



Prior Authorization Criteria

2020 MCORE PH

Last Updated: 11/01/2020

## ACTEMRA SC (EH)

### Products Affected

- Actemra Actpen
- Actemra INJ 162MG/0.9ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance (TF/C/I) to both Enbrel (etanercept) and Humira (adalimumab) OR for continuation of prior Actemra therapy if within the past 120 days. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. Trial and failure, contraindication, or intolerance to a glucocorticoid (i.e., prednisone). Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. TF/C/I to one of the following: NSAID or systemic glucocorticoid. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. TF/C/I to one of the following nonbiologic DMARDs: Arava (leflunomide) or Rheumatrex/Trexall (methotrexate). One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab) OR for continuation of prior Actemra therapy if within the past 120 days.
Age Restrictions	N/A
Prescriber Restrictions	RA, GCA, SJIA, PJIA (Initial): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	RA, GCA, SJIA, PJIA (initial, reauth): plan year

<b>Other Criteria</b>	RA, GCA, SJIA, PJIA (Reauth): Documentation of positive clinical response to Actemra therapy.
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# ADEMPAS

## Products Affected

- Adempas

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. Chronic thromboembolic pulmonary hypertension (CTEPH): One of the following: A) Both of the following: 1) Diagnosis of inoperable or persistent/recurrent CTEPH and 2) CTEPH is symptomatic OR B) Patient is currently on any therapy for the diagnosis of CTEPH.
Age Restrictions	N/A
Prescriber Restrictions	PAH, CTEPH: Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH, CTEPH: plan year
Other Criteria	N/A

# AFINITOR

## Products Affected

- Afinitor
- Afinitor Disperz
- Everolimus TABS 2.5MG, 5MG, 7.5MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Advanced Neuroendocrine Tumors (NET): Diagnosis (Dx) of neuroendocrine tumors of pancreatic origin, gastrointestinal origin, lung origin, or thymic origin. Disease is progressive. Disease is unresectable, locally advanced or metastatic. Advanced Renal Cell Carcinoma: Dx of renal cell cancer. One of the following: (1) disease has relapsed or (2) both of the following: medically or surgically unresectable tumor and diagnosis of stage IV disease. One of the following: Patient with non-clear cell histology or patient with predominantly clear cell histology. Renal cell carcinoma patient with predominantly clear cell histology: Trial and failure, contraindication, or intolerance (TF/C/I) to at least one prior systemic therapy [eg, Nexavar (sorafenib), Sutent (sunitinib), Opdivo (nivolumab), Cabometyx (cabozantinib)]. Renal angiomyolipoma with tuberous sclerosis complex (TSC): Dx of renal angiomyolipoma and TSC, not requiring immediate surgery. Subependymal Giant Cell Astrocytoma (SEGA) with tuberous sclerosis (TS): Dx of SEGA associated with TS. Patient is not a candidate for curative surgical resection. Breast Cancer: Dx of recurrent or metastatic breast cancer. One of the following: Disease is hormone receptor positive (HR+) [i.e., estrogen-receptor-positive (ER+) or progesterone-receptor-positive (PR+)] OR both of the following: disease is HR- and disease has clinical characteristics that predict a HR+ tumor. Disease is HER2-negative. One of the following: Patient is a postmenopausal woman, patient is a premenopausal woman being treated with ovarian ablation/suppression, or patient is male. One of the following: A) Both of the following: a) one of the following: 1) Disease progressed while on or within 12 months of non-steroidal aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole)] therapy or 2) patient was treated with tamoxifen at any time AND b) Used in combination with Aromasin (exemestane) OR B) Used in combination with Fulvestrant or Tamoxifen.</p>

<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	NET, SEGA with TS: Prescribed by or in consultation with an oncologist or neuro-oncologist. Renal Angiomyolipoma with TSC: Prescribed by or in consultation with a nephrologist. TSC seizures: Prescribed by or in consultation with a neurologist. All other uses: Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	For Afinitor Disperz Only: TSC Associated Partial-Onset Seizures: Dx of TSC associated partial-onset seizures. Used as adjunctive therapy. All uses: Approve for continuation of prior therapy if within the past 120 days.

# AIMOVIG

## Products Affected

- Aimovig

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Episodic Migraines (EM) (initial): Diagnosis of EM with both of the following: 1) Less than 15 headache days per month and 2) Patient has 4 to 14 migraine days per month. Trial and failure (after a trial of at least two months), contraindication, or intolerance to two of the following prophylactic therapies: a) Amitriptyline (Elavil), b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol, c) Divalproex sodium (Depakote/Depakote ER), d) Topiramate (Topamax), e) Venlafaxine (Effexor). Chronic Migraines (CM) (initial): Diagnosis of CM with both of the following: 1) Greater than or equal to 15 headache days per month and 2) Greater than or equal to 8 migraine days per month. Trial and failure (after a trial of at least two months), contraindication, or intolerance to two of the following prophylactic therapies: a) Amitriptyline (Elavil), b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol, c) Divalproex sodium (Depakote/Depakote ER), d) OnabotulinumtoxinA (Botox), e) Topiramate (Topamax), f) Venlafaxine (Effexor).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	EM (init): Prescribed by or in consultation with one of the following specialists with expertise in the treatment of episodic migraine: neurologist, pain specialist, headache specialist. CM (init): Prescribed by or in consultation with one of the following specialists with expertise in the treatment of chronic migraine: neurologist, pain specialist, headache specialist
<b>Coverage Duration</b>	EM, CM (initial, reauth): Plan year.
<b>Other Criteria</b>	EM, CM (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity.

# ALECENSA

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## Products Affected

- Alecensa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Metastatic non-small cell lung cancer (NSCLC): Diagnosis of metastatic or recurrent NSCLC. Patient has anaplastic lymphoma kinase (ALK)-positive disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# ALOSETRON

## Products Affected

- Alosetron Hydrochloride

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Irritable bowel syndrome (IBS) (Initial): Exclude if patient is of the male gender.
Required Medical Information	IBS (Initial): Diagnosis of chronic severe diarrhea-predominant IBS. IBS (Reauthorization): Symptoms of IBS continue to persist. Documentation of positive clinical response to therapy.
Age Restrictions	IBS (Initial): 18 years and older.
Prescriber Restrictions	N/A
Coverage Duration	IBS (Initial): 12 weeks. IBS (Reauthorization): 6 months.
Other Criteria	IBS (initial): Trial and failure, contraindication, or intolerance to an anti-diarrheal agent [eg, loperamide].



# ALPHA - 1 PROTEINASE INHIBITORS

## Products Affected

- Aralast Np INJ 1000MG
- Glassia
- Prolastin-c INJ 1000MG
- Zemaira

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Alpha-1 antitrypsin (AAT) deficiency: Diagnosis of congenital AAT deficiency. One of the following: Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous) or Other rare AAT disease-causing alleles associated with serum AAT level less than 11 $\mu$ mol/L [eg, Pi(Malton, Malton)]. Circulating serum concentration of AAT level less than 11 $\mu$ mol/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry). One of the following: 1) FEV1 level is between 30% and 65% of predicted, or 2) patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment. Continued optimal conventional treatment for emphysema (eg, bronchodilators). Diagnosis of emphysema.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	AAT deficiency: plan year
Other Criteria	N/A

# ALUNBRIG

## Products Affected

- Alunbrig

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic or recurrent NSCLC and tumor is anaplastic lymphoma kinase (ALK)-positive.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days

# AMBRISENTAN

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## Products Affected

- Ambrisentan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH: Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: plan year
Other Criteria	N/A

## ANADROL - 50

### Products Affected

- Anadrol-50

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acquired Aplastic Anemia: Diagnosis of acquired aplastic anemia. Congenital aplastic anemia: Diagnosis of congenital aplastic anemia (Fanconi anemia). Myelofibrosis: Diagnosis of myelofibrosis. Hypoplastic Anemia due to myelotoxic drugs: Diagnosis of hypoplastic anemia due to myelotoxic drugs. Pure Red Cell Aplasia: Diagnosis of pure red cell aplasia. Chronic Renal failure: Diagnosis of chronic renal failure.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Acquired Aplastic Anemia: One of the following: Trial and failure, contraindication, or intolerance to antilymphocyte/antithymocyte globulin (eg, Atgam, Thymoglobulin) or antilymphocyte/antithymocyte globulin plus corticosteroid treatment, OR Used in combination with antilymphocyte/antithymocyte globulin (eg, Atgam, Thymoglobulin) or antilymphocyte/antithymocyte globulin plus corticosteroids (eg, methylprednisolone, prednisone). Hypoplastic Anemia Due to Myelotoxic Drugs: Trial and failure, contraindication, or intolerance to Aranesp (darbepoetin alfa) or Epogen/Procrit (epoetin alfa). Pure Red Cell Aplasia: Trial and failure, contraindication, or intolerance to immunosuppressive therapy (eg, cyclosporine A, prednisone). Chronic Renal Failure: Trial and failure, contraindication, or intolerance to Aranesp (darbepoetin alfa) or Epogen/Procrit (epoetin alfa).

