



MedMutual Advantage HMO and PPO Plans

2019 Prior Authorization Criteria

ACTEMRA SQ

Products Affected

- Actemra ACTPen
- Actemra subcutaneous

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started in tocilizumab (IV/SC) for a Covered Use. |
| 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 | RA/GCA/PJIA - Prescribed by or in consultation with a rheumatologist. |
| Coverage Duration | GCA-6 mo initial, 3 yr cont.PJIA-4 mo initial, 3 yr cont.All other dx-3 mo initial, 3 yr cont. |
| Other Criteria | RA initial - approve if the patient has tried TWO of the following: Enbrel, Humira, Oencia (IV/SC), Rinvoq or Xeljanz/XR (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the try TWO requirement: Cimzia, infliximab, golimumab SC/IV) OR if, according to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, approve if the patient has tried etanercept, Oencia or adalimumb. (Note: the patient does not have to have a trial with etanercept, Oencia or adalimumb if they have had a trial with infliximab in the past.) Cont tx - pt must have had a response as determined by the prescriber. |

ACYCLOVIR (TOPICAL)

Products Affected

- acyclovir topical cream
- acyclovir topical ointment
- Zovirax topical cream

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | Medication history |
| Age Restrictions | Zovirax 5% cream, 12 yrs or older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 12 months |
| Other Criteria | N/A |

ADEMPAS

Products Affected

- Adempas

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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 | 3 years |
| 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). Right heart catheterization is not required in pts who are currently receiving Adempas or another agent indicated for WHO group 1. |

AFINITOR

Products Affected

- Afinitor
- Afinitor Disperz

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already taking Afinitor for a Covered Use. Advanced, unresectable or metastatic neuroendocrine tumors. Perivascular Epitheloid Cell Tumors (PEComa), Recurrent Angiomyolipoma, Lymphangiomyomatosis, relapsed or refractory classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Thymomas and Thymic carcinomas, Differentiated (i.e. papillary, follicular, and Hurthle cell) Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST) and Recurrent or progressive Meningioma. |
| 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) Patient has recurrent, Stage IV, or metastatic breast cancer, B) Patient has tried anastrozole, letrozole, or tamoxifen, C) Patient is postmenopausal or is premenopausal/perimenopausal and is receiving ovarian suppression/ablation with a GnRH agonist (e.g., Lupron, Trelstar, Zoladex), or has had surgical bilateral oophorectomy/ovarian irradiation, D) Patient has HR+ (i.e., ER+ and/or PR+ disease) or patient has HR-negative disease with clinical characteristics predicting a HR+ tumor (e.g., long disease-free interval, limited sites of recurrence, indolent disease, older age), E) Patient has HER2-negative breast cancer and Afinitor will be used in combination with exemestane or Afinitor will be used in combination with Faslodex or tamoxifen, F) Patient has not had disease |

| PA Criteria | Criteria Details |
|-------------|---|
| | <p>progression while on Afinitor. RCC-approve if patient has advanced RCC with predominant clear cell histology and has tried Inlyta, Votrient, Sutent, Caboxmetyx or Nexavar (patient only has to try ONE of these drugs) OR if the patient has RCC with non-clear cell histology. Tuberous sclerosis complex (TSC) for the treatment of subependymal giant cell astrocytoma (SEGA)-approve if the patient requires therapeutic intervention but cannot be curatively resected. NET-approve. Thymomas and Thymic Carcinomas-approve if the patient has tried one prior chemotherapy (e.g., cisplatin plus doxorubicin, cisplatin plus etoposide, carboplatin plus paclitaxel). Renal angiomyolipoma with TSC-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 Afinitor 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 Afinitor will be used in combination with one of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST. Tuberous sclerosis complex (TSC)-associated partial-onset seizures-approve.</p> |

AIMOVIG

Products Affected

- Aimovig Autoinjector subcutaneous auto-injector 140 mg/mL, 70 mg/mL

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, number of migraine headaches per month, prior therapies tried |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 1 year |
| Other Criteria | Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least two standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, beta-blocker), and has had inadequate responses to those therapies or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. |

ALECENSA

Products Affected

- Alecensa

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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. |

ALUNBRIG

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on brigatinib for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | ALK status, treatment history and results |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Metastatic NSCLC must be ALK-positive. |

AMPYRA

Products Affected

- Ampyra
- dalfampridine

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patient already started on dalfampridine extended-release for Multiple Sclerosis (MS). |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | MS. If prescribed by, or in consultation with, a neurologist or MS specialist. |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | N/A |

ANABOLIC STEROIDS

Products Affected

- oxandrolone

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. 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. |
| 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 |

ARANESP

Products Affected

- Aranesp (in polysorbate) injection solution 100 mcg/mL, 200 mcg/mL, 25 mcg/mL, 300 mcg/mL, 40 mcg/mL, 60 mcg/mL
- Aranesp (in polysorbate) injection syringe

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D worded as anemia associated with chronic renal failure (CRF), including patients on dialysis and not on dialysis, and worded as anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Anemia due to myelodysplastic syndrome (MDS). |
| Exclusion Criteria | N/A |
| Required Medical Information | Anemia w/CRF on and not on dialysis. A hemoglobin (Hb) of less than 10.0 g/dL for adults and less than or equal to 11 g/dL for children required for start, Hb has to be less than or equal 11.5 g/dL adults or less than or equal to 12 g/dL in children if previously receiving epoetin alfa (EA) or Aranesp or less than or equal to 11.5 g/dL in adults currently receiving Mircera. Anemia due to myelosuppressive chemotx, Hb is 10.0 g/dL or less to start or less than or equal to 12.0 g/dL if previously on EA or Aranesp AND currently receiving myelosuppressive chemo. MDS, approve tx if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. If the pt has previously been receiving Aranesp or EA, approve only if Hb is 12.0 g/dL or less. All conds, deny if Hb exceeds 12.0 g/dL. |
| Age Restrictions | MDS anemia = 18 years of age and older. |
| Prescriber Restrictions | MDS anemia, prescribed by or in consultation with, a hematologist or oncologist. |
| Coverage Duration | Anemia w/myelosuppressive = 4 mos, Other=6 mos. |
| Other Criteria | For all covered uses, the patient is required to try Procrit first line. |

ARCALYST

Products Affected

- Arcalyst

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concurrent biologic therapy |
| Required Medical Information | N/A |
| Age Restrictions | Initial tx CAPS-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. |
| Coverage Duration | 3 mos initial, 3 years cont |
| Other Criteria | CAPS renewal - approve if the patient has had a response as determined by the prescriber. |

ARIKAYCE

Products Affected

- Arikayce

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, previous medication history |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections |
| Coverage Duration | 1 year |
| Other Criteria | MAC Lung disease-approve if the patient has NOT achieved negative sputum cultures for Mycobacterium avium complex after greater than or equal to 6 consecutive months 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). |

AUBAGIO

Products Affected

- Aubagio

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concurrent use of Aubagio with other disease-modifying agents used for multiple sclerosis (MS) |
| Required Medical Information | MS, patient must have a relapsing form of MS (RRMS, SPMS with relapses, or PRMS). MS, previous MS therapies tried. |
| 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 | For patients already taking Aubagio, approve. |

AVONEX

Products Affected

- Avonex intramuscular pen injector kit
- Avonex intramuscular syringe kit

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concurrent use of other disease-modifying agent used for multiple sclerosis |
| Required Medical Information | Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS or have experienced an attack and who are at risk of MS. |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or after consultation with a neurologist or an MS specialist. |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | N/A |

BALVERSA

Products Affected

- Balversa

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Balversa for a covered use. |
| 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 |

BENLYSTA

Products Affected

- Benlysta subcutaneous

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concurrent use with other biologics or with cyclophosphamide intravenous (IV) |
| Required Medical Information | Diagnosis, medications that will be used in combination, autoantibody status |
| Age Restrictions | SC-18 years and older (initial) IV-5 years and older (initial) |
| Prescriber Restrictions | Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation) |
| Coverage Duration | Initial-4 months, cont-3 years |
| Other Criteria | Initial-The patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician. Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician AND The patient has responded to Benlysta as determined by the prescriber. |

BETASERON/EXTAVIA

Products Affected

- Betaseron subcutaneous kit
- Extavia subcutaneous kit

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concurrent use with other disease-modifying agent used for multiple sclerosis |
| Required Medical Information | Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS or have experienced an attack and who are at risk of MS. |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or after consultation with a neurologist or an MS specialist. |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | For patients requesting Extavia, approve if the patient has tried two of the following: interferon beta-1a intramuscular (Avonex), interferon beta-1a subcutaneous (Rebif), interferon beta-1b (Betaseron), pegylated interferon beta-1a (Plegridy) or glatiramer acetate (Copaxone). |

BOSULIF

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia. Plus patients already started on Bosulif for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis. For CML/ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For ALL, prior therapies tried |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 months. |
| Other Criteria | For CML, patient must have Ph-positive CML For ALL, patient must have Ph-positive ALL and has tried ONE other tyrosine kinase inhibitors that are used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc). |

BRAFTOVI

Products Affected

- Braftovi oral capsule 75 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients with colon or rectal cancer. Plus patients already started on Braftovi for a covered use. |
| 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. |

C1 ESTERASE INHIBITORS

Products Affected

- Cinryze
- Haegarda

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on the prescribed drug for a covered use. |
| 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 | 3 years |
| Other Criteria | N/A |

CABLIVI

Products Affected

- Cablivi injection kit

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| 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 | 3 months |
| Other Criteria | aTTP-approve if the patient is currently receiving at least one immunosuppressive therapy. |

CABOMETYX

Products Affected

- Cabometyx

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients with Non-Small Cell Lung Cancer with RET Gene Rearrangements. Plus patients already taking Cabometyx for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, histology, RET gene rearrangement status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Advance Renal Cell Carcinoma (Predominant Clear Cell or Non-Clear Cell Histology)-Approve. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). |

CALQUENCE

Products Affected

- Calquence

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus Chronic Lymphocytic Leukemia (CLL). Plus Small Lymphocytic Lymphoma (SLL). |
| Exclusion Criteria | N/A |
| Required Medical Information | Previous medications/therapies tried |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | CLL and SLL-approve if the patient has tried one prior therapy. |

CAPRELSA

Products Affected

- Caprelsa oral tablet 100 mg, 300 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma. Plus Non-Small Cell Lung Cancer with RET Gene Rearrangements |
| 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. |

CHEMET

Products Affected

- Chemet

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| 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. |

CHENODAL

Products Affected

- Chenodal

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | For the treatment of gallstones, approve if the patient has tried or is currently using an ursodiol product. |

CHOLBAM

Products Affected

- Cholbam oral capsule 250 mg, 50 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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. 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 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. |

