZELCA

## Products Affected

- Zepzelca

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Small cell lung cancer-approve if the patient has metastatic disease and has previously received platinum-based chemotherapy. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# 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 |

# ZTALMY

## Products Affected

- Ztalmy

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 2 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder-approve if the patient has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene. |
| **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

| 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. |

# ZYNLONTA

## Products Affected

- Zynlonta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse Large B-Cell Lymphoma- approve if the patient has tried at least two systemic regimens. |
| **Indications** | All FDA-approved Indications. |
| **Off-Label Uses** | N/A |

# ZYTIGA

## Products Affected

- abiraterone oral tablet 250 mg, 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)-Approve if abiraterone is being used in combination with prednisone or dexamethasone and the medication is used concurrently used with a gonadotropin-releasing hormone (GnRH) analog or the medication is concurrently used with Firmagon or the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration-sensitive (mCSPC)-approve if the medication is used in combination with prednisone and the medication is concurrently used with a gonadotropin-releasing hormone analog or concurrently used with Firmagon 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, ii or iii): i.abiraterone with prednisone is used in combination with gonadotropin-releasing hormone (GnRH) analog OR ii. Patient has had an orchiectomy OR iii. the medication is used in combination with Firmagon. Prostate cancer-very-high-risk-group-approve if according to the prescriber the patient is in the very-high-risk group, the medication will be used in combination with external beam radiation therapy and the patient meets one of the following criteria (i, ii or iii): i. abiraterone is used in combination with gonadotropin-releasing hormone |

| PA Criteria | Criteria Details |
|---|---|
| | (GnRH) analog OR ii. Patient has had an orchiectomy OR iii. the medication is used in combination with Firmagon. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off-Label Uses** | Prostate Cancer-Regional Risk Group, Prostate cancer-very-high-risk group |

# PART B VERSUS PART D

## Products Affected

- Abelcet
- Abraxane
- acetylcysteine
- Actimmune
- acyclovir sodium intravenous solution
- Adcetris
- albuterol sulfate inhalation solution for nebulization
- Alimta
- Aliqopa
- AmBisome
- amiodarone intravenous
- amphotericin B
- aprepitant
- arformoterol
- Arranon
- arsenic trioxide
- Arzerra
- azacitidine
- azathioprine oral tablet 50 mg
- azathioprine sodium
- Bavencio
- Beleodaq
- Bendeka
- Besponsa
- bleomycin
- Blincyto intravenous kit
- bortezomib injection recon soln 1 mg, 2.5 mg
- bortezomib injection recon soln 3.5 mg
- bortezomib intravenous recon soln
- budesonide inhalation suspension for nebulization 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL
- busulfan
- carboplatin intravenous solution
- carmustine intravenous recon soln 100 mg
- cidofovir
- cisplatin intravenous solution
- cladribine
- Clinimix 5%/D15W Sulfite Free
- Clinimix 4.25%/D10W Sulf Free
- Clinimix 4.25%/D5W Sulfit Free
- Clinimix 5%-D20W(sulfite-free)
- Clinimix 6%-D5W (sulfite-free)
- Clinimix 8%-D10W(sulfite-free)
- Clinimix 8%-D14W(sulfite-free)
- clofarabine
- Cosmegen
- cromolyn inhalation
- cyclophosphamide intravenous recon soln
- cyclophosphamide oral capsule
- cyclophosphamide oral tablet
- cyclosporine intravenous
- cyclosporine modified
- cyclosporine oral capsule
- Cyramza
- cytarabine
- cytarabine (PF)
- dacarbazine
- dactinomycin
- Darzalex
- daunorubicin intravenous solution
- decitabine
- deferoxamine
- dexrazoxane HCl
- dobutamine in D5W intravenous parenteral solution 1,000 mg/250 mL (4,000 mcg/mL), 250 mg/250 mL (1 mg/mL), 500 mg/250 mL (2,000 mcg/mL)
- dobutamine intravenous solution 250 mg/20 mL (12.5 mg/mL)
- docetaxel intravenous solution 160 mg/16 mL (10 mg/mL), 160 mg/8 mL (20 mg/mL), 20 mg/2 mL (10 mg/mL), 20 mg/mL (1 mL), 80 mg/4 mL (20 mg/mL), 80 mg/8 mL (10 mg/mL)
- dopamine in 5 % dextrose
- dopamine intravenous solution 200 mg/5 mL (40 mg/mL), 400 mg/10 mL (40 mg/mL)
- doxorubicin
- doxorubicin, peg-liposomal
- dronabinol
- Emend oral suspension for reconstitution
- Empliciti