# APOKYN

## Products Affected

- Apokyn INJ 30MG/3ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Patient is not using Apokyn with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron).
Required Medical Information	Advanced Parkinson's disease diagnosis. Unable to control off symptoms with at least one adequate combination of conventional oral therapy [eg, Comtan (entacapone), Mirapex (pramipexole), Requip (ropinirole), Sinemet (carbidopa/levodopa), Stalevo (carbidopa/levodopa/entacapone), Symmetrel (amantadine), Tasmar (tolcapone)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	Plan year
Other Criteria	N/A

# APREPITANT

## Products Affected

- Aprepitant

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute Chemotherapy-induced Nausea and Vomiting (CINV): Patient is currently receiving moderately or highly emetogenic chemotherapy. Patient is concurrently on both corticosteroid [eg, Decadron (dexamethasone)] and 5-HT <sub>3</sub> receptor antagonist [eg, Aloxi (palonosetron), Anzemet (dolasetron), Kytril (granisetron), Zofran (ondansetron)]. Delayed Chemotherapy-induced Nausea and Vomiting Prevention: Patient is currently receiving highly emetogenic chemotherapy and corticosteroid [eg, Decadron (dexamethasone)], or patient is receiving an anthracycline [eg, Adriamycin (doxorubicin), Ellence (epirubicin)] and Cytosan (cyclophosphamide), or patient is currently receiving moderately emetogenic chemotherapy and was given Emend (oral or IV) on day 1 of chemotherapy. Postoperative Nausea and Vomiting (PONV): For the prevention of postoperative nausea and vomiting when administered prior to the induction of anesthesia.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Acute CINV, Delayed CINV: plan year. PONV: 1 month
Other Criteria	Subject to Part B vs. Part D review.

# ARCALYST

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## Products Affected

- Arcalyst

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of Cryopyrin-Associated Period Syndromes (CAPS), Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CAPS (initial, reauth): plan year
Other Criteria	N/A

# AURYXIA

## Products Affected

- Auryxia

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Exclude if used for iron deficiency anemia in chronic kidney disease (CKD) not on dialysis.
Required Medical Information	Hyperphosphatemia in chronic kidney disease: Diagnosis of hyperphosphatemia. Patient has chronic kidney disease (CKD). Patient is on dialysis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A



# AUSTEDO

## Products Affected

- Austedo

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chorea associated with Huntington's disease (initial): Diagnosis of Chorea associated with Huntington's disease. Tardive dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication or 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Huntington's disease chorea (initial): Prescribed by a neurologist. Tardive dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist.
<b>Coverage Duration</b>	Initial: 3 months, Reauth: Plan year
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to Austedo therapy.

# AYVAKIT

## Products Affected

- Ayvakit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. Disease is one of the following: unresectable or metastatic. Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Plan Year
Other Criteria	Approve for continuation of therapy if within the past 120 days.

# BALVERSA

## Products Affected

- Balversa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Urothelial Carcinoma: Diagnosis of urothelial carcinoma (UC). One of the following: Locally advanced or metastatic. Patient has fibroblast growth factor receptor (FGFR) 3 or FGFR2 genetic alterations. One of the following: 1) Patient has progressed during or following at least one line of prior chemotherapy or immunotherapy OR 2) Patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# BENLYSTA

## Products Affected

- Benlysta INJ 200MG/ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Systemic Lupus Erythematosus (SLE): (Initial): Diagnosis of active SLE. Autoantibody positive (ie, anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL). Currently receiving at least one standard of care treatment for active SLE (eg, antimalarials [eg, Plaquenil (hydroxychloroquine)], corticosteroids [eg, prednisone], or immunosuppressants [eg, methotrexate, Imuran (azathioprine)]). (Reauthorization): Documentation of positive clinical response to Benlysta therapy.
Age Restrictions	N/A
Prescriber Restrictions	SLE (initial): Prescribed by or in consultation with a rheumatologist
Coverage Duration	SLE (initial and reauth): 6 months
Other Criteria	N/A

# BERINERT

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## Products Affected

- Berinert

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	Plan year
Other Criteria	N/A

# BEXAROTENE

## Products Affected

- Bexarotene
- Targretin GEL

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cutaneous T-cell lymphoma (CTCL): Diagnosis of cutaneous T-cell lymphoma (CTCL).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# BOSULIF

## Products Affected

- Bosulif

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of chronic myelogenous/myeloid leukemia (CML).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# BRAFTOVI

## Products Affected

- Braftovi CAPS 75MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Patient is positive for BRAF V600 mutation. Used in combination with Mektovi (binimetinib). Colorectal Cancer: One of the following diagnoses: Colon Cancer or Rectal Cancer. One of the following: 1) Unresectable or advanced disease or 2) Metastatic disease. Patient has received prior therapy. Patient is positive for BRAF V600E mutation. Used in combination with one of the following: 1) Erbitux (cetuximab) or 2) Vectibix (panitumumab).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days



# BRIVIACT

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## Products Affected

- Briviact ORAL SOLN
- Briviact TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Partial-onset seizures: Diagnosis of partial-onset seizures.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# BRUKINSA

## Products Affected

- Brukinsa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of mantle cell lymphoma (MCL). Patient has received at least one prior therapy for MCL.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist.
Coverage Duration	Plan Year.
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# CABLIVI

## Products Affected

- Cablivi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acquired thrombocytic thrombocytopenic purpura (aTTP): Diagnosis of aTTP. First dose was/will be administered by a healthcare provider as a bolus intravenous injection. Used in combination with immunosuppressive therapy (e.g. rituximab, glucocorticoids). One of the following: 1) Used in combination with plasma exchange or 2) both of the following: patient has completed plasma exchange and less than 59 days have or will have elapsed beyond the last plasma exchange.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	3 months
Other Criteria	N/A

# CABOMETYX

## Products Affected

- Cabometyx

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: a) Trial and failure or intolerance to Nexavar (sorafenib tosylate), or b) Patient has metastatic disease, or c) Patient has extensive liver tumor burden, or d) Patient is inoperable by performance status or comorbidity, or has local disease or local disease with minimal extrahepatic disease only, or e) Both of the following: patient is not a transplant candidate and disease is unresectable.
Age Restrictions	N/A
Prescriber Restrictions	RCC: Prescribed by or in consultation with one of the following: an oncologist or nephrologist. HCC: Prescribed by or in consultation with one of the following: oncologist, hepatologist, or gastroenterologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# CALQUENCE

## Products Affected

- Calquence

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Mantle Cell Lymphoma: Diagnosis of mantle cell lymphoma (MCL) AND patient has received at least one prior therapy for MCL. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Plan Year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

## CARAC (BRAND)

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### Products Affected

- Carac

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Trial and failure or intolerance to generic topical fluorouracil 0.5% cream.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# CAYSTON

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## Products Affected

- Cayston

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic Fibrosis (CF): Diagnosis of CF and lung infection with positive culture demonstrating <i>Pseudomonas aeruginosa</i> infection.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# CHOLBAM

## Products Affected

- Cholbam

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of peroxisomal disorder, 2) patient exhibits at least one of the following: a) liver disease (eg, jaundice, elevated serum transaminases), OR b) steatorrhea, OR c) complications from decreased fat-soluble vitamin absorption (eg, poor growth), AND 3) Cholbam will be used as an adjunctive treatment.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.
Coverage Duration	Initial: 3 months Reauth: Plan year
Other Criteria	All uses (reauth): documentation of positive clinical response to Cholbam therapy.