CIALIS

Products Affected

- tadalafil oral tablet 2.5 mg, 5 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | Indication for which tadalafil is being prescribed. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 mos. |
| Other Criteria | Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed as once daily dosing, to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED). |

CIMZIA

Products Affected

- Cimzia
- Cimzia Powder for Reconst

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D plus patients already started on certolizumab pegol for Covered use. |
| Exclusion Criteria | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD |
| Required Medical Information | Diagnosis, concurrent medications, previous therapies tried |
| Age Restrictions | Adults for CD. |
| Prescriber Restrictions | RA/AS, prescribed by or in consultation with a rheumatologist. Crohn's disease, prescribed by or in consultation with a gastroenterologist. PsA prescribed by or in consultation with a rheumatologist or dermatologist |
| Coverage Duration | 3 months initial, 3 years cont. |
| Other Criteria | AS, approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx. PsA, approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx, Stelara, Otezla, Orencia or Xeljanz/XR. RA, approve if the patient has tried two of the following: Enbrel, Humira, Orencia, Rinvoq or Xeljanz/XR. CD, approve if patient has previously tried Humira. Plaque Psoriasis-approve if the patient has tried TWO of the following: Enbrel, Humira, Skyrizi, Stelara SC, Otezla, or Cosentyx. Cont tx - approve if the patient has had a response to therapy, as according to the prescribing physician. Non-radiographic axial spondylitis (nr-axSpA)-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroiliitis reported on MRI. nr-axSpA continuation-approve if the patient has had a response as determined by the prescriber. |

COMETRIQ

Products Affected

- Cometriq

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma and patients already started on Cometriq for a Covered Use. |
| 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. |

COPAXONE

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| Exclusion Criteria | Concurrent use with other disease-modifying agent used for multiple sclerosis |
| Required Medical Information | Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS or have experienced an attack and who are at risk of MS. |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or after consultation with a neurologist or an MS specialist. |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | N/A |

COPIKTRA

Products Affected

- Copiktra

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Copiktra for a covered use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, previous therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | CLL/Follicular Lymphoma/SLL-approve if the patient has tried two prior therapies |

CORLANOR

Products Affected

- Corlanor

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | Previous use of a Beta-blocker, LVEF, sinus rhythm, and resting HR |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 12 months |
| Other Criteria | HF in adult pts not currently receiving Corlanor - must have LVEF of less than or equal 35 percent AND tried or is currently receiving a Beta-blocker for HF (e.g., metoprolol succinate sustained-release, carvedilol, bisoprolol, carvedilol ER) unless the patient has a contraindication to the use of beta blocker therapy (e.g., bronchospastic disease such as COPD and asthma, severe hypotension or bradycardia). HF in adult pts currently receiving Corlanor - had a LVEF of less than or equal to 35 percent prior to initiation of Corlanor therapy AND has tried or is currently receiving a Beta-blocker for HF unless the patient has a contraindication to the use of beta blocker therapy. Children with heart failure due to dilated cardiomyopathy-approve. |

COSENTYX

Products Affected

- Cosentyx (2 Syringes)
- Cosentyx Pen (2 Pens)

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already taking Cosentyx for a Covered Use. |
| Exclusion Criteria | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) |
| Required Medical Information | Diagnosis and previous medications use |
| Age Restrictions | PP/AS/PsA initial - 18 years of age and older |
| Prescriber Restrictions | PP initial - prescribed by or in consultation with a dermatologist or rheumatologist. AS initial- by or in consultation with rheumatologist, PsA initial- by or in consultation with rheumatologist or dermatologist. |
| Coverage Duration | PP/AS - initial tx 3 mos, PsA-initial tx 3 mos, cont tx 3 years |
| 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. PP/AS/PsA cont - patient must have responded, as determined by the prescriber. |

COTELLIC

Products Affected

- Cotellic

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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. |

CRINONE GEL

Products Affected

- Crinone vaginal gel 8 %

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus, secondary amenorrhea, support of an established pregnancy. |
| Exclusion Criteria | Use in patients to supplement or replace progesterone in the management of infertility. |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Secondary amenorrhea, 12 months.Support of an established pregnancy, 9 months. |
| Other Criteria | N/A |

DALIRESP

Products Affected

- Daliresp

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| 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 3 years. |
| 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). |

DARAPRIM

Products Affected

- Daraprim

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis. |
| 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. |

DAURISMO

Products Affected

- Daurismo

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients continuing Daurismo as post-remission therapy. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, medications that will be used in combination, comorbidities |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | AML - approve if Daurismo will be used in combination with cytarabine AND the patient meets i. OR ii: i. patient is using Daurismo for treatment induction and is greater than or equal to 75 years old or the patient has comorbidities that preclude the use of intensive induction chemotherapy according to the prescribing physician, OR ii. patient is continuing Daurismo as post-remission therapy. |

DOPTELET

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, platelet count, date of procedure |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Chronic ITP-prescribed by or after consultation with a hematologist |
| Coverage Duration | Thrombo w/chronic liver disease-5 days, chronic ITP-3 years |
| Other Criteria | Thrombocytopenia with chronic liver disease-Approve if the patient has a current platelet count less than $50 \times 10^9/L$ AND the patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. Chronic ITP-approve if the patient has tried one other therapy or if the patient has undergone splenectomy. |

DUPIXENT

Products Affected

- Dupixent

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, prescriber specialty, other medications tried and length of trials |
| Age Restrictions | asthma/AD-12 years of age and older. Chronic Rhinosinusitis-18 and older |
| Prescriber Restrictions | Asthma-Prescribed by or in consultation with a an allergist, immunologist, pulmonologist. AD-prescribed by or in consultation with allergist, immunologist or dermatologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist. |
| Coverage Duration | Asthma/Rhinosinusitis initial-6 months, AD-Initial-16 weeks, Continuation-1 year |
| Other Criteria | Atopic Dermatitis-Initial Therapy- Patient meets both of the following criteria: a. Patient has used at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid OR patient has atopic dermatitis affecting ONLY the face, eyes/eyelids, skin folds, and/or genitalia and has tried tacrolimus ointment, AND b. Inadequate efficacy was demonstrated with these previously tried topical prescription therapies, according to the prescribing physician. Continuation- Approve if the patient has responded to Dupixent therapy as determined by the prescribing physician (e.g., marked improvements erythema, induration/papulation/edema, excoriations, and lichenification, reduced pruritus, decreased requirement for other topical or systemic therapies, reduced body surface area (BSA) affected with atopic dermatitis, or other responses observed). Asthma-approve for add-on maintenance treatment in patients with moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma. Chronic rhinosinusitis with Nasal Polyposis-Initial-patient is currently receiving therapy with an intranasal corticosteroid AND is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell according to the prescriber AND meets ONE of the following (a or b): a) |

| PA Criteria | Criteria Details |
|-------------|---|
| | <p>Patient has received treatment with a systemic corticosteroid within the previous 2 years or has a contraindication to systemic corticosteroid therapy OR b) Patient has had prior surgery for nasal polyps. Continuation-approve if the patient continues to receive therapy with an intranasal corticosteroid AND patient has responded to Dupixent therapy as determined by the prescriber.</p> |

EMGALITY

Products Affected

- Emgality Pen
- Emgality Syringe subcutaneous syringe 120 mg/mL, 300 mg/3 mL (100 mg/mL x 3)

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| 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 | 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 two standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, beta-blocker), and has had inadequate responses to those therapies or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day. |

ENBREL

Products Affected

- Enbrel Mini
- Enbrel subcutaneous recon soln
- Enbrel subcutaneous syringe
- Enbrel SureClick

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D plus patient already on etanercept for a Covered Use. Graft versus host disease (GVHD). Behcet's disease. Uveitis |
| Exclusion Criteria | Concurrent use with biologic therapy or targeted synthetic DMARD |
| Required Medical Information | Diagnosis, concurrent medications, previous therapies tried. |
| Age Restrictions | N/A |
| Prescriber Restrictions | RA/Ankylosing spondylitis/JIA/JRA, prescribed by or in consult w/ rheumatologist. Psoriatic arthritis, prescribed by or in consultation w/ rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consult w/ dermatologist. GVHD, prescribed by or in consult w/ oncologist, hematologist, or physician affiliated w/ transplant center. Behcet's disease, prescribed by or in consult w/ rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist. |
| Coverage Duration | FDA approved indications - 3 months initial, 3 years cont, others 12 months. |
| Other Criteria | RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA, approve if the pt has aggressive disease, as determined by the prescriber, or the pt has tried one other agent for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID, biologic DMARD or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide. Plaque psoriasis (PP) initial approve if the patient meets one of the following conditions: 1) patient has tried at least one traditional systemic agent for at least 3 months |

| PA Criteria | Criteria Details |
|-------------|---|
| | <p>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) OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD. Tried or currently is receiving with etanercept 1 conventional GVHD tx (high-dose systemic corticosteroid, CSA, tacrolimus, MM, thalidomide, antithymocyte globulin, etc.). Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Uveitis-tried one of the following: periocular, intraocular, or systemic corticosteroid, immunosuppressives, Humira or an infliximab product. RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit, approve additional quantity (to allow for 50 mg twice weekly dosing) if one of the following is met: 1) Patient has plaque psoriasis, OR 2) Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR 3) Patient has RA and the dose is being increased to 50 mg twice weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is contraindicated or intolerant, OR 4) Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months.</p> |

EPCLUSA

Products Affected

- Epclusa

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients started on Epclusa for a Covered Use. |
| 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 | 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. |

EPIDIOLEX

Products Affected

- Epidiolex

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Epidiolex for a covered use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, previous therapies |
| Age Restrictions | Patients 2 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 1 year |
| Other Criteria | N/A |

EPOETIN/PROCRIT

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus anemia in patients with HIV who are receiving zidovudine. Anemic patients (Hb of 13.0 g/dL or less) at high risk for perioperative transfusions (secondary to significant, anticipated blood loss and are scheduled to undergo elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusions). Plus anemia due to myelodysplastic syndrome (MDS). |
| Exclusion Criteria | N/A |
| Required Medical Information | CRF anemia in patients on and not on dialysis. Hemoglobin (Hb) of less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children to start. Hb less than or equal to 11.5 g/dL for adults or 12 g/dL or less for children if previously on epoetin alfa or Aranesp or less than or equal to 11.5 g/dL if currently receiving Mircera. 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 - 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, prescribed by or in consultation with, a hematologist or oncologist. |
| Coverage Duration | Anemia w/myelosuppressive = 4 mos. Transfus=1 mo. Other=6mo. HIV + zidovudine = 4 mo |

| PA Criteria | Criteria Details |
|-----------------------|---|
| Other Criteria | For all covered uses, if the request is for Epogen, then the patient is required to try Procrit or Retacrit first line. |