- Engerix-B (PF)
- Engerix-B Pediatric (PF)
- epirubicin intravenous solution 200 mg/100 mL
- epoprostenol (glycine)
- Erbitux
- Erwinase
- Etopophos
- etoposide intravenous
- everolimus (immunosuppressive)
- Firmagon kit w diluent syringe
- floxuridine
- fludarabine
- fluorouracil intravenous
- Folotyn
- formoterol fumarate
- fulvestrant
- ganciclovir sodium
- Gazyva
- gemcitabine intravenous recon soln
- gemcitabine intravenous solution 1 gram/26.3 mL (38 mg/mL), 2 gram/52.6 mL (38 mg/mL), 200 mg/5.26 mL (38 mg/mL)
- gemcitabine intravenous solution 100 mg/mL
- Gengraf
- granisetron HCl oral
- Halaven
- Hizentra
- HyQvia
- idarubicin
- ifosfamide
- Imfinzi
- Intralipid intravenous emulsion 20 %
- Intron A injection recon soln 10 million unit (1 mL), 50 million unit (1 mL)
- ipratropium bromide inhalation
- ipratropium-albuterol
- irinotecan
- Istodax
- Ixempra
- Jevtana
- Khapzory
- Kyprolis
- levoleucovorin calcium
- Lioresal
- melphalan
- melphalan HCl
- mesna
- methotrexate sodium
- methotrexate sodium (PF)
- methylprednisolone oral tablet
- milrinone
- milrinone in 5 % dextrose
- mitomycin intravenous
- mitoxantrone
- Mozobil
- Mvasi
- mycophenolate mofetil
- mycophenolate mofetil (HCl)
- mycophenolate sodium
- Mylotarg
- nelarabine
- nitroglycerin in 5 % dextrose intravenous solution 100 mg/250 mL (400 mcg/mL), 25 mg/250 mL (100 mcg/mL), 50 mg/250 mL (200 mcg/mL)
- nitroglycerin intravenous
- Nulojix
- Oncaspar
- ondansetron
- ondansetron HCl oral solution
- ondansetron HCl oral tablet 4 mg, 8 mg
- Onivyde
- oxaliplatin
- paclitaxel
- Paraplatin
- pemetrexed disodium intravenous recon soln
- pentamidine inhalation
- Perjeta
- Plenamine
- Portrazza
- Prehevbrio (PF)
- Premasol 10 %
- Prograf intravenous
- Prograf oral granules in packet
- Pulmozyme
- Recombivax HB (PF)
- romidepsin intravenous recon soln
- Sandimmune oral solution

- Simulect
- sirolimus
- sodium nitroprusside
- Synribo
- tacrolimus oral
- Tecentriq
- Temodar intravenous
- temsirolimus
- thiotepa
- Tice BCG
- tobramycin in 0.225 % NaCl
- tobramycin inhalation
- Toposar
- topotecan intravenous recon soln
- topotecan intravenous solution 4 mg/4 mL (1 mg/mL)
- Travasol 10 %
- Trazimera
- Treanda
- Trelstar intramuscular suspension for reconstitution
- TrophAmine 10 %
- Tyvaso
- Tyvaso Institutional Start Kit
- Tyvaso Refill Kit
- Tyvaso Starter Kit
- Unituxin
- valrubicin
- Varubi
- Vectibix
- Velcade
- Veletri
- vinblastine
- Vincasar PFS
- vincristine
- vinorelbine
- Vyxeos
- Xatmep
- Xgeva
- Yervoy
- Yondelis
- Zaltrap
- Zanosar
- Zirabev
- zoledronic acid intravenous solution
- zoledronic acid-mannitol-water intravenous piggyback 4 mg/100 mL
- 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.

**Index**