## CIMZIA (EH)

### Products Affected

- Cimzia

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Rheumatoid Arthritis (RA): Diagnosis (dx) of moderately to severely active RA. Crohn's Disease (CD): Dx of moderately to severely active CD. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), Azathioprine (Imuran), Corticosteroid (eg, prednisone, methylprednisolone), Methotrexate (Rheumatrex, Trexall). One of the following: TF/C/I to Humira (adalimumab) OR for continuation of prior Cimzia therapy if within the past 120 days. Psoriatic Arthritis (PsA): Dx of active psoriatic arthritis. Ankylosing Spondylitis (AS): Dx of active AS. RA, PsA, AS (initial): TF/C/I to Enbrel and Humira OR for continuation of prior Cimzia therapy. Plaque Psoriasis (initial): Dx of moderate to severe plaque psoriasis. TF/C/I to Cosentyx AND either Humira or Enbrel OR for continuation of prior Cimzia therapy if within the past 120 days. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of nr-axSpA with signs of inflammation. TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	CD (initial): Prescribed by or in consultation with a gastroenterologist. RA, AS, nr-axSpA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.
<b>Coverage Duration</b>	All indications (initial/reauth): plan year
<b>Other Criteria</b>	Reauthorization (all indications): Documentation of positive clinical response to Cimzia therapy.

# CINRYZE

## Products Affected

- Cinryze

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For prophylaxis against HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE (prophylaxis): Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	HAE (prophylaxis): plan year
Other Criteria	N/A

# CLOBAZAM

## Products Affected

- Clobazam

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lennox-Gastaut syndrome: Diagnosis of Lennox-Gastaut syndrome. Used for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome. Dravet syndrome: Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with Diacomit.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# CLONIDINE ER

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## Products Affected

- Clonidine Hcl Er

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of attention deficit hyperactivity disorder (ADHD).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# COMETRIQ

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## Products Affected

- Cometriq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medullary Thyroid Cancer (MTC): Diagnosis of one of the following: metastatic medullary thyroid cancer (MTC).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# COPIKTRA

## Products Affected

- Copiktra

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. Disease is relapsed or refractory. Trial and failure, contraindication, or intolerance to at least two prior therapies for CLL/SLL [e.g., Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), etc.]. Follicular Lymphoma: Diagnosis of follicular lymphoma. Disease is relapsed or refractory. Trial and failure, contraindication, or intolerance to at least two prior systemic therapies for follicular lymphoma [e.g., Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Rituxan (rituximab), etc.].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# CORLANOR

## Products Affected

- Corlanor

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic heart failure (CHF) (initial): Diagnosis of CHF. Patient has NYHA Class II, III, or IV symptoms. Patient has a left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm. Patient has a resting heart rate of greater than or equal to 70 beats per minute. One of the following: patient is on a beta-blocker at a maximally tolerated dose, or patient has a contraindication or intolerance to beta-blocker therapy. Patient has been hospitalized for worsening HF in the previous 12 months. Trial and failure, contraindication, or intolerance to maximally tolerated doses of an ACE inhibitor or ARB. Dilated Cardiomyopathy (DCM) (initial): Diagnosis of heart failure due to DCM. Patient has NYHA Class II, III, or IV symptoms. Patient is in sinus rhythm. Patient has an elevated heart rate. Trial and failure, contraindication or intolerance to one of the following: 1) Beta blocker (e.g., bisoprolol, metoprolol succinate extended release), 2) Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), or 3) Diuretic Agent (e.g., spironolactone, furosemide).
Age Restrictions	N/A
Prescriber Restrictions	CHF, DCM (initial): Prescribed by or in consultation with a cardiologist
Coverage Duration	Initial, reauth: plan year
Other Criteria	CHF, DCM (reauth): Documentation of positive clinical response to therapy.

## COSENTYX (EH)

### Products Affected

- Cosentyx
- Cosentyx Sensoready Pen

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication, or intolerance (TF/C/I) to Enbrel (etanercept) OR Humira (adalimumab), OR for continuation of prior Cosentyx therapy if within the past 120 days.</p> <p>Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Cosentyx therapy if within the past 120 days.</p> <p>Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Cosentyx therapy if within the past 120 days.</p> <p>Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with signs of inflammation. TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, meloxicam, naproxen).</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	<p>Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist. Psoriatic Arthritis (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. AS, nr-axSpA (initial): Prescribed by or in consultation with a rheumatologist.</p>
<b>Coverage Duration</b>	Initial and reauth: plan year
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to Cosentyx therapy.



# COTELLIC

## Products Affected

- Cotellic

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable or metastatic melanoma. Disease is positive for BRAF V600E or V600K mutation. Used in combination with Zelboraf (vemurafenib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# CRINONE

## Products Affected

- Crinone

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	All indications: Excluded if for fertility uses.
Required Medical Information	Secondary amenorrhea: Diagnosis of secondary amenorrhea (the absence of menses in women who have already started menstruation who are not pregnant, breastfeeding, or in menopause).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# CUPRIMINE

## Products Affected

- Penicillamine CAPS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Both of the following: 1) One of the following: A) Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration), B) diagnosis of cystinuria AND trial and failure, contraindication, or intolerance to Thiola (tiopronin), or C) Diagnosis of severe active rheumatoid arthritis AND patient has been unresponsive to conventional therapy (e.g., traditional DMARDs, TNF inhibitor, Non-TNF biologic) AND 2) Trial and failure or intolerance to Depen (penicillamine).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# CUVPOSA

## Products Affected

- Cuvposa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic severe drooling: Diagnosis of chronic severe drooling (sialorrhea). Diagnosis of a neurologic condition (e.g., cerebral palsy, mental retardation, Parkinson disease) associated with chronic severe drooling (sialorrhea).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# CYCLOSET

## Products Affected

- Cycloset

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diabetes Mellitus (Initial): Diagnosis of type 2 diabetes mellitus (DM). Both of the following: 1) Trial and failure, contraindication, or intolerance to metformin or a metformin containing product AND 2) Trial and failure, contraindication or intolerance to a medication from one of the following drug classes: sulfonylurea, thiazolidinedione, DPP-4 Inhibitor, SGLT2 inhibitor, GLP-1 receptor agonist, or basal insulin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	DM (Reauth): Patient has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline.

# DALIRESP

## Products Affected

- Daliresp

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD): (Initial) Diagnosis of COPD. History of COPD exacerbations which required the use of systemic corticosteroids, antibiotics, or hospital admission. Trial and failure, intolerance, or contraindication to two prior therapies for COPD.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, reauth: plan year
Other Criteria	COPD (reauth): Documentation of positive clinical response to Daliresp therapy.

# DALVANCE

## Products Affected

- Dalvance

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acute bacterial skin and skin structure infection (aSSSI): One of the following: a) Both of the following: i) Diagnosis (dx) of aSSSI with infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report OR empirical treatment of patients with aSSSI where presence of MRSA infection is likely AND ii) trial and failure to one or resistance, contraindication, or intolerance to all of the following antibiotics: sulfamethoxazole-trimethoprim (SMX-TMP), a tetracycline, clindamycin. OR b) both of the following: i) dx of aSSSI, and infection caused by methicillin-susceptible Staphylococcus aureus (MSSA), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), or Enterococcus faecalis (vancomycin susceptible strains) documented by culture and sensitivity report, and ii) trial and failure to two or resistance, contraindication, or intolerance to all of the following antibiotics: dicloxacillin, a cephalosporin, a tetracycline, amoxicillin/clavulanate, clindamycin, SMX-TMP, a fluoroquinolone.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	aSSSI: 8 Day
<b>Other Criteria</b>	Approve for continuation of therapy upon hospital discharge. aSSSI: Patient does not have osteomyelitis or diabetic foot infection.

## DARBEPOETIN ALFA (NON - PREFERRED)

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### Products Affected

- Aranesp Albumin Free INJ  
100MCG/0.5ML, 100MCG/ML,  
10MCG/0.4ML, 150MCG/0.3ML,  
200MCG/0.4ML, 200MCG/ML,  
25MCG/0.42ML, 25MCG/ML,  
300MCG/0.6ML, 300MCG/ML,  
40MCG/0.4ML, 40MCG/ML,  
500MCG/ML, 60MCG/0.3ML,  
60MCG/ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A



<b>Required Medical Information</b>	<p>Anemia due to Chronic Kidney Disease (CKD) (Initial): Diagnosis of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) within 30 days of request. The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. (Reauth): Diagnosis of CKD. Most recent or average (avg) Hct over 3 mo is 33% or less (Hgb 11 g/dL or less) for patients on dialysis, without ESRD OR Most recent or average (avg) Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis OR Most recent or average (avg) Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Anemia w/ chemo (Initial): Other causes of anemia ruled out. Anemia w/ labs (Hct less than 30%, Hgb less than 10 g/dL) within prior 2 weeks of request. Cancer is non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for minimum of 2 months, or anemia caused by cancer chemo. (Reauth): Anemia by labs (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-tx level. Patient is concurrently on chemo, or will receive concomitant chemo for minimum of 2 months, or anemia is caused by cancer chemo. Anemia in MDS (Init): Diagnosis of MDS. Serum erythropoietin 500 mU/mL or less, or transfusion dependent MDS. (Reauth): Most recent or avg Hct over 3 months was 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	<p>CKD(Init): 6 mo. CKD(reauth):plan yr. Chemo(init, reauth): 3 mo. MDS(init): 3 mo,(reauth): plan yr</p>
<b>Other Criteria</b>	<p>ESRD patients: Coverage is excluded under Medicare Part D for patients with ESRD on dialysis for any indication related or unrelated to treatment of ESRD since the payment for the drug is included in the ESRD PPS payment bundle. NON-ESRD PATIENTS for the following indications: Off-label uses (except Anemia in Myelodysplastic Syndrome (MDS): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.CKD (init, reauth), Chemo (init), MDS (init): Verify Fe eval for adequate Fe stores. All uses (init): One of the following: A) History of use of Retacrit or B) History of intolerance, adverse event, or contraindication to Retacrit.</p>