ERIVEDGE

Products Affected

- Erivedge

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus, patient already started on Erivedge for a covered use. |
| 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 12 months |
| 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. |

ERLEADA

Products Affected

- Erleada

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | N/A |

ESBRIET

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Combination use with nintedanib |
| 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 | 3 years |
| Other Criteria | IPF baseline - must have FVC greater than or equal to 50 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. |

EXJADE/JADENU

Products Affected

- deferasirox
- Exjade

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D worded as transfusion-related chronic iron overload and non-transfusion-dependent thalassemia syndromes chronic iron overload |
| Exclusion Criteria | N/A |
| Required Medical Information | Serum ferritin level |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a hematologist |
| Coverage Duration | 1 year |
| Other Criteria | Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve if the patient is benefiting from therapy as confirmed by the prescribing physician. |

FARYDAK

Products Affected

- Farydak oral capsule 10 mg, 15 mg, 20 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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 |

FASENRA

Products Affected

- Fasenra

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| Exclusion Criteria | Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody |
| Required Medical Information | Diagnosis, severity of disease, peripheral blood eosinophil count, previous therapies tried and current therapies, FEV1/FVC |
| Age Restrictions | 12 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an allergist, immunologist, or pulmonologist |
| Coverage Duration | Authorization will be for 6 months initial, 12 months continuation. |
| Other Criteria | Initial - must have peripheral blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks (prior to treatment with any anti-interleukin (IL)-5 therapy) AND meet both of the following criteria: 1) Patient has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid AND one of the following: inhaled LABA, inhaled long-acting muscarinic antagonist, Leukotriene receptor antagonist, or Theophylline, AND 2) Patient's asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy as defined by ONE of the following: a) patient experienced one or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, OR b) patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year, OR c) patient has a FEV1 less than 80 percent predicted, OR d) Patient has an FEV1/FVC less than 0.80, OR e) Patient's asthma worsens upon tapering of oral corticosteroid therapy. Continuation - The patient has responded to Fasenra therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, emergency department (ED)/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy) AND patient continues to receive therapy with an inhaled corticosteroid. |

FERRIPROX

Products Affected

- Ferriprox

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D worded as transfusion-related due to thalassemia syndromes chronic iron overload |
| 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 | Initial therapy - approve if prior to starting therapy the serum ferritin level was greater than 2,500 mcg/L. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician. |

FIRAZYR

Products Affected

- Firazyr
- icatibant

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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 3 years. |
| Other Criteria | N/A |

FIRDAPSE

Products Affected

- Firdapse

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| 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. |

FLECTOR

Products Affected

- Flector

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 mos. |
| Other Criteria | Patients must try a generic oral NSAID or diclofenac 1% gel. |

FORTEO

Products Affected

- Forteo

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, calcitonin nasal spray [Fortical], abaloparatide), except calcium and Vitamin D. |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 2 years of therapy over a patient's lifetime |
| Other Criteria | Treatment of PMO, approve if pt has tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR pt has severe renal impairment (creatinine clearance less than 35 mL/min) or CKD or pt has had an osteoporotic fracture or fragility fracture. Increase bone mass in men (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) with primary or hypogondal osteoporosis/Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), |

| PA Criteria | Criteria Details |
|-------------|--|
| | OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture. |

FULPHILA

Products Affected

- Fulphila

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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. |
| Coverage Duration | Cancer pts receiving chemo-6 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. |

GABAPENTIN/LYRICA

Products Affected

- gabapentin oral capsule 100 mg, 300 mg, 400 mg
- gabapentin oral solution 250 mg/5 mL
- gabapentin oral tablet 600 mg, 800 mg
- Lyrical oral capsule 100 mg, 150 mg, 200 mg, 225 mg, 25 mg, 300 mg, 50 mg, 75 mg
- Lyrical oral solution
- pregabalin oral capsule 100 mg, 150 mg, 200 mg, 225 mg, 25 mg, 300 mg, 50 mg, 75 mg
- pregabalin oral solution

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. Plus, patients already started on Lyrical for a Covered Use. |
| 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 |

GATTEX

Products Affected

- Gattex 30-Vial

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

GILENYA

Products Affected

- Gilenya oral capsule 0.5 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concurrent use of Gilenya with other disease-modifying agents used for multiple sclerosis (MS). |
| Required Medical Information | For use in MS, patient has a relapsing form of MS. |
| 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 |

GILOTRIF

Products Affected

- Gilotrif

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | For NSCLC - EGFR exon deletions or mutations, or if NSCLC is squamous cell type |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | NSCLC EGFR pos - For the treatment of metastatic non small cell lung cancer (NSCLC) must be used in tumors with non-resistant EGFR mutation positive NSCLC as detected by an approved test. NSCLC metastatic squamous cell must have disease progression with first line treatment with platinum based chemotherapy. |

GLUCAGON-LIKE PEPTIDE-1 AGONISTS

Products Affected

- Bydureon BCise
- Bydureon subcutaneous pen injector
- Byetta subcutaneous pen injector 10 mcg/dose(250 mcg/mL) 2.4 mL, 5 mcg/dose (250 mcg/mL) 1.2 mL
- Ozempic subcutaneous pen injector 0.25 mg or 0.5 mg(2 mg/1.5 mL), 1 mg/dose (2 mg/1.5 mL)
- Trulicity
- Victoza 3-Pak

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

GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

Products Affected

- Lupron Depot
- Lupron Depot (3 month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | For abnormal uterine bleeding/endomet/uterine leiomyomata approve 6 months/all other dx 12 mo |
| Other Criteria | N/A |

GRALISE/HORIZANT/LYRICA CR

Products Affected

- Gralise 30-Day Starter Pack
- Gralise oral tablet extended release 24 hr 300 mg, 600 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| 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 |

GRANIX

Products Affected

- Granix

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA -approved indications not otherwise excluded from Part D. Plus patients undergoing peripheral blood progenitor cell (PBPC) Collection and Therapy. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | Cancer patient receiving chemo-Prescribed by or in consultation with an oncologist, infectious disease specialist, or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist or physician that specializes in transplantation. |
| Coverage Duration | PBPC-1 month, All others-6 months |
| Other Criteria | Cancer patients receiving Myelosuppressive Chemotherapy-Must meet ONE of the following - 1. be receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen) 2. be receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (e.g., at least 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, HIV infection) 3. have had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a CSF (e.g., Granix, Neulasta, Zarxio, Neupogen, or Leukine) and a reduced dose or frequency of chemotherapy may compromise treatment OR 4. has received chemotherapy has febrile neutropenia and has at least one risk factor for poor clinical outcomes or for developing infection-associated complications according to the |

| PA Criteria | Criteria Details |
|-------------|--|
| | prescribing physician (e.g., sepsis syndrome, older than 65 years, severe neutropenia - ANC less than 100 cells/mm ³ , neutropenia expected to be more than 10 days in duration, invasive fungal infection, other clinically documented infections, or prior episode of febrile neutropenia). |

GROWTH HORMONES

Products Affected

- Norditropin FlexPro
- Omnitrope

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | GHD in children/adolescents initial must meet ONE of the following - 1. had hypophysectomy, 2. has congenital hypopituitarism AND had growth hormone response to one preferred GH test of less than 10 ng/mL (preferred tests are levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon), 3. has panhypopituitarism AND had growth hormone response to one preferred GH test of less than 10 ng/mL, has 3 or more pituitary hormone deficiencies (ACTH, TSH, LH/FSH, or prolactin), or pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior "bright spot" on MRI or CT, 4. pt had brain radiation, had growth hormone response to one preferred GH test of less than 10 ng/mL, AND meets one of these a. pretreatment growth rate (GR) is less than 7 cm/yr in children younger than 3 or b. GR is less than 4 cm/yr in 3 y/o or older, c. or if 18 y/o or younger with growth velocity that is less than 10th percentile for age/gender on last 6 months of data, OR 5. had growth hormone response to one preferred GH test of less than 10 ng/mL, ht less than the 10th percentile for age/gender, AND meets one of these a. pretreatment growth rate (GR) is less than 7 cm/yr in children younger than 3 or b. GR is less than 4 cm/yr in 3 y/o or older, c. or if 18 y/o or younger with growth velocity that is less than 10th percentile for age/gender on last 6 months of data. Continuation of tx-approve if the patient has experienced improvement, according to the prescribing physician. |
| 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 4 weeks, others 12 mos |

| PA Criteria | Criteria Details |
|----------------|--|
| Other Criteria | <p>GHD initial in adults and adolescents 1. endocrine must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. childhood onset has known mutations, embryonic lesions, congenital defects or irreversible structural hypothalamic pituitary lesion/damage, 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, if insulin and glucagon contraindicated then Arginine alone test with peak of less than or equal to 0.4 mcg/L, GHRH plus arginine peak of less than or equal to 11 mcg/L if BMI is less than 25, peak less than 8 mcg/L if BMI is more than 25 but less than 30, or peak less than 4 mcg/L if BMI if more than 30) 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 older than 5 or b. growth velocity is less than 10th percentile for age/gender. Cont tx - prescriber confirms response to therapy. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by chromo analysis, open epiphyses, height less than 3rd percentile for age/gender. SGA initial -baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). Cont tx - prescriber confirms response to therapy. Cont Tx for CKD, Noonan, PW in child/adolescents, SHOX, and TS - prescriber confirms response to therapy. SBS initial pt receiving specialized nutritional support. Cont tx - 2nd course if pt responded to tx with a decrease in the requirement for specialized nutritional support.</p> |

HARVONI

Products Affected

- Harvoni oral tablet 90-400 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients with recurrent HCV post-liver transplant. Plus patients started on Harvoni for a covered use |
| 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. |

HETLIOZ

Products Affected

- HetlioZ

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | patient is totally blind with no perception of light |
| Age Restrictions | 18 years or older |
| Prescriber Restrictions | prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders |
| Coverage Duration | 6 mos initial, 12 mos cont |
| Other Criteria | Initial - dx of Non-24 is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for at least 1 week plus evaluation of sleep logs recorded for at least 1 month. Cont - Approve if pt has received at least 6 months of continuous therapy (i.e., 6 consecutive months of daily treatment) with HetlioZ under the guidance of a physician who specializes in the treatment of sleep disorders AND 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). |

HIGH RISK MEDICATIONS - BENZODIAZEPINES

Products Affected

- clobazam oral suspension
- clobazam oral tablet
- clonazepam oral tablet 0.5 mg, 1 mg, 2 mg
- clonazepam oral tablet, disintegrating 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, 2 mg
- clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg
- Diazepam Intensol
- diazepam oral solution 5 mg/5 mL (1 mg/mL)
- diazepam oral tablet
- lorazepam oral concentrate
- lorazepam oral tablet 0.5 mg, 1 mg, 2 mg
- Onfi oral suspension
- Onfi oral tablet 10 mg, 20 mg
- Sympazan