# DAURISMO

## Products Affected

- Daurismo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute myeloid leukemia (AML): Diagnosis of newly-diagnosed acute myeloid leukemia (AML) AND Daurismo therapy to be given in combination with low-dose cytarabine AND One of the following: 1) Patient is greater than or equal to 75 years old, or 2) Patient has significant comorbidities that preclude the use of intensive induction chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# DEGARELIX

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## Products Affected

- Firmagon INJ 120MG/VIAL, 80MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Diagnosis of advanced prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

## DICLOFENAC GEL 3%

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### Products Affected

- Diclofenac Sodium GEL 3%

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Actinic Keratosis (initial): Diagnosis of Actinic Keratosis. Actinic Keratosis (reauthorization): Documentation of positive clinical response to diclofenac sodium 3% topical gel therapy. At least 30 days have elapsed since cessation of diclofenac sodium 3% topical gel therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	90 days
Other Criteria	N/A

# DOXEPIN TOPICAL

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## Products Affected

- Doxepin Hydrochloride CREA

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of moderate pruritus. Patient has atopic dermatitis or lichen simplex chronicus. Trial and failure, contraindication, or intolerance to at least one medium potency topical corticosteroid, or is not a candidate for topical corticosteroids (e.g., treatment is on face, axilla, or groin).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	14 days
Other Criteria	N/A

# DRONABINOL

## Products Affected

- Dronabinol

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. Trial and failure, contraindication, or intolerance (TF/C/I) to a 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). TF/C/I to one of the following: Ativan (lorazepam), Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Phenergan (promethazine), Reglan (metoclopramide), Zyprexa (olanzapine). AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CINV: 6 months. AIDS anorexia: 3 months.
Other Criteria	Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving cancer chemotherapy.

# EGRIFTA

## Products Affected

- Egrifta Sv

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	(Initial): Diagnosis of HIV-associated lipodystrophy. Waist-circumference greater than or equal to 95 cm (37.4 inches) in men, or greater than or equal to 94 cm (37 inches) for women. Waist-to-hip ratio greater than or equal to 0.94 for men, or greater than or equal to 0.88 for women. Body mass index (BMI) greater than 20 kg/m <sup>2</sup> . Fasting blood glucose (FBG) levels less than or equal to 150 mg/dL (8.33 mmol/L). Patient has been on a stable regimen of antiretrovirals (eg, NRTIs, NNRTI, Protease Inhibitors, Integrase Inhibitors) for at least 8 weeks. (Reauth): Documentation of clinical improvement (eg, improvement in VAT, decrease in waist circumference, belly appearance) while on Egrifta therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial and reauth: 6 months
Other Criteria	N/A

# EMGALITY (I)

## Products Affected

- Emgality

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Episodic Migraines (EM) (initial): Diagnosis of EM with both of the following: 1) Less than 15 headache days per month and 2) Patient has 4 to 14 migraine days per month. Trial and failure (after a trial of at least two months), contraindication, or intolerance to two of the following prophylactic therapies: a) Amitriptyline (Elavil), b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol, c) Divalproex sodium (Depakote/Depakote ER), d) Topiramate (Topamax), e) Venlafaxine (Effexor). Chronic Migraines (CM) (initial): Diagnosis of CM with both of the following: 1) Greater than or equal to 15 headache days per month and 2) Greater than or equal to 8 migraine days per month. Trial and failure (after a trial of at least two months), contraindication, or intolerance to two of the following prophylactic therapies: a) Amitriptyline (Elavil), b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol, c) Divalproex sodium (Depakote/Depakote ER), d) OnabotulinumtoxinA (Botox), e) Topiramate (Topamax), f) Venlafaxine (Effexor). Episodic Cluster Headaches (ECH) (initial): Diagnosis of ECH. Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	<p>EM, CM (init): Prescribed by or in consultation with one of the following specialists with expertise in the treatment of episodic/chronic migraine: neurologist, pain specialist, headache specialist. ECH (init): Prescribed by or in consultation with one of the following specialists with expertise in the treatment of ECH: neurologist, pain specialist, headache specialist.</p>
<b>Coverage Duration</b>	EM, CM, ECH (initial, reauth): Plan year.



<b>Other Criteria</b>	EM, CM, ECH (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity.
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# ENBREL

## Products Affected

- Enbrel
- Enbrel Mini
- Enbrel Sureclick

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease-modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to two NSAIDs.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA, JIA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. Plaque Psoriasis (Initial): Prescribed by or in consultation with a dermatologist.
<b>Coverage Duration</b>	All indications (initial, reauth): plan year
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to Enbrel therapy.

# EPCLUSA

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## Products Affected

- Sofosbuvir/velpatasvir
- Epclusa TABS 400MG; 100MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C virus. Patient is not receiving sofosbuvir/velpatasvir in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
Coverage Duration	12 to 24 weeks. (84 - 168 tabs) Criteria applied consistent with current AASLD/IDSA guideline
Other Criteria	N/A

# EPIDIOLEX

## Products Affected

- Epidiolex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lennox-Gastaut syndrome (LGS): Diagnosis of seizures associated with LGS. Trial of, contraindication, or intolerance to two formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate). Dravet syndrome (DS): Diagnosis of seizures associated with DS.
Age Restrictions	N/A
Prescriber Restrictions	LGS, DS: Prescribed by or in consultation with a neurologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

## EPOETIN ALFA (NON - PREFERRED)

### Products Affected

- Procrit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Anemia due to Chronic Kidney Disease (CKD) (Initial): Diagnosis (dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) within 30 days of request. The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. (Reauth): Diagnosis of CKD. Most recent or average (avg) Hct over 3 months is 33% or less (Hgb 11 g/dL or less) for patients on dialysis, without ESRD OR Most recent or average (avg) Hct over 3 months is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis OR Most recent or average (avg) Hct over 3 months is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level.</p> <p>Anemia w/ HIV (Initial): Anemia by labs (Hgb less than 12 g/dL or Hct less than 36%) within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level.</p> <p>Anemia with chemo (Initial): Other causes of anemia ruled out. Anemia with labs (Hct less than 30%, Hgb less than 10 g/dL) within prior 2 weeks of request. Cancer is non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for minimum of 2 mos, or anemia caused by cancer chemo. (Reauth): Anemia by labs (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 wks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for minimum of 2 months, or anemia is caused by cancer chemo.</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	CKD,HIV(Init):6mo.(reauth):plan yr.Chemo(init, reauth):3mo.MDS(init):3mo,(reauth):plan yr.Preop:1mo.
<b>Other Criteria</b>	<p>Anemia in Myelodysplastic Syndrome (MDS) (Init): Diagnosis of MDS. Serum erythropoietin 500 mU/mL or less, or transfusion dependent MDS. (Reauth): Most recent or avg Hct over 3 months was 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. ESRD patients: Coverage is excluded under Medicare Part D for patients with ESRD on dialysis for any indication related or unrelated to treatment of ESRD since the payment for the drug is included in the ESRD PPS payment bundle. NON-ESRD PATIENTS for the following indications: Off-label uses (except Anemia in MDS and Hep C patients being treated with combo ribavirin and interferon/peginterferon): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.CKD (init, reauth), Chemo (init), Preop, MDS (init): Verify Fe eval for adequate Fe stores. All uses (init): One of the following: A) History of use of Retacrit OR B) History of intolerance, adverse event, or contraindication to Retacrit.</p>

## EPOETIN ALFA (PREFERRED)

### Products Affected

- Retacrit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Anemia due to Chronic Kidney Disease (CKD) (Initial): Diagnosis (dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) within 30 days of request. The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. (Reauth): Diagnosis of CKD. Most recent or average (avg) Hct over 3 months is 33% or less (Hgb 11 g/dL or less) for patients on dialysis, without ESRD OR Most recent or average (avg) Hct over 3 months is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis OR Most recent or average (avg) Hct over 3 months is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level.</p> <p>Anemia w/ HIV (Initial): Anemia by labs (Hgb less than 12 g/dL or Hct less than 36%) within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level.</p> <p>Anemia with chemo (Initial): Other causes of anemia ruled out. Anemia with labs (Hct less than 30%, Hgb less than 10 g/dL) within prior 2 weeks of request. Cancer is non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for minimum of 2 mos, or anemia caused by cancer chemo. (Reauth): Anemia by labs (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 wks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for minimum of 2 months, or anemia is caused by cancer chemo.</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	CKD,HIV(Init):6mo.(reauth):plan yr.Chemo(init, reauth):3mo.MDS(init):3mo,(reauth):plan yr.Preop:1mo.
<b>Other Criteria</b>	<p>Anemia in Myelodysplastic Syndrome (MDS) (Init): Diagnosis of MDS. Serum erythropoietin 500 mU/mL or less, or transfusion dependent MDS. (Reauth): Most recent or avg Hct over 3 months was 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. ESRD patients: Coverage is excluded under Medicare Part D for patients with ESRD on dialysis for any indication related or unrelated to treatment of ESRD since the payment for the drug is included in the ESRD PPS payment bundle. NON-ESRD PATIENTS for the following indications: Off-label uses (except Anemia in MDS and Hep C patients being treated with combo ribavirin and interferon/peginterferon): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.CKD (init, reauth), Chemo (init), preop, MDS (init): Verify Fe eval for adequate Fe stores.</p>



# ERIVEDGE

## Products Affected

- Erivedge

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Metastatic basal cell carcinoma (BCC): Diagnosis of metastatic basal cell carcinoma. Advanced basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma. One of the following: Cancer has recurred following surgery, Patient is not a candidate for surgery, or Patient is not a candidate for radiation.
Age Restrictions	N/A
Prescriber Restrictions	Metastatic and Advanced BCC: Prescribed by or in consultation with a dermatologist or oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

## ERLEADA (NON - PREFERRED)

### Products Affected

- Erleada

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-metastatic castration-resistant prostate cancer (NM-CRPC): Diagnosis of non-metastatic, castration-resistant (chemical or surgical) prostate cancer. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog OR 2) Patient received a bilateral orchiectomy. Trial and failure or intolerance to Xtandi (enzalutamide) or Nubeqa (darolutamide). Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of metastatic, castration-sensitive prostate cancer. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron [leuprolide], Trelstar [triptorelin], etc.) OR 2) Patient received bilateral orchiectomy. Trial and failure or intolerance to Xtandi (enzalutamide).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	NM-CRPC, M-CSPC: Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days

# ESBRIET

## Products Affected

- Esbriet

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF, defined as exclusion of other known causes of interstitial lung disease and either the presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF in patients not subjected to lung biopsy, or HRCT and surgical lung biopsy pattern revealing IPF or probable IPF in patients subjected to a lung biopsy. IPF (reauth): Documentation of positive clinical response to therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	(initial): Prescribed by or in consultation with a pulmonologist.
<b>Coverage Duration</b>	(initial, reauth): plan year
<b>Other Criteria</b>	(initial, reauth): Not used in combination with Ofev.

# EXJADE

## Products Affected

- Deferasirox TBSO

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Iron Overload due to Blood Transfusions (initial): Diagnosis of chronic iron overload (eg, sickle cell anemia, thalassemia, etc.) due to blood transfusion. Patient has blood transfusion of at least 100 mL/kg of packed red blood cells (eg, at least 20 units of packed red blood cells for a 40-kg person or more in individuals weighing more than 40 kg) prior to initiation of treatment with deferasirox. Patient has serum ferritin levels consistently greater than 1000 mcg/L prior to initiation of treatment with deferasirox. Chronic Overload in non-transfusion dependent thalassemia syndromes (initial): Diagnosis of chronic iron overload in non-transfusion dependent thalassemia syndrome. Patient has liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of treatment with deferasirox. Patient has serum ferritin levels consistently more than 300 mcg/L prior to initiation of treatment with deferasirox. Chronic Iron Overload due to Blood Transfusions, Chronic Overload in non-transfusion dependent thalassemia syndromes (reauthorization): Documentation of positive clinical response.
Age Restrictions	N/A
Prescriber Restrictions	Chronic Iron Overload due to Blood Transfusions, Chronic Overload in non-transfusion dependent thalassemia syndromes (initial): Prescribed by a hematologist/oncologist or hepatologist.
Coverage Duration	Plan year
Other Criteria	N/A

# FARYDAK

## Products Affected

- Farydak CAPS 10MG, 20MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma: Diagnosis of multiple myeloma. Used in combination with one of the following: 1) Velcade (bortezomib) and dexamethasone OR 2) Kyprolis (carfilzomib) OR 3) Both of the following: Revlimid (lenalidomide) and Dexamethasone. Patient has received at least two prior treatment regimens which included both of the following: Velcade (bortezomib) and an immunomodulatory agent (eg, Revlimid (lenalidomide), Thalomid (thalidomide)).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# FASENRA

## Products Affected

- Fasenra

- Fasenra Pen

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: a) Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months, OR b) Any prior intubation for an asthma exacerbation, OR c) Prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: 1) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and 2) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline] OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)]
Age Restrictions	Initial: Patient is 12 years of age or older
Prescriber Restrictions	Initial: Prescribed by or in consultation with a pulmonologist or allergy/immunology specialist
Coverage Duration	Plan year

<b>Other Criteria</b>	<p>Reauth: Documentation of a positive clinical response (e.g., reduction in exacerbations). Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: 1) inhaled corticosteroid (ICS) and 2) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline] OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)]</p>
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## FENTANYL (PREFERRED)

### Products Affected

- Fentanyl Citrate Oral Transmucosal

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cancer pain: Chart documentation provided reflecting oral transmucosal fentanyl will be used to manage pain related to an active cancer diagnosis. At least a one week history of one of the following medications to demonstrate tolerance to opioids: morphine sulfate at doses of greater than or equal to 60 mg/day, fentanyl transdermal patch at doses greater than or equal to 25 µg/hr, oxycodone at a dose of greater than or equal to 30 mg/day , oral hydromorphone at a dose of greater than or equal to 8 mg/day, oral oxymorphone at a dose of greater than or equal to 25 mg/day, an alternative opioid at an equianalgesic dose (eg, oral methadone greater than or equal to 20 mg/day). The patient is currently taking a long-acting opioid around the clock for cancer pain
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, pain specialist, hematologist, hospice care specialist, or palliative care specialist.
Coverage Duration	Plan year
Other Criteria	N/A



# FERRIPROX

## Products Affected

- Ferriprox

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Transfusional iron overload due to thalassemia syndromes: Diagnosis of transfusional iron overload due to thalassemia syndromes. Absolute neutrophil count (ANC) greater than $1.5 \times 10^9/L$ . One of the following: A) Trial and failure, defined as serum ferritin greater than 2,500 mcg/L, to Desferal (deferoroxamine), Exjade (deferasirox) or Jadenu (deferasirox) OR B) History of contraindication or intolerance to Desferal (deferoroxamine), Exjade (deferasirox) or Jadenu (deferasirox).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	All uses (reauth): Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline. ANC greater than $1.5 \times 10^9/L$ .

# FINTEPLA

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## Products Affected

- Fintepla

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of seizures associated with Dravet syndrome
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# FIRAZYR

## Products Affected

- Firazyr
- Icatibant Acetate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	Plan year
Other Criteria	N/A

# FLECTOR

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## Products Affected

- Flector
- Diclofenac Epolamine

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute Pain: Topical treatment of acute pain due to one of the following: minor strain, sprain, contusion.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# FORTEO

## Products Affected

- Forteo INJ 600MCG/2.4ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Postmenopausal osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia: Diagnosis of one of the following: a) postmenopausal osteoporosis or osteopenia or b) primary or hypogonadal osteoporosis or osteopenia. One of the following: Set I) Both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) Both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Treatment duration of parathyroid hormones (e.g., Forteo [teriparatide], Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All indications: plan year (up to 24 months per lifetime).