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| 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. |

HIGH RISK MEDICATIONS - BENZTROPINE

Products Affected

- benztropine oral

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| 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 |

HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

Products Affected

- cyclobenzaprine oral tablet

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| 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. |

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

Products Affected

- hydroxyzine HCl oral tablet
- promethazine oral

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| 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. |

HIGH RISK MEDICATIONS - PHENOBARBITAL

Products Affected

- phenobarbital

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| 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. |

HIGH RISK MEDICATIONS - TERTIARY TRICYCLIC ANTIDEPRESSANTS

Products Affected

- amitriptyline
- amoxapine
- clomipramine
- desipramine
- doxepin oral
- imipramine HCl
- imipramine pamoate
- nortriptyline
- trimipramine

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| 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 the treatment of depression, approve if the patient has tried at least two of the following agents (brand or generic): citalopram, escitalopram, fluoxetine, paroxetine, sertraline, venlafaxine, desvenlafaxine, duloxetine, bupropion, mirtazapine or trazodone. For the treatment of pain, may approve amitriptyline (single-entity only, not amitriptyline combination products), desipramine, nortriptyline or imipramine (brand or generic) if the patient has tried at least two of the following agents: duloxetine, pregabalin, gabapentin, venlafaxine or venlafaxine Er. For the treatment of obsessive compulsive disorder (OCD), may approve clomipramine (brand or generic) or desipramine (brand or generic) if the patient has tried at least one of the following medications: fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, escitalopram, or venlafaxine. 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. |

HIGH RISK MEDICATIONS- ESTROGENS

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically-accepted indications not otherwise excluded from Part D. |
| 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, Estring, 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. |

HUMIRA

Products Affected

- Humira Pediatric Crohns Start subcutaneous syringe kit 40 mg/0.8 mL, 40 mg/0.8 mL (6 pack)
- Humira Pen
- Humira Pen Crohns-UC-HS Start
- Humira Pen Psor-Uveits-Adol HS
- Humira subcutaneous syringe kit 10 mg/0.2 mL, 20 mg/0.4 mL, 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 Psor-Uv-Adol HS
- HUMIRA(CF) SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.4 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 |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D plus patients already started on adalimumab for a Covered Use. |
| 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. Ulcerative colitis (UC), adults. |
| Prescriber Restrictions | RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist.UV- ophthalmologist |
| Coverage Duration | initial 3 mo, cont tx 3 years. |
| Other Criteria | RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to 'step back' and try a conventional synthetic DMARD). JIA/JRA initial. Tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to |

| PA Criteria | Criteria Details |
|-------------|---|
| | <p>MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. PP initial-approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other agent for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ileocolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) or was intolerant to one of these agents, or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. FDA approve indications cont tx - must respond to tx as determined by prescriber. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Clinical criteria incorporated into the Humira 40 mg quantity limit edit allow for approval of additional quantities to accommodate induction dosing. The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling.</p> |

IBRANCE

Products Affected

- Ibrance

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus liposarcoma. Plus men with breast cancer. |
| 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 for patients who have not had disease progression while on Ibrance, Kisqali or Verzenio 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 premonopausal 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 Faslodex 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 agonist AND Ibrance with be used in combination with anastrozole, exemestane, tamoxifen or letrozole or Ibrance will be used in combination with Faslodex 4. Pt is postmenopausal and Ibrance will be used in combination with Faslodex |

ICLUSIG

Products Affected

- Iclusig oral tablet 15 mg, 45 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Iclusig for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status |
| Age Restrictions | CML/ALL - Adults |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | CML Ph+, T315I-positive or has tried TWO other TKIs indicated for use in Philadelphia chromosome positive CML (e.g., Gleevec, Sprycel, Tasigna). ALL Ph+, T315I-positive or has tried TWO other TKIs indicated for use in Ph+ ALL (e.g. Gleevec, Sprycel.) |

IDHIFA

Products Affected

- Idhifa

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Idhifa for a Covered Use. |
| 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 |

IMATINIB

Products Affected

- imatinib oral tablet 100 mg, 400 mg

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus chordoma, advanced or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, AIDS Related Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor. Plus patients already started on imatinib or Gleevec for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | GVHD-1 year, all others-3 years. |
| Other Criteria | For ALL/CML, new patient must have Ph-positive for approval of imatinib. AIDS related Kaposi's Sarcoma-approve if the patient has tried one prior regimen AND has relapsed or refractory disease. |

IMBRUVICA

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus relapsed or refractory Central Nervous System Lymphoma (Primary). Plus relapsed or refractory Hairy Cell Leukemia. Plus Diffuse Large B-Cell Lymphoma (e.g., follicular lymphoma, gastric MALT lymphoma, nongastric MALT lymphoma, primary DLBCL of the central nervous system). Plus patients already taking Imbruvica for a Covered Use. |
| 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). Diffuse large B-cell lymphoma-approve if the patient is using Imbruvica as second-line or subsequent therapy according to the prescribing physician. |

INJECTABLE TESTOSTERONE PRODUCTS

Products Affected

- testosterone cypionate
- testosterone enanthate

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. |
| 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 cypionate or testosterone enanthate. Palliative treatment of inoperable metastatic breast cancer in females. 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 |

INLYTA

Products Affected

- Inlyta oral tablet 1 mg, 5 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma. Plus, patients already started on Inlyta for a Covered Use. |
| 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. |

INREBIC

Products Affected

- Inrebic

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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. |

IRESSA

Products Affected

- Iressa

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Metastatic NSCLC - The patient has epidermal growth factor receptor (EGFR) exon 19 deletions OR has exon 21 (L858R) substitution mutations as detected by an FDA-approved test. |

IVIG

Products Affected

- Privigen

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| 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. |

JAKAFI

Products Affected

- Jakafi

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus, patients already started on Jakafi for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | For polycythemia vera patients must have tried hydroxyurea. GVHD-approve if the patient has tried one systemic corticosteroid. |

JUXTAPID

Products Affected

- Juxtapid

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| Exclusion Criteria | Combination use with Kynamro, Praluent, or Repatha. |
| Required Medical Information | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a cardiologist, an endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders. |
| Coverage Duration | 12 months |
| Other Criteria | <p>Patient must meet ALL of the following criteria: 1) Patient has had genetic confirmation of two mutant alleles at the LDL receptor, apolipoprotein B APOB, PCSK9, or LDLRAP1 gene locus OR the patient has an untreated LDL-C level greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents) OR the patient has a treated LDL-C level greater than or equal to 300 mg/dL (after treatment with antihyperlipidemic agents but prior to agents such as Repatha or Kynamro) OR the patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) Patient has tried Repatha and had an inadequate response according to the prescribing physician OR the patient is known to have two LDL-receptor negative alleles, AND 3) Patient has tried one high-intensity statin therapy (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than 20 mg daily [as a single-entity or as a combination product]) for greater than or equal to 8 continuous weeks and the LDL-C level remains greater than or equal to 70 mg/dL OR the patient has been determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or patient experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation.</p> |

KALYDECO

Products Affected

- Kalydeco oral granules in packet 25 mg, 50 mg, 75 mg
- Kalydeco oral tablet

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Combination use with Orkambi or Symdeko |
| Required Medical Information | N/A |
| Age Restrictions | 6 months 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 one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, S945L, S977F, F1052V, K1060T, A1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, D1270N, G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, G1349D, 2789+5G A, 3272-26A G, 3849+10kbC T, 711+3A G, E831X OR R117H AND must NOT be Homozygous for the F508del Mutation in the CFTR Gene or have unknown CFTR gene mutations. |

KISQALI

Products Affected

- Kisqali
- Kisqali Femara Co-Pack

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus men with breast cancer. |
| 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 in patients who have not had disease progression while on Kisqali, Ibrance or Verzenio 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 agonist AND Kisqali will be used in combination with anastrozole, exemestane, tamoxifen or letrozole. 4. Patient is postmenopausal, pre/perimenopausal or a man, and Kisqali (not Co-Pack) will be used in combination with Faslodex 5. Patient is pre/perimenopausal and Kisqali (not Co-Pack) will be used in combination with tamoxifen as first line therapy. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane, letrozole or tamoxifen. |

KORLYM

Products Affected

- Korlym

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus patients with Endogenous Cushing's Syndrome, awaiting surgery |
| 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 | Authorization will be for 3 years |
| Other Criteria | 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. |

KUVAN

Products Affected

- Kuvan

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| 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. |

LENVIMA

Products Affected

- Lenvima

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients with Medullary Thyroid Carcinoma (MTC). Plus patients with anaplastic thyroid carcinoma. |
| 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 - approve if the pt meets ONE of the following criteria: 1) pt has RCC with predominant clear-cell histology AND the pt has tried one antiangiogenic therapy (eg, Inlyta, Votrient, Sutent, Cabometyx) AND Lenvima will be used in combination with everolimus (Afinitor), OR 2) pt has RCC with non-clear cell histology AND Lenvima will be used in combination with everolimus (Afinitor). MTC-approve if the patient has tried Caprelsa or Cometriq. Anaplastic thyroid cancer-approve if the disease does not have a curative option. |

LETAIRIS/TRACLEER

Products Affected

- ambrisentan
- bosentan
- Letairis
- Tracleer oral tablet

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Chronic thromboembolic pulmonary hypertension (CTEPH) (bosentan). |
| Exclusion Criteria | N/A |
| Required Medical Information | Pulmonary arterial hypertension (PAH) WHO Group 1 patients not currently on ambrisentan or bosentan or another agent indicated for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1 patients currently on ambrisentan or bosentan or another agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization. |
| 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 3 years. |
| Other Criteria | CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving bosentan for CTEPH. |

LIDODERM

Products Affected

- lidocaine topical adhesive patch,medicated

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus diabetic neuropathic pain. Plus chronic back pain. |
| 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 | Chronic back pain-approve if the patient has tried two pharmacologic therapies with each one from a different class of medication used to treat low back pain (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], muscle relaxants, celecoxib, duloxetine, gabapentin). |