<b>Other Criteria</b>	<p>Glucocorticoid-Induced Osteoporosis: Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: 1) BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site), or 2) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions, or 3) History of one of the following fractures resulting from minimal trauma: vertebral compression fx, fx of the hip, fx of the distal radius, fx of the pelvis, or fx of the proximal humerus. TF/C/I to one bisphosphonate (e.g., alendronate). Treatment duration of parathyroid hormones (e.g., Forteo (teriparatide), Tymlos (abaloparatide)) has not exceeded a total of 24 months during the patient's lifetime.</p>
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# GATTEX

## Products Affected

- Gattex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of short bowel syndrome. One of the following: 1) Patient is new to Gattex therapy and is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 months, or 2) Patient is currently treated with Gattex and patient has had a reduction in weekly PN/IV support from baseline.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Plan year
Other Criteria	N/A

# GILOTRIF

## Products Affected

- Gilotrif

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. One of the following: 1) Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by an FDA-approved test OR 2) squamous disease progressing after previous platinum-based chemotherapy OR 3) tumors are positive for a known sensitizing EGFR mutation.
Age Restrictions	N/A
Prescriber Restrictions	NSCLC: Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



## GROWTH HORMONES (NON - PREFERRED)

### Products Affected

- Humatrope INJ 12MG, 24MG, 6MG
- Humatrope Combo Pack
- Norditropin Flexpro
- Saizen
- Saizenprep Reconstitutionkit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>PGHD(initial):less than 4mo w/suspected GD based on clinical presentation (eg, persistent neonatal hypoglycemia, persistent/prolonged neonatal jaundice/elev bilirubin, male infant with microgenitalia, midline anatomical defects, failure to thrive),OR hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)].</p> <p>PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender assoc with growth rates unlikely to permit attainment of adult height in the normal range. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.</p>

<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist
<b>Coverage Duration</b>	All indications (initial, reauth): Plan year

<p><b>Other Criteria</b></p>	<p>All(initial): Trial and failure/intolerance to Genotropin and Nutropin AQ.  AGHD(initial):dx of AGHD as a result of clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1 GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD  w/corresponding peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L],[macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins following macimorelin administration]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab.  AGHD,IGHDA(reauth):evidence of ongoing monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level.  TransitionPhaseAdolescent Pts(TPAP)(initial): attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones: ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3). IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).</p>
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## GROWTH HORMONES (PREFERRED)

### Products Affected

- Genotropin
- Genotropin Miniquick
- Nutropin Aq Nuspin 10
- Nutropin Aq Nuspin 20
- Nutropin Aq Nuspin 5

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>PGHD(initial):less than 4mo w/suspected GD based on clinical presentation (eg, persistent neonatal hypoglycemia, persistent/prolonged neonatal jaundice/elev bilirubin, male infant with microgenitalia, midline anatomical defects, failure to thrive),OR hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)].</p> <p>PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender assoc with growth rates unlikely to permit attainment of adult height in the normal range. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.</p>

<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist
<b>Coverage Duration</b>	All indications (initial, reauth): Plan year

<p><b>Other Criteria</b></p>	<p>AGHD(initial):dx of AGHD as a result of clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1 GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/corresponding peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L],[macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins following macimorelin administration]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab.</p> <p>AGHD,IGHDA(reauth):evidence of ongoing monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level.</p> <p>TransitionPhaseAdolescent Pts(TPAP)(initial): attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones: ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3). IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).</p>
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# HAEGARDA

## Products Affected

- Haegarda

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For prophylaxis against HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE (prophylaxis): Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	HAE (prophylaxis): plan year
Other Criteria	N/A

# HEPA VACCINE

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## Products Affected

- Havrix INJ 1440ELU/ML, 720ELU/0.5ML
- Vaqta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	2 injections per lifetime
Other Criteria	N/A



# HETLIOZ

## Products Affected

- HetlioZ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-24-hour sleep-wake disorder: Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernycthemeral syndrome).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Patient is totally blind (has no light perception).

# HUMIRA

## Products Affected

- Humira
- Humira Pediatric Crohns Disease Starter Pack INJ 0, 80MG/0.8ML
- Humira Pen
- Humira Pen-cd/uc/hs Starter
- Humira Pen-ps/uv Starter

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Rheumatoid Arthritis (RA)(Initial): Diagnosis (dx) of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (MTX) (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Juvenile Idiopathic Arthritis (JIA)(Initial): dx of moderately to severely active polyarticular JIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or MTX (Rheumatrex/Trexall). Psoriatic Arthritis (PsA)(Initial): dx of active PsA. Plaque psoriasis (PSO)(Initial): dx of moderate to severe chronic PSO. Ankylosing Spondylitis (AS) (Initial): dx of active AS. TF/C/I to two NSAIDs. Crohn's Disease (CD)(Initial): dx of moderately to severely active CD. TF/C/I to one of the following conventional therapies: 6-mercaptopurine (6-MP), Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), MTX (Rheumatrex/Trexall), or failure (ie, lost response) or intolerance to Remicade (infliximab). Ulcerative Colitis (UC)(Initial): dx of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-MP, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol, Pentasa, Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Hidradenitis suppurativa(Initial): dx of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). Uveitis(initial): dx of non-infectious uveitis classified as intermediate, posterior, or panuveitis.</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	RA, AS, JIA: (Initial) Prescribed by or in consultation with a rheumatologist. PsA: (Initial) Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS: (Initial) Prescribed by or in consultation with a dermatologist. CD, UC: (Initial) Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with a rheumatologist or an ophthalmologist.
<b>Coverage Duration</b>	UC: (Initial) 12 wks, (reauth) plan year. Other indications (initial/reauth): plan year.
<b>Other Criteria</b>	RA, JIA, PsA, Plaque psoriasis, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to Humira therapy. UC (Reauth): For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on Humira therapy for longer than 12 weeks: Documentation of positive clinical response to Humira therapy.

# IBRANCE

## Products Affected

- Ibrance

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of breast cancer. Disease is a) locally advanced, metastatic, recurrent, or Stage IV
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# ICLUSIG

## Products Affected

- Iclusig

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Myelogenous / Myeloid Leukemia (CML): Diagnosis of chronic myelogenous/myeloid leukemia (CML). One of the following: a) The patient is unable to take or has failed treatment with two or more alternative tyrosine kinase inhibitors (TKI) [eg, Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib)], or b) confirmed documentation of T315I mutation. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL). One of the following: a) the patient is unable to take or has failed treatment with two or more alternative tyrosine kinase inhibitors (TKI) [eg, Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib)], b) confirmed documentation of T315I mutation, c) used in combination with an induction regimen not previously used, d) used as a component of HyperCVAD (hyper-fractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone, alternating with high-dose methotrexate and cytarabine) induction or consolidation, e) used as maintenance therapy in combination with vincristine and prednisone with or without methotrexate and mercaptopurine, or f) used as maintenance therapy post-hematopoietic stem cell transplant.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# IDHIFA

## Products Affected

- Idhifa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute Myeloid Leukemia (AML): Diagnosis of AML. AML is isocitrate dehydrogenase-2 (IDH2) mutation-positive. One of the following: A) Disease is relapsed or refractory OR B) Both of the following: Patient is greater than 60 years of age AND one of the following: 1) Patient is not a candidate for intensive induction therapy or 2) Used for post remission therapy following response to low intensity induction therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# IMATINIB

## Products Affected

- Imatinib Mesylate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Myelogenous/Myeloid Leukemia (CML): Diagnosis of CML (CML). Acute Lymphoblastic Leukemia (ALL): Diagnosis of Philadelphia chromosome positive/BCR ABL-positive ALL (Ph+/BCR ABL+ ALL). Myelodysplastic/ myeloproliferative disease (MDS/MPD): Diagnosis of MDS/MPD. One of the following: 1) Disease is associated with 5q31-33 translocations or 2) Disease is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements. Aggressive systemic mastocytosis (ASM): Diagnosis of ASM. Patient is without the D816V c-Kit mutation or c-Kit mutational status unknown. Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL): Diagnosis of at least one of the following: HES or CEL. Dermatofibrosarcoma protuberans (DFSP): Diagnosis of DFSP. Gastrointestinal Stromal Tumors (GIST): Diagnosis of GIST.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# IMBRUVICA

## Products Affected

- Imbruvica

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Mantle cell lymphoma (MCL): Diagnosis of MCL and one of the following: 1) patient has received at least one prior therapy for MCL (eg, Rituxan [rituximab]) or 2) used in pre-treatment therapy in combination with Rituxan (rituximab) to limit the number of cycles with RHyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Marginal zone lymphoma (MZL): Diagnosis of MZL and patient has received at least one prior anti-CD20-based therapy for MZL [e.g., Rituxan (rituximab), Zevalin (ibritumomab), Gazyva (obinutuzumab, etc.)]. Chronic Graft Versus Host Disease (cGVHD): Diagnosis of cGVHD AND trial and failure of at least one other systemic therapy (e.g., corticosteroids, mycophenolate, etc.).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	All uses (except cGVHD): Prescribed by or in consultation with a hematologist/oncologist. cGVHD: Prescribed by or in consultation with a hematologist, oncologist, or physician experienced in the management of transplant patients.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.



# IMMUNE GLOBULIN

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## Products Affected

- Bivigam INJ 5GM/50ML
- Flebogamma Dif INJ 5GM/50ML
- Gammagard Liquid INJ 2.5GM/25ML
- Gammagard S/d Iga Less Than 1mcg/ml
- Gammaked INJ 1GM/10ML
- Gammaplex INJ 10GM/100ML, 10GM/200ML, 20GM/200ML, 5GM/50ML
- Gamunex-c INJ 1GM/10ML
- Octagam INJ 1GM/20ML, 2GM/20ML
- Panzyga
- Privigen INJ 20GM/200ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A

<b>Required Medical Information</b>	<p>Primary immunodeficiency syndrome (PIS): patients with PIS. Idiopathic Thrombocytopenic Purpura (ITP): diagnosis (dx) of ITP. Documented (doc) platelet count of less than <math>50 \times 10^9/L</math>. Kawasaki disease (KD): dx of KD. B-cell Chronic Lymphocytic Leukemia (CLL): dx of B-Cell CLL. Doc hypogammaglobulinemia (IgG less than 500mg/dL) or history of bacterial infections associated with B-cell CLL. Bone Marrow Transplant (BMT): Confirmed allogeneic BMT within the last 100 days. Doc severe hypogammaglobulinemia (IgG less than 400 mg/dL). HIV:dx of HIV. 13 years of age or less. Doc hypogammaglobulinemia (IgG less than 400 mg/dL) or functional antibody deficiency demonstrated by poor specific antibody titers or recurrent bacterial infections. Guillain-Barre Syndrome (GBS) initial: dx of GBS. severe disease requiring aid to walk. Onset of neuropathic symptoms in the last 4 weeks. Myasthenia Gravis (MG): dx of generalized MG. Evidence of myasthenic exacerbation, defined by 1 of the following sx's in the last month: difficulty swallowing, acute respiratory failure, or major functional disability responsible for the discontinuation of physical activity. Concomitant immunomodulator therapy (tx)(eg, azathioprine, cyclosporine), unless contraindicated, will be used for long-term management of MG. Dermatomyositis and Polymyositis (D/P) initial: dx of dermatomyositis or polymyositis. Trial and failure, contraindication or intolerance (TF/C/I) to immunosuppressive tx (eg corticosteroids, methotrexate, azathioprine, cyclophosphamide). Stiff person syndrome (SPS) initial:dx of SPS. TF/C/I to GABAergic medication (eg, baclofen). TF/C/I to immunosuppressive tx (eg, azathioprine, corticosteroids). Lambert-Eaton myasthenic syndrome (LEMS) initial: dx of LEMS. TF/C/I to immunomodulator monotherapy (eg, azathioprine, corticosteroids). Concomitant immunomodulator tx (eg, azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	MG: Prescribed by a neurologist.
<b>Coverage Duration</b>	KD: 1 mo. GBS,CIDP (initial), MG: 3 mo. ITP: 6 mo. CIDP,GBS (reauth), other uses: plan year.

<p><b>Other Criteria</b></p>	<p>Subject to Part B vs. Part D review. PIS: Clinically significant functional deficiency of humoral immunity as evidenced by doc failure to produce antibodies to specific antigens or hx of significant recurrent infxns. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) initial: dx of CIDP confirmed by: (1) progressive sx's present for at least 2 mo, (2) symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor impairment of more than 1 limb, OR Progressive or relapsing sensory impairment of more than 1 limb, (3) Electrophysiologic findings when 3 of the following 4 criteria are present: Partial conduction block of 1 or more motor nerve, Reduced conduction velocity of 2 or more motor nerves, Prolonged distal latency of 2 or more motor nerves, Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves. Multifocal motor neuropathy (MMN) initial: dx of MMN as confirmed by all of the following: (1) weakness with slowly progressive or stepwise progressive course over at least 1 month, (2) asymmetric involvement of 2 or more nerves, AND (3) absence of motor neuron signs and bulbar signs. CIDP, MMN reauth: documentation of positive clinical response to tx as measured by an objective scale [eg, Rankin, Modified Rankin, Medical Research Council (MRC) scale]. Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect. Relapsing remitting Multiple Sclerosis (MS) initial: dx of relapsing remitting form of MS (RRMS). Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin tx. TF/c/I to 2 of the following: Aubagio (teriflunomide), Betaseron (interferon beta-1b), Avonex (interferon beta-1a), Copaxone (glatiramer acetate), Rebif (interferon beta-1a), Tysabri (natalizumab), Tecfidera (dimethyl fumarate), Extavia (interferon beta-1b), Gilenya (Fingolimod). RRMS reauth: The prescriber maintains and provides chart documentation of the patient's evaluation, including all of the following: findings of interval examination including neurological deficits incurred, and assessment of disability (eg, Expanded Disability Status Score [EDSS], Functional Systems Score [FSS], Multiple Sclerosis Functional Composite [MSFC], Disease Steps [DS]). Stable or improved disability score (eg, EDSS, FSS, MSFC, DS). Documentation of decreased number of relapses since starting immune globulin tx. Dx continues to be the relapsing-remitting form of MS. Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect. GBS, D/P, SPS, LEMS reauth: Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect.</p>
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# IMVEXXY

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## Products Affected

- Imvexxy Maintenance Pack
- Imvexxy Starter Pack

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Dyspareunia: Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# INGREZZA

## Products Affected

- Ingrezza

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Tardive Dyskinesia: Diagnosis of moderate to severe tardive dyskinesia. One of the following: a) patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication OR b) patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or psychiatrist.
Coverage Duration	Plan year
Other Criteria	N/A

# INLYTA

## Products Affected

- Inlyta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Advanced Renal Cell Carcinoma: Diagnosis of renal cell cancer. One of the following: (1) disease has relapsed or (2) diagnosis of stage IV disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# INQOVI

## Products Affected

- Inqovi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome. Patient has ONE of the following French- American-British subtypes: a) refractory anemia, b) refractory anemia with ringed sideroblasts, c) refractory anemia with excess blasts, or d) chronic myelomonocytic leukemia (CMML).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# INREBIC

## Products Affected

- Inrebic

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Myelofibrosis: Diagnosis of one of the following: primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# INSULIN - LIKE GROWTH FACTOR

## Products Affected

- Increlex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial therapy: IGF-1 deficiency: Diagnosis of severe primary IGF-1 deficiency. Height standard deviation score of -3.0 or less. Basal IGF-1 standard deviation score of -3.0 or less. Normal or elevated growth hormone (GH). GH gene deletion: Diagnosis of growth hormone gene deletion who have developed neutralizing antibodies to GH. Reauthorization: Documentation of positive clinical response to therapy. Both of the following: (1) Expected adult height is not obtained and (2) Documentation of expected adult height goal
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with a pediatric endocrinologist
Coverage Duration	Initial, reauth: plan year
Other Criteria	N/A

# INTRON - A

## Products Affected

- Intron A

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Diagnosis of chronic hepatitis C, patient without decompensated liver disease, patients who have not previously been treated with interferon, and one of the following - 1) used in combination with ribavirin or 2) contraindication or intolerance to ribavirin. Metastatic renal cell carcinoma (RCC): diagnosis of metastatic RCC, used in combination with Avastin (bevacizumab). Other: diagnosis of condylomata acuminata (genital or perianal), diagnosis of hairy cell leukemia, diagnosis of AIDS-related Kaposi's sarcoma, diagnosis of malignant melanoma, diagnosis of Stage III or IV follicular Non-Hodgkin's Lymphoma, as maintenance therapy for the treatment of multiple myeloma.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RCC: Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	HepB, HepC: 48 wks. Condylomata acuminata (genital or perianal): 6 wks. Other: 12 months
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# IRESSA

## Products Affected

- Iressa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC, and One of the following: tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions or tumors are positive for EGFR exon 21 (L858R) substitution mutations or tumors are positive for a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# ISOTRETINOIN