LONG ACTING OPIOIDS

Products Affected

- buprenorphine transdermal patch weekly 10 mcg/hour, 15 mcg/hour, 20 mcg/hour, 5 mcg/hour
- hydromorphone oral tablet extended release 24 hr
- methadone oral solution 10 mg/5 mL, 5 mg/5 mL
- methadone oral tablet 10 mg, 5 mg
- morphine oral capsule, ER multiphase 24 hr
- morphine oral capsule, extend. release pellets
- morphine oral tablet extended release
- OxyContin oral tablet, oral only, ext. rel. 12 hr 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D worded as pain severe enough to require daily, around-the-clock, long-term opioid treatment. Plus patients with a cancer diagnosis, patients in a hospice program/end-of-life care/palliative care and patients who reside in a long term care facility. |
| Exclusion Criteria | Acute (ie, non-chronic) pain |
| Required Medical Information | Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 months. |
| Other Criteria | For pain severe enough to require daily, around-the-clock, long-term opioid treatment (with no cancer diagnosis, not in long term care facility and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been 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 |

| PA Criteria | Criteria Details |
|-------------|---|
| | <p>there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.</p> |

LONSURF

Products Affected

- Lonsurf

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

LORBRENA

Products Affected

- Lorbrena

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Lorbrena for a covered use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, ALK status, previous therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | NSCLC - Approve if the patient has ALK-positive metastatic NSCLC and meets one of the following: a) patient has disease progression on Xalkori (crizotinib capsules) and at least one other ALK inhibitor (e.g., Zykadia [ceritinib capsules], Alecensa [alectinib capsules], Alunbrig [brigatinib tablets]), or b) patient has disease progression on Alecensa (alectinib capsules) as the first ALK inhibitor therapy, or c) patient has disease progression on Zykadia (ceritinib capsules) as the first ALK inhibitor therapy. |

LYNPARZA

Products Affected

- Lynparza oral tablet

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Lynparza. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Ovarian cancer approve if the patient has a germline BRCA mutation confirmed by an approved test AND as per product labeling, has progressed on three or more prior lines of chemotherapy. Breast Cancer- Approve if the patient meets the following criteria (A, B, C, and D)-A. The patient has metastatic, germline BRCA mutation-positive breast cancer AND B. The patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND C. The patient meets ONE of the following criteria (i or ii)- i. The patient meets BOTH of the following criteria (a and b)-a) The patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive ER+ and/or progesterone receptor positive PR+] disease AND b) The patient meets ONE of the following criteria (1 or 2)-1- The patient has been treated with prior endocrine therapy OR-2 The patient is considered inappropriate for endocrine therapy OR ii. Patient has triple negative disease (i.e., ER-negative, PR-negative, and HER2-negative) AND D. The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. |

MEGACE

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D |
| 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 |

MEKINIST

Products Affected

- Mekinist oral tablet 0.5 mg, 2 mg

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus colon or rectal cancer. Plus patients already started on Mekinist for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer, colon or rectal cancer and NSCLC must have documentation of BRAF V600 mutations |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | Melanoma must be used in patients with BRAF V600 mutation, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC requires BRAF V600E Mutation and use in combination with Tafenlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafenlar, unless intolerant AND the patient has BRAF V600-positive disease. 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. |

MEKTOVI

Products Affected

- Mektovi

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients with colon or rectal cancer. Plus patients already started on Mektovi for a covered use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, BRAF V600 status, concomitant medications |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi. Colon or Rectal cancer-approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer. |

MEMANTINE

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus patients with mild to moderate vascular dementia. |
| 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 |

MULPLETA

Products Affected

- Mulpleta

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, platelet count, date of procedure |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 7 days |
| Other Criteria | Approve if the patient has a current platelet count less than $50 \times 10^9/L$ AND the patient is scheduled to undergo a procedure within 8 to 14 days after starting Mulpleta therapy. |

MYALEPT

Products Affected

- Myalept

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by, or in consultation with, an endocrinologist or a geneticist physician specialist |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | N/A |

NATPARA

Products Affected

- Natpara

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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 | 3 years |
| 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. |

NERLYNX

Products Affected

- Nerlynx

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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 | Approve for 12 months |
| Other Criteria | Breast cancer - approve if the patient meets all of the following criteria: 1. Patient has early stage disease, AND 2. Patient has HER2-positive breast cancer, AND 3. Patient has completed one year of adjuvant therapy with trastuzumab OR could not tolerate one year of therapy. |

NEULASTA

Products Affected

- Neulasta subcutaneous syringe

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients undergoing PBPC collection and therapy |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| 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. Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome. |
| Coverage Duration | Cancer pts receiving chemo-6 mo. PBPC/Radiation Syndrome-1 mo |
| Other Criteria | Cancer patients receiving chemotherapy, approve if the patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, 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. |

NEUPOGEN

Products Affected

- Neupogen

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D worded more broadly as cancer patients receiving myelosuppressive chemotherapy, patients with acute myeloid leukemia (AML) receiving chemotherapy, cancer patients receiving bone marrow transplantation (BMT), patients undergoing peripheral blood progenitor cell (PBPC) collection and therapy, and patients with severe chronic neutropenia [SCN] (e.g., congenital neutropenia, cyclic neutropenia, idiopathic neutropenia). 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). |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | AML, HIV/AIDS, MDS - adults |
| Prescriber Restrictions | Cancer/AML, MDS, ALL, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. |
| Coverage Duration | chemo/SCN/AML-6 mo.HIV/AIDS-4 months.MDS-3 mo.PBPC,Drug induce A/N,AA,ALL,BMT-3 mo.All others=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, |

| PA Criteria | Criteria Details |
|-------------|--|
| | <p>prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver or renal dysfunction, poor performance status, HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, Neulasta, Neupogen Granix, or Zarxio) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm³], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).</p> |

NEXAVAR

Products Affected

- Nexavar

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus , patients already started on Nexavar for a covered use, osteosarcoma, angiosarcoma, advanced or unresectable desmoids tumors, 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 |
| 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. Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and Nexavar is used in combination with topotecan. |

NINLARO

Products Affected

- Ninlaro oral capsule 2.3 mg, 3 mg, 4 mg

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus, patients with systemic light chain amyloidosis. Plus, patients already started on Ninlaro. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | MM - be used in combination with Revlimid and dexamethasone AND pt had received at least ONE previous therapy for multiple myeloma (e.g., Thalomid, Revlimid, Pomalyst, Alkeran, dexamethasone, prednisone). Systemic light chain amyloidosis-approve if the patient has tried at least one other regimen for this condition. |

NORTHERA

Products Affected

- Northera

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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 |

NUBEQA

Products Affected

- Nubeqa

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | N/A |

NUEDEXTA

Products Affected

- Nuedexta

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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 |

NUPLAZID

Products Affected

- Nuplazid oral capsule
- Nuplazid oral tablet 10 mg

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

NUVIGIL/PROVIGIL

Products Affected

- armodafinil
- modafinil

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D.Excessive daytime sleepiness (EDS) due to myotonic dystrophy - modafinil only. Adjunctive/augmentation for treatment of depression in adults - modafinil only. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | Patients must be greater than or equal to 17 years of age. |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 months. |
| Other Criteria | Excessive sleepiness due to SWSD 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. |

OCALIVA

Products Affected

- Ocaliva

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Ocaliva for a covered use. |
| 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 and continuation therapy) |
| Prescriber Restrictions | Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial and continuation therapy) |
| Coverage Duration | 6 months initial, 3 years 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) 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)). |

ODOMZO

Products Affected

- Odomzo

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus metastatic BCC. |
| 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. |

OFEV

Products Affected

- Ofev

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Combination use with pirfenidone |
| 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 | 3 years |
| Other Criteria | IPF baseline - must have FVC greater than or equal to 50 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. |

OPSUMIT

Products Affected

- Opsumit

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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 - 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 not currently on Opsumit or another agent indicated for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1 patients currently on Opsumit or another agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization. |

ORENCIA

Products Affected

- Orenzia
- Orenzia ClickJect

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients who have already been started on abatacept (IV or SC) for a covered use. |
| 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 | 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 | 3 mos initial, 3 years cont |
| Other Criteria | RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to 'step back' and try a conventional synthetic DMARD). Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)], approve. Cont tx - responded to therapy as per the prescriber. |

ORKAMBI

Products Affected

- Orkambi oral granules in packet
- Orkambi oral tablet

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Combination use with Kalydeco |
| Required Medical Information | N/A |
| Age Restrictions | 2 years of age and older |
| Prescriber Restrictions | prescribed by or in consultation with a pulmonologist or a physician who specializes in CF |
| Coverage Duration | 3 years |
| Other Criteria | CF - homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation) |

OTEZLA

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients currently taking Otezla for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, previous drugs tried |
| Age Restrictions | N/A |
| Prescriber Restrictions | 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 rheumatologist or dermatologist. |
| Coverage Duration | All dx-4 months initial, PP/PsA-3 years cont. Behcet's-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. |

OXERVATE

Products Affected

- Oxervate

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by, or in consultation with, an ophthalmologist. |
| Coverage Duration | 2 months |
| Other Criteria | 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 |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, phenylalanine concentrations |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases |
| Coverage Duration | 1 year (initial and continuation) |
| Other Criteria | Initial therapy - approve if the patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., restriction of dietary phenylalanine and protein intake, prior treatment with Kuvan). Maintenance therapy - approve if the patient's blood phenylalanine concentration is less than or equal to 600 micromol/L OR the patient has achieved at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline. |

PHEOCHROMOCYTOMA

Products Affected

- Demser
- phenoxybenzamine

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, prior medication trials |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial therapy for phenoxybenzamine, initial and continuation therapy for Demser) |
| Coverage Duration | Authorization will be for 1 year |
| Other Criteria | If brand Dibenzylamine is being requested, approve if the patient has tried and cannot take generic phenoxybenzamine due to a formulation difference in the inactive ingredients between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction. If the requested drug is Demser for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin) AND the patient has tried phenoxybenzamine (brand or generic). If the requested drug is Demser for continuation therapy, approve if the patient is currently receiving Demser or has received Demser in the past. |

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | Pulmonary arterial hypertension (PAH) WHO Group 1, patients not currently taking an agent indication for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1 patients currently receiving an agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization. |
| 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 3 years. |
| Other Criteria | 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. |

PIQRAY

Products Affected

- Piqray

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D |
| 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, and E): A) The patient is a postmenopausal female or a male AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, Faslodex, tamoxifen, toremifene). |

PLEGRIDY

Products Affected

- Plegridy subcutaneous pen injector 125 mcg/0.5 mL, 63 mcg/0.5 mL- 94 mcg/0.5 mL
- Plegridy subcutaneous syringe 125 mcg/0.5 mL, 63 mcg/0.5 mL- 94 mcg/0.5 mL

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concurrent use of with other disease-modifying agents used for multiple sclerosis (MS). |
| Required Medical Information | For use in MS, patient has a relapsing form of MS. |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by, or in consultation with, a neurologist or an MS specialist. |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | N/A |

POMALYST

Products Affected

- Pomalyst

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus Myelofibrosis, Systemic Light Chain Amyloidosis, AIDS-Related Kaposi Sarcoma, relapsed or refractory disease, Central Nervous System (CNS) Lymphoma, relapsed or refractory disease |
| 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 | N/A |

PRALUENT

Products Affected

- Praluent Pen subcutaneous pen injector
150 mg/mL, 75 mg/mL

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

| PA Criteria | Criteria Details |
|-------------|--|
| | calcification (CAC) score 300 Agatston units or higher, AND 2) 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). |

PROLIA

Products Affected

- Prolia

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, calcitonin nasal spray [Fortical], abaloparatide), except calcium and Vitamin D. |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| 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, |

| PA Criteria | Criteria Details |
|-------------|--|
| | <p>approve if the patient has breast cancer that is not metastatic to the bone and in receiving concurrent AI therapy (eg, anastrozole, letrozole, exemestane). Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture.</p> |

PROMACTA

Products Affected

- Promacta

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Use in the management of thrombocytopenia in myelodysplastic syndrome (MDS). |
| Required Medical Information | Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy. |
| Age Restrictions | N/A |
| Prescriber Restrictions | Thrombocytopenia due to chronic ITP or Aplastic Anemia, approve if prescribed by, or after consultation with, a hematologist. Thrombocytopenia due to HCV-related cirrhosis, approve if prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease. |
| Coverage Duration | Chronic ITP - 3 years, others 12 months. |
| Other Criteria | Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura, approve if the patient has tried ONE other therapy or has undergone a splenectomy. Treatment of thrombocytopenia due to HCV-related cirrhosis, approve to allow for initiation of antiviral therapy if the patient has low platelet counts (eg, less than 75,000 mm ³) and the patient has chronic HCV infection and is a candidate for hepatitis C therapy. Aplastic anemia - has low platelet counts at baseline/pre-treatment (e.g., less than 30,000 mm ³) AND tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate mofetil, sirolimus) OR patient will be using Promacta in combination with standard immunosuppressive therapy. |

REBIF

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients who experienced an attack and are at risk for multiple sclerosis. |
| Exclusion Criteria | Concurrent use with other disease-modifying agent used for multiple sclerosis |
| Required Medical Information | Diagnosis of MS includes the following patient types: patients with actual diagnosis of MS, patients who have experienced an MS attack, and patients who are at risk for developing MS. |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or after consultation with a neurologist or an MS specialist. |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | N/A |

REPATHA

Products Affected

- Repatha
- Repatha Pushtronex
- Repatha SureClick

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concurrent use of Juxtapid, Kynamro, or Praluent. |
| Required Medical Information | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history |
| Age Restrictions | ASCVD/HeFH/Primary Hyperlipidemia - 18 yo and older, HoFH 13 yo and older. |
| Prescriber Restrictions | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders |
| Coverage Duration | Approve for 3 years for ASCVD/HeFH/HoFH. Approve for 1 year for primary hyperlipidemia. |
| Other Criteria | Hyperlipidemia with HeFH - approve if: 1) diagnosis of HeFH AND 2) tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or Crestor greater than or equal to 20 mg daily) and LDL remains 70 mg/dL or higher unless pt is statin intolerant defined by experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the symptoms resolved upon discontinuation. Hyperlipidemia with ASCVD -approve if: 1) has one of the following conditions: prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND 2) tried ONE high intensity statin (defined above) and LDL remains 70 mg/dL or higher unless pt is statin intolerant (defined above). HoFH - approve if: 1) has one of the following: a) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR b) untreated LDL greater than 500 mg/dL (prior to treatment), OR c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha, Kynamro or Juxtapid), OR d) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) tried ONE high intensity statin |

| PA Criteria | Criteria Details |
|-------------|---|
| | <p>(defined above) for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if all of the following are met: 1) coronary artery calcium or calcification (CAC) score 300 Agatston units or higher, AND 2) tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above).</p> |

REVLIMID

Products Affected

- Revlimid

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Revlimid for a Covered Use. Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Follicular Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis, Castleman's Disease, Hodgkin lymphoma (Classical), Marginal Zone Lymphoma, Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis and previous therapies or drug regimens tried. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | MCL-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). Diffuse, Large B Cell Lymphoma (Non-Hodgkin's Lymphoma)-approve if the pt has tried one other medication treatment regimen. Myelofibrosis-approve if the pt has tried one other therapy. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve if the pt has tried one other chemotherapy regimen. |

RINVOQ

Products Affected

- Rinvoq ER

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concurrent use with a biologic or with a targeted synthetic DMARD. Concurrent use with other potent immunosuppressants. |
| Required Medical Information | Diagnosis, concurrent medications, previous drugs tried. |
| Age Restrictions | 18 years and older |
| Prescriber Restrictions | RA, prescribed by or in consultation with a rheumatologist. |
| Coverage Duration | Authorization will be for 3 months initial, 3 years cont. |
| Other Criteria | RA initial-approve if the patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). Continuation Therapy - Patient must have responded, as determined by the prescriber |

ROZLYTREK

Products Affected

- Rozlytrek

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis |
| Age Restrictions | Solid Tumors-12 years and older |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | <p>Solid Tumors-Approve if the patient meets the following criteria (A, B, and C): A) The patient has locally advanced or metastatic solid tumor AND B) The patient's tumor has neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND C) The patient meets one of the following criteria (i or ii): i. The patient has progressed on prior therapies OR ii. There are no acceptable standard therapies and the medication is used as initial therapy.</p> <p>Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease.</p> |

RUBRACA

Products Affected

- Rubraca

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Rubraca for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3years |
| Other Criteria | Initial Therapy-treatment. Approve for 3 years 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. Recurrence, Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-i. The patient is in a complete response or a partial response to platinum-based chemotherapy. |

RYDAPT

Products Affected

- Rydapt

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on midostaurin for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | For AML, FLT3 status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | AML-approve if the patient is FLT3-mutation positive as detected by an approved test. |

SAMSCA

Products Affected

- Samsca

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion). |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 30 days |
| Other Criteria | Hyponatremia - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on Samsca and has received less than 30 days of therapy. |

SIMPONI

Products Affected

- Simponi

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus patients already started on golimumab (IV or SC) for a covered use. |
| Exclusion Criteria | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD |
| Required Medical Information | Diagnosis, concurrent medications, previous therapies tried. |
| Age Restrictions | N/A |
| Prescriber Restrictions | RA/Ankylosing spondylitis, prescribed by or in consultation with a rheumatologist. Psoriatic arthritis, prescribed by or in consultation with a rheumatologist or dermatologist. UC-prescribed by or in consultation with a gastroenterologist |
| Coverage Duration | 3 mos initial, 3 years cont |
| Other Criteria | AS approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx. PsA-approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx, Stelara, Otezla, Orencia, Xeljanz/XR. RA, approve if the patient has tried two of the following: Enbrel, Humira, Orencia, Rinvoq or Xeljanz/XR. Ulcerative colitis - approve if the patient has had a trial with Humira. Cont tx - must have a response to therapy as according to prescriber |

SKYRIZI

Products Affected

- Skyrizi subcutaneous syringe kit

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

SOLARAZE

Products Affected

- diclofenac sodium topical gel 3 %

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 6 months. |
| Other Criteria | N/A |

SPRYCEL

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus GIST, chondrosarcoma or chordoma and patients already started on Sprycel for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis for which Sprycel is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | For CML, new patient must have Ph-positive CML for approval of Sprycel. For ALL, new patient must have Ph-positive ALL for approval of Sprycel. GIST - has D842V mutation AND previously tried Sutent and Gleevec. |

STELARA

Products Affected

- Stelara subcutaneous

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus approve Stelara SC in patients already started on Stelara (IV/SC) for a Covered Use. |
| 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 | Adults-PsA and CD. PP-12 years and older. |
| Prescriber Restrictions | Plaque psoriasis.Prescribed by or in consultation with a dermatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. CD-prescribed by or in consultation with a gastroenterologist. |
| Coverage Duration | PP/PsA Init-3mo,CD load-approve 1 dose IV,CD post IV load-approve SC 3 mo,cont tx-approve SC 3 yr |
| Other Criteria | PP initial - approve Stelara SC. CD, induction therapy - approve single dose of IV formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD (eg, azathioprine, 6-MP, MTX, certolizumab, vedolizumab, adalimumab, infliximab). CD, initial therapy (only after receiving single IV loading dose) - 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 cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy. |

STIVARGA

Products Affected

- Stivarga

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus Soft tissue Sarcoma. Plus patients already started on Stivarga for a Covered Use. |
| 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. |

SUTENT

Products Affected

- Sutent

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Sutent for a Covered Use. Advanced, unresectable neuroendocrine tumors, 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. |
| 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 Sutent will be used as a single agent and the patient has previously tried imatinib (Gleevec) OR Sutent will be used in combination with Afinitor AND the patient has tried TWO of the following: imatinib, Sutent, or Stivarga. 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. |

SYMDEKO

Products Affected

- Symdeko

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| Exclusion Criteria | Patients with unknown CFTR gene mutations |
| Required Medical Information | Diagnosis, specific CFTR gene mutations |
| Age Restrictions | 6 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF |
| Coverage Duration | 3 years |
| Other Criteria | CF - must have at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A G, S945L, S977F, F1052V, E831X, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G A, 3272-26A G, or 3849 + 10kbC T OR the patient has two copies of the F508del mutation |

SYMLIN

Products Affected

- SymlinPen 120
- SymlinPen 60

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D worded as patient has type 1 or 2 diabetes mellitus. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | N/A |

SYPRINE

Products Affected

- trientine

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Trientine for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, medication history, pregnancy status, disease manifestations |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician. |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | For Wilson's Disease, approve if the patient meets ONE of the following: 1) Patient has tried a penicillamine product and per the prescribing physician the patient is intolerant to penicillamine therapy, OR 2) Per the prescribing physician, the patient has clinical features indicating the potential for intolerance to penicillamine therapy (ie, history of any renal disease, congestive splenomegaly causing severe thrombocytopenia, autoimmune tendency), OR 3) Per the prescribing physician, the patient has a contraindication to penicillamine therapy, OR 4) The patient has neurologic manifestations of Wilson's disease, OR 5) The patient is pregnant. |

TAFAMIDIS

Products Affected

- Vyndaqel

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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 patient meets all of the following: patient has genetic testing to identify a transthyretin (TTR) mutation (e.g., Val122Ile mutation, Thr60Ala mutation) or wild-type amyloidosis AND diagnosis was confirmed by one of the following (i or ii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy) OR ii. Amyloid deposits are identified on cardiac biopsy 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). |

TAFINLAR

Products Affected

- Tafinlar

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients with Differentiated Thyroid Cancer. Plus patients with Colon or Rectal Cancer. Plus patients already started on Tafinlar for a Covered Use. |
| 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. 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. |

TAGRISSO

Products Affected

- Tagrisso

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | NSCLC - prior therapies and EGFR T790M mutation or EGFR exon 19 deletion or exon 21 (L858R) substitution |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | NSCLC - Must have metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC as detected by an approved test AND has progressed on one of the EGFR tyrosine kinase inhibitors (e.g., Tarceva, Iressa, Vizimpro or Gilotrif) therapy OR Advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who have EGFR exon 19 deletion or exon 21 (L858R) substitution as detected by an approved test. |

TALZENNA

Products Affected

- Talzenna

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Talzenna for a covered use. |
| 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 |

TARCEVA

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus Renal Cell Carcinoma and Bone Cancer-Chordoma. Plus patients already started on erlotinib for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Advanced, recurrent, or metastatic non small cell lung cancer (NSCLC), EGFR mutation or gene amplification status. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | Metastatic NSCLC, approve if the patient meets both of the following: 1. patient is EGFR mutation positive, AND 2. patient has EGFR exon 19 deletions OR exon 21 (L858R) substitution mutations as detected by an FDA-approved test. Advanced RCC, approve if the patient has non-clear cell histology. |

TARGRETIN ORAL

Products Affected

- bexarotene

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. |
| 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 | Initial therapy- approve if the following criteria are met: Patient has tried ONE oral retinoid, methotrexate, or phototherapy. (NOTE: An exception to the requirement for a trial of an oral retinoid, methotrexate, or phototherapy can be made if the patient has already used one of the following: interferons, histone deacetylase [HDAC] inhibitors, Poteligeo or extracorporeal photopheresis. These patients are not required to step back and try an oral retinoid, methotrexate, or phototherapy) OR the patient has a type of CTCL (e.g., folliculotropic disease, advanced disease) that, according to the prescribing physician, requires treatment with oral bexarotene capsules. If brand Targretin is requested, the patient has tried and cannot take generic bexarotene capsules due to a formulation difference in the inactive ingredient(s) between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction. Continuation therapy- approve if brand Targretin is requested, the patient has tried and cannot take generic bexarotene capsules due to a formulation difference in the inactive ingredient(s) between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction. |

TARGRETIN TOPICAL

Products Affected

- Targretin topical

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. |
| 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 | Initial therapy-approve if the patient has tried a topical corticosteroid and topical imiquimod cream (Aldara, generics, Zyclara). (NOTE: An exception to the requirement for a trial of a topical corticosteroid and topical imiquimod cream can be made if the patient has already used one of the following: a skin-directed therapy, e.g., topical chemotherapy, topical retinoids, local radiation, phototherapy [UVB, NB-UVB, PUVA], TSEBT, or a systemic therapy, e.g., oral retinoids, interferons, histone deacetylase [HDAC] inhibitors, extracorporeal photopheresis, methotrexate, systemic chemotherapeutic agents, Poteligeo). These patients are not required to step back and try a topical corticosteroid and topical imiquimod cream). |

TASIGNA

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tasigna for a Covered Use. Plus Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST). |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis for which Tasigna is being used. For indication of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and ALL, prior therapies tried. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 12 months. |
| Other Criteria | For CML, new patient must have Ph-positive CML for approval of Tasigna. For GIST, patient must have tried TWO of the following - sunitinib (Sutent), imatinib (Gleevec), or regorafenib (Stivarga). For ALL, Approve if the patient has tried one other tyrosine kinase inhibitor that is used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc). |

TAZORAC

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Cosmetic uses |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | PP/acne vulgaris - 3 years, other - 12 months. |
| Other Criteria | Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene). |

TECFIDERA

Products Affected

- Tecfidera

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concurrent use with other disease-modifying agents used for multiple sclerosis (MS). |
| Required Medical Information | MS, patient must have a relapsing form of MS (RRMS, SPMS with relapses, or PRMS). MS, previous MS therapies tried. |
| 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 |

THALOMID

Products Affected

- Thalomid

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Thalomid for a Covered Use, Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, Systemic Light Chain Amyloidosis, AIDS related Kaposi's Sarcoma, Castleman's Disease (relapsed/refractory or progressive). |
| 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 | Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Myelofibrosis, approve if the patient has tried one other therapy (eg, ruxolitinib [Jakafi], danazol, epoetin alfa [Epogen/Procrit], prednisone, lenalidomide [Revlimid], hydroxyurea). Prurigo nodularis, approve. Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). AIDS Related Kaposi's Sarcoma-approve if the patient has tried one regimen and has relapsed or refractory disease. |

TIBSOVO

Products Affected

- Tibsovo

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Tibsovo for a covered use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, IDH1 Status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | AML- approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. |

TOPICAL AGENTS FOR ATOPIC DERMATITIS

Products Affected

- pimecrolimus
- tacrolimus topical

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| 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. |

TOPICAL RETINOID PRODUCTS

Products Affected

- tretinoin topical

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| 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 |

TOPICAL TESTOSTERONE PRODUCTS

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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 has been confirmed by a low for age serum testosterone (total or free) level defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all |

| PA Criteria | Criteria Details |
|-------------|---|
| | <p>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.]</p> |

TOPIRAMATE/ZONISAMIDE

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| 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 3 years. |
| Other Criteria | N/A |

TRANSDERMAL FENTANYL

Products Affected

- fentanyl

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| 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 (with no cancer diagnosis, not in long term care facility and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been 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. 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. |

TRANSMUCOSAL FENTANYL DRUGS

Products Affected

- fentanyl citrate buccal lozenge on a handle

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| 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. |

TYKERB

Products Affected

- Tykerb

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus bone cancer-chordoma, EGFR positive recurrent disease. Plus patients already started on Tykerb for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis for which Tykerb 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 Tykerb will be used in combination with Xeloda or Herceptin and the patient has received prior therapy with Herceptin. HER2-positive HR positive metastatic breast cancer, approve if the patient is a man receiving a LHRH agonist, a premenopausal or perimenopausal woman receiving ovarian suppression/ablation with a LHRH agonist, or a postmenopausal woman and Tykerb 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. |

TYMLOS

Products Affected

- Tymlos

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, calcitonin nasal spray [Fortical], Forteo), except calcium and Vitamin D. Previous use of Tymlos and/or Forteo for a combined total no greater than 2 years duration during a patient's lifetime. |
| Required Medical Information | Previous medications tried, renal function |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 2 years of therapy over a patient's lifetime |
| Other Criteria | Treatment of PMO, approve if the patient meets ONE of the following criteria: patient has tried one oral bisphosphonate or cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or patient cannot remain in an upright position post oral bisphosphonate administration or patient 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 patient has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR patient has severe renal impairment or CKD, OR patient has had an osteoporotic fracture or fragility fracture |

UPTRAVI

Products Affected

- Uptravi

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients currently taking Uptravi. |
| Exclusion Criteria | N/A |
| Required Medical Information | Confirmation of right heart catheterization (select populations), medication history. |
| Age Restrictions | N/A |
| Prescriber Restrictions | PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist. |
| Coverage Duration | 3 years |
| Other Criteria | Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Right heart catheterization is NOT required in pts who are currently receiving Uptravi or another agent indicated for PAH (WHO group 1). Patient must meet a) OR b): a) tried TWO or is currently taking TWO oral therapies for PAH (either alone or in combination) each 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). |

VENCLEXTA

Products Affected

- Venclexta
- Venclexta Starting Pack

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus Small Lymphocytic Lymphoma (SLL). Plus Mantle Cell Lymphoma. Plus patients currently taking Venclexta for a Covered Use. |
| 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. |

VERZENIO

Products Affected

- Verzenio

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA approved indications not otherwise excluded from Part D. Plus men with breast cancer. |
| Exclusion Criteria | N/A |
| Required Medical Information | HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | 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 in patients who have not had disease progression while on Kisqali, Ibrance or Verzenio when the pt meets ONE of the following 1. Pt is postmenopausal and Verzenio will be used in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Verzenio will be used in combination with anastrozole, exemestane, or letrozole 3. Patient is postmenopausal and meets the following conditions: Verzenio will be used in combination with Faslodex. 4. patient is premenopausal or perimenopausal and meets the following conditions: The patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND Verzenio will be used in combination with Faslodex 5. patient is postmenopausal, premenopausal/ perimenopausal (patient is receiving ovarian suppression/ablation with GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man (a man is defined as an individual with the biological traits of a man, |

| PA Criteria | Criteria Details |
|-------------|--|
| | <p>regardless of the individual's gender identity or gender expression) and meets the following conditions: Verzenio will be used as monotherapy AND patient's breast cancer has progressed on at least one prior endocrine therapy (e.g., anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus Afinitor, Faslodex, Afinitor plus Faslodex or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol) AND patient has tried chemotherapy for metastatic breast cancer. 6. pt is a man who is receiving GnRH agonist AND Verzenio with be used in combination with anastrozole, exemestane, tamoxifen or letrozole 7. Patient is a man and Verzenio will be used in combination with Faslodex</p> |

VITRAKVI

Products Affected

- Vitrakvi

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| 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. |

VIZIMPRO

Products Affected

- Vizimpro

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D.Plus patients already started on Vizimpro for a covered use. |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, EGFR status, exon deletions or substitutions |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Metastatic-NSCLC-Epidermal Growth Factor Receptor (EGFR) mutation positive AND has epidermal growth factor receptor (EGFR) exon 19 deletion as detected by an approved test OR exon 21 (L858R) substitution mutations as detected by an approved test. |

VOTRIENT

Products Affected

- Votrient

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus, patients already taking Votrient for a Covered Use. Differentiated (ie, papillary, follicular, Hurthle cell) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST). |
| 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 other non-lipogenic (non-adipocytic) soft tissue 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. Advanced RCC - approve. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease OR the patient has complete clinical remission after receiving primary treatment with chemotherapy and/or surgery. 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). |

XALKORI

Products Affected

- Xalkori

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus soft tissue sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation, Plus peripheral T-Cell Lymphoma - Anaplastic Large Cell Lymphoma (ALCL), Plus NSCLC with high level MET amplification or MET Exon 14 skipping mutation. Plus patients already started on crizotinib for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | For the FDA-approved indication of NSCLC for patients new to therapy, ALK status, high level MET amplification status, MET Exon 14 skipping mutation, and ROS1 rearrangement required. For soft tissue sarcoma IMT, ALK translocation. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | NSCLC, patient new to therapy must be ALK-positive, have high level MET amplification, have MET Exon 14 skipping mutation, or have ROS1 rearrangement for approval. For IMT, patient new to therapy must have ALK translocation for approval. |

XELJANZ

Products Affected

- Xeljanz
- Xeljanz XR

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Xeljanz/XR for a Covered Use. |
| Exclusion Criteria | Concurrent use with a biologic 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, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. |
| Coverage Duration | Authorization will be for 3 months initial, 3 years cont. |
| Other Criteria | RA/PsA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to 'step back' and try a conventional synthetic DMARD). Continuation Therapy - Patient must have responded, as determined by the prescriber |

XENAZINE

Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist. |
| Coverage Duration | Authorization will be for 1 year. |
| Other Criteria | N/A |

XERMELO

Products Affected

- Xermelo

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, previous therapy, concomitant therapy |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| 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]) for at least 3 consecutive months, 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. |

XOLAIR

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Seasonal or perennial allergic rhinitis (SAR or PAR). |
| Exclusion Criteria | Concurrent use with an Interleukin (IL) Antagonist Monoclonal Antibody |
| Required Medical Information | Moderate to severe persistent asthma and SAR/PAR, baseline IgE level of at least 30 IU/mL. For asthma, patient has a 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). For SAR/PAR, patient has positive skin testing (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach) and/or positive in vitro testing (ie, a blood test for allergen-specific IgE antibodies) for one or more relevant allergens (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach). CIU - must have urticaria for more than 6 weeks, 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. All other diagnoses-12 years and older |
| Prescriber Restrictions | Moderate to severe persistent asthma/SAR/PAR 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. |
| Coverage Duration | Initial tx 4 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 |

| PA Criteria | Criteria Details |
|-------------|---|
| | <p>antagonist, or theophylline, and 2) inadequate control demonstrated by hospitalization for asthma or requirement for systemic corticosteroids to control asthma exacerbation(s). For continued Tx for asthma - patient has responded to therapy as determined by the prescribing physician.</p> <p>SAR/PAR - approve if pt meets all of the following criteria: 1) pt has tried concurrent therapy with at least one drug from 2 of the following classes: an oral non-sedating or low-sedating antihistamine, a nasal antihistamine, a nasal corticosteroid, or montelukast, AND 2) pt has had immunotherapy, is receiving immunotherapy, or will be receiving immunotherapy or has contraindications to immunotherapy. For continued tx SAR/PAR - pt must have responded to therapy as determined by the prescribing physician. For CIU cont tx - must have responded to therapy as determined by the prescribing physician.</p> |

XOSPATA

Products Affected

- Xospata

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

XPOVIO

Products Affected

- Xpovio

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D |
| Exclusion Criteria | N/A |
| Required Medical Information | Diagnosis, prior therapies |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Approve if the if the patient meets ALL of the following (A, B, and C): A) The patient has tried at least two proteasome inhibitors. Note: Examples include Velcade (bortezomib injection), Kyprolis (carfilzomib infusion), Ninlaro (ixazomib capsules) AND B) The patient has tried at least two immunomodulatory drugs. Note: Examples include Revlimid (lenalidomide capsules), Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules) AND C) The patient has tried an anti-CD38 monoclonal antibody.Note: For example, Darzalex (daratumumab infusion). |

XTANDI

Products Affected

- Xtandi

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus non-metastatic, castration-resistant prostate cancer, Plus patients already started on Xtandi for a Covered Use. |
| 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 | N/A |

XYREM

Products Affected

- Xyrem

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | N/A |
| Required Medical Information | Medication history |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescribed by a sleep specialist physician or a Neurologist |
| Coverage Duration | 12 months. |
| Other Criteria | For Excessive daytime sleepiness (EDS) in patients with narcolepsy - approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dexamethylphenidate, dextroamphetamine), modafinil, or Nuvigil. |

YONSA

Products Affected

- Yonsa

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Yonsa for a covered use. |
| 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. |

ZARXIO

Products Affected

- Zarxio

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D worded more broadly as cancer patients receiving myelosuppressive chemotherapy, patients with acute myeloid leukemia (AML) receiving chemotherapy, cancer patients receiving bone marrow transplantation (BMT), patients undergoing peripheral blood progenitor cell (PBPC) collection and therapy, and patients with severe chronic neutropenia [SCN] (e.g., congenital neutropenia, cyclic neutropenia, idiopathic neutropenia). 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). |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | AML, HIV/AIDS, MDS - adults |
| Prescriber Restrictions | Cancer/AML, MDS, ALL, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. |
| Coverage Duration | chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,AA,ALL,BMT- 3 mo.All 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, |

| PA Criteria | Criteria Details |
|-------------|---|
| | <p>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, Neulasta, Neupogen) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm³], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).</p> |

ZEJULA

Products Affected

- Zejula

| PA Criteria | Criteria Details |
|------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Zejula for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | 3 years |
| Other Criteria | Recurrent ovarian, fallopian tube, or primary peritoneal cancer - approve if the patient has had a complete or partial response after platinum-based chemotherapy regimen AND Zejula is requested for maintenance treatment. |

ZELBORAF

Products Affected

- Zelboraf

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus, 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, colon or rectal cancer and patients already started on vemurafenib for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | BRAFV600 mutation status required. |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | Melanoma, patient new to therapy must have BRAFV600 mutation for approval AND have unresectable, advanced or metastatic melanoma. HCL - must have relapsed or refractory disease AND tried at least one therapy for hairy cell leukemia. Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy. 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. |

ZYDELIG

Products Affected

- Zydelig

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus Marginal Zone Lymphoma. |
| 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 one prior therapy. Marginal Zone Lymphoma/Follicular B-Cell Non-Hodgkin Lymphoma/SLL - approve if the patient has tried two prior therapies. |

ZYKADIA

Products Affected

- Zykadia

| PA Criteria | Criteria Details |
|------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus Soft Tissue Sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Plus patients with NSCLC with ROS1 Rearrangement-First-line therapy. |
| 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 |

ZYTIGA

Products Affected

- abiraterone
- Zytiga oral tablet 250 mg, 500 mg

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. Plus Prostate Cancer-Regional Risk Group or Locally Advanced. Plus Prostate Cancer - Metastatic (Castration-Resistant or Castration-Sensitive), Post-External Beam Radiation Therapy (EBRT). Plus, patients already started on Zytiga for a Covered Use. |
| Exclusion Criteria | N/A |
| Required Medical Information | N/A |
| Age Restrictions | N/A |
| Prescriber Restrictions | N/A |
| Coverage Duration | Authorization will be for 3 years. |
| Other Criteria | Prostate Cancer-Metastatic, Castration-Resistant (mCRPC) and Metastatic, Castration-Sensitive (mCSPC), high risk-Approve if Zytiga is being used in combination with prednisone. Prostate Cancer - Regional Risk Group or Locally Advanced. Approve if the patient meets all of the following criteria (A, B, and C): A) Zytiga is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i or ii): i. Zytiga with prednisone is used in combination with gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide acetate for injection], Lupron Depot [leuprolide acetate for depot suspension], Trelstar [triptorelin pamoate for injectable suspension], Zoladex [goserelin acetate implant], Vantas [histrelin acetate subcutaneous implant]) OR ii. Patient has had an orchiectomy. Prostate Cancer - Metastatic (Castration-Resistant or Castration-Sensitive), Post-External Beam Radiation Therapy (EBRT)-Approve if the patient meets all of the following criteria (A, B, C, D, and E): A) Zytiga is used in combination with prednisone AND B) Patient meets one of the following criteria (i, ii, or iii): i. Zytiga with prednisone is |

| PA Criteria | Criteria Details |
|-------------|---|
| | <p>used in combination with gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide acetate for injection], Lupron Depot [leuprolide acetate for depot suspension], Trelstar [triptorelin pamoate for injectable suspension], Zoladex [goserelin acetate implant], Vantas [histrelin acetate subcutaneous implant]) OR ii. Zytiga with prednisone is used in combination with GnRH antagonist (e.g., Firmagon [degarelix for injection]) OR iii. Patient has had an orchiectomy. C) Patient meets one of the following criteria (i or ii): i. There is an increase in prostate specific antigen (PSA) after EBRT OR ii Patient has had a positive digital rectal exam (DRE) after EBRT AND D) Patient is not a candidate for local therapy AND E) Patient has had a positive bone scan.</p> |

PART B VERSUS PART D

Products Affected

- Abelcet
- acetylcysteine
- Actimmune
- acyclovir sodium intravenous solution
- albuterol sulfate inhalation solution for nebulization 0.63 mg/3 mL, 1.25 mg/3 mL, 2.5 mg /3 mL (0.083 %), 5 mg/mL
- AmBisome
- Aminosyn II 10 %
- Aminosyn II 15 %
- Aminosyn-PF 10 %
- Aminosyn-PF 7 % (sulfite-free)
- amphotericin B
- aprepitant
- azathioprine
- Bethkis
- budesonide inhalation
- caspofungin
- Clinimix 5%/D15W Sulfite Free
- Clinimix 5%/D25W sulfite-free
- Clinimix 4.25%/D10W Sulf Free
- Clinimix 4.25%/D5W Sulfite Free
- Clinimix 4.25%-D25W sulf-free
- Clinimix 5%-D20W(sulfite-free)
- cromolyn inhalation
- cyclophosphamide oral capsule
- cyclosporine modified
- cyclosporine oral capsule
- dronabinol
- Emend oral suspension for reconstitution
- Engerix-B (PF) intramuscular syringe
- Engerix-B Pediatric (PF) intramuscular syringe
- Envarsus XR
- Firmagon kit w diluent syringe
- Gengraf oral capsule 100 mg, 25 mg
- Gengraf oral solution
- granisetron HCl oral
- Hepatamine 8%
- Intralipid intravenous emulsion 20 %
- Intron A injection
- ipratropium bromide inhalation
- ipratropium-albuterol
- levalbuterol HCl
- methotrexate sodium
- methotrexate sodium (PF) injection solution
- methylprednisolone oral tablet
- Millipred oral tablet
- mycophenolate mofetil
- mycophenolate sodium
- Nebupent
- Nephramine 5.4 %
- ondansetron
- ondansetron HCl oral
- Perforomist
- Plenamine
- prednisolone sodium phosphate oral tablet, disintegrating
- Prednisone Intensol
- prednisone oral tablet
- Premasol 10 %
- Premasol 6 %
- Prograf oral granules in packet
- Pulmozyme
- Rapamune oral solution
- Recombivax HB (PF) intramuscular suspension 10 mcg/mL, 40 mcg/mL
- Recombivax HB (PF) intramuscular syringe
- Sandimmune oral solution
- sirolimus
- Synribo
- tacrolimus oral
- tobramycin in 0.225 % NaCl
- Travasol 10 %
- Trelstar intramuscular suspension for reconstitution
- TrophAmine 10 %
- Trophamine 6%
- Varubi oral
- Xatmep
- Xgeva
- Zortress

Details

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

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