## Products Affected

- Claravis

- Isotretinoin CAPS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	(initial): Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy OR diagnosis of treatment resistant acne. Trial and failure, contraindication or intolerance to an adequate trial on two of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin),] b) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)], c) topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]. Retreatment (Reauthorization): After greater than or equal to 2 months off therapy, persistent or recurring severe recalcitrant nodular acne is still present. Dose Titration (Reauthorization): Confirmation that the total cumulative dose for total duration of therapy is less than 150 mg/kg.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Reauth: Retreatment - 6 months, Dose Titration - 1 month
Other Criteria	N/A

# ITRACONAZOLE (CAPSULES)

## Products Affected

- Itraconazole CAPS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Systemic Fungal Infections: Diagnosis of blastomycosis, histoplasmosis, or aspergillosis. Onychomycosis (initial): Diagnosis of fingernail or toenail onychomycosis confirmed by one of the following: KOH test, fungal culture, or nail biopsy. (retreatment): One of the following: Nine months has elapsed since completion of initial therapy for toenail onychomycosis or three months have elapsed since completion of initial therapy for fingernail onychomycosis. Documentation of positive clinical response to therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Systemic Fungal infxns: plan year. Onychomycosis: (Fingernail) 2 mo. (Toenail) 3 mo.
Other Criteria	N/A

## ITRACONAZOLE (SOLUTION)

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### Products Affected

- Itraconazole SOLN

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Fungal Infections: Diagnosis of oropharyngeal or esophageal candidiasis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# JADENU

## Products Affected

- Deferasirox PACK
- Deferasirox TABS
- Jadenu
- Jadenu Sprinkle

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Iron Overload due to Blood Transfusions (initial): Diagnosis of chronic iron overload (eg, sickle cell anemia, thalassemia, etc.) due to blood transfusion. Patient has blood transfusion of at least 100 mL/kg of packed red blood cells (eg, at least 20 units of packed red blood cells for a 40-kg person or more in individuals weighing more than 40 kg) prior to initiation of treatment with deferasirox. Patient has serum ferritin levels consistently greater than 1000 mcg/L prior to initiation of treatment with deferasirox. Chronic Overload in non-transfusion dependent thalassemia syndromes (initial): Diagnosis of chronic iron overload in non-transfusion dependent thalassemia syndrome. Patient has liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of treatment with deferasirox. Patient has serum ferritin levels consistently more than 300 mcg/L prior to initiation of treatment with deferasirox. Chronic Iron Overload due to Blood Transfusions, Chronic Overload in non-transfusion dependent thalassemia syndromes (reauthorization): Documentation of positive clinical response to therapy.
Age Restrictions	N/A
Prescriber Restrictions	Initial authorization: Prescribed by a hematologist/oncologist or hepatologist.
Coverage Duration	Plan year
Other Criteria	N/A

# JAKAFI

## Products Affected

- Jakafi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Myelofibrosis: One of the following: Primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera and trial and failure, contraindication, or intolerance to one of the following: hydroxyurea or interferon therapy (e.g., Intron A, pegasys, etc.). Acute graft versus host disease (aGVHD): Diagnosis of aGVHD. Disease is steroid-refractory.
Age Restrictions	N/A
Prescriber Restrictions	Myelofibrosis, polycythemia vera: Prescribed by or in consultation with a hematologist/oncologist. Acute graft versus host disease: Prescribed by or in consultation with one of the following: hematologist, oncologist, physician experienced in the management of transplant patients.
Coverage Duration	6 months
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# JUXTAPID

## Products Affected

- Juxtapid

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Homozygous familial hypercholesterolemia (HoFH) (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. Patient is receiving other lipid-lowering therapy. Trial and failure, contraindication, or intolerance to Repatha therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.
Age Restrictions	N/A
Prescriber Restrictions	HoFH (initial, reauth): Prescribed by a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	HoFH (initial): 6 months. (reauth): plan year
Other Criteria	HoFH (reauthorization): Patient continues to receive other lipid-lowering therapy. Submission of medical records (eg, chart notes, laboratory values) documenting LDL-C reduction while on Juxtapid therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.

# KALYDECO

## Products Affected

- Kalydeco

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Submission of laboratory records confirming patient has one of the following mutations in the CFTR gene: A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, E831X, F1052V, F1074L, G178R, G551D, G551S, G1069R, G1244E, G1349D, K1060T, L206W, P67L, R74W, R117C, R117H, R347H, R352Q, R1070Q, R1070W, S549N, S549R, S945L, S977F, S1251N, S1255P, 711+3A-G, 2789+5G-A, 3272-26A-G, or 3849+10kbC-T. (Reauthorization): Documentation of one of the following while on Kalydeco therapy: Improved lung function or stable lung function.
Age Restrictions	N/A
Prescriber Restrictions	CF (initial, reauth): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
Coverage Duration	CF (initial): 6 mos, (reauth): plan year
Other Criteria	N/A

# KINERET (EH)

## Products Affected

- Kineret

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Kineret therapy if within the past 120 days. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID. Dx of NOMID confirmed by one of the following: 1) NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3) gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation or 2) Both of the following: a) two of the following clinical symptoms: urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia), chronic aseptic meningitis, or skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing) AND b) elevated acute phase reactants (eg, erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA]).
Age Restrictions	N/A
Prescriber Restrictions	RA (initial): Prescribed by or in consultation with a rheumatologist. NOMID (initial): Prescribed by or in consultation with an allergist/immunologist, pediatrician, or rheumatologist.
Coverage Duration	All uses (initial and reauth): plan year
Other Criteria	All Uses (Reauth): Documentation of positive clinical response to Kineret therapy.

# KISQALI

## Products Affected

- Kisqali

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of advanced, recurrent, or metastatic breast cancer. Cancer is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: A) Kisqali is used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) or B) Used in combination with Faslodex (fulvestrant).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days

## KISQALI - FEMARA PACK

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### Products Affected

- Kisqali Femara 200 Dose
- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of advanced, recurrent, or metastatic breast cancer. Cancer is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days

# KORLYM

## Products Affected

- Korlym

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	(Initial): Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Diagnosis of either type 2 diabetes mellitus or diagnosis of glucose intolerance. Patient has either failed surgery or patient is not a candidate for surgery. Patient is not pregnant. (Reauthorization): Documentation of one of the following: patient has improved glucose tolerance while on Korlym therapy or patient has stable glucose tolerance while on Korlym therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by an endocrinologist.
Coverage Duration	6 months
Other Criteria	N/A

# KOSELUGO

## Products Affected

- Koselugo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Neurofibromatosis Type 1 (NF1): Diagnosis of NF1. Patient has plexiform neurofibromas that are both of the following: inoperable and causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment). Patient is able to swallow a capsule whole.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: oncologist or neurologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# LENVIMA

## Products Affected

- Lenvima 10 Mg Daily Dose
- Lenvima 12mg Daily Dose
- Lenvima 14 Mg Daily Dose
- Lenvima 18 Mg Daily Dose
- Lenvima 20 Mg Daily Dose
- Lenvima 24 Mg Daily Dose
- Lenvima 4 Mg Daily Dose
- Lenvima 8 Mg Daily Dose

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Differentiated thyroid cancer (DTC): Diagnosis of DTC. Renal cell carcinoma: Diagnosis of Advanced Renal cell carcinoma. Hepatocellular Carcinoma (HCC): Diagnosis of Hepatocellular Carcinoma or liver cell carcinoma. Endometrial Carcinoma: Diagnosis of advanced endometrial carcinoma.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# LEUKINE

## Products Affected

- Leukine INJ 250MCG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Bone Marrow/Stem Cell Transplant (BMSCT): Patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT), or for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, or for peripheral stem cell transplant (PSCT) patients who have received myeloablative chemotherapy. Acute myeloid leukemia (AML): For patients with AML following induction or consolidation chemotherapy. Neutropenia Associated Dose Dense Chemotherapy (NDDC): Patient is receiving NCI's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, or a dose-dense regimen for which the incidence of febrile neutropenia is unknown. Chemotherapy-Induced Febrile Neutropenia (CFN): Patient is receiving a chemotherapy regimen associated with more than 20% incidence of febrile neutropenia, or patient is receiving chemotherapy regimen associated with 10-20% incidence of febrile neutropenia and has 1 or more risk factors associated with chemotherapy-induced infection, febrile neutropenia or neutropenia. Secondary prophylaxis of FN (SPFN): For patients who are receiving myelosuppressive anticancer drugs associated with neutropenia. Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of Febrile Neutropenia (FN): For patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia. Patient has febrile neutropenia at high risk for infection-associated complications. HIV-Related Neutropenia (HIVN): HIV-infected patients with an ANC less than or equal to 1,000 cells/mm<sup>3</sup>. Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).</p>
Age Restrictions	AML: greater than or equal to 55 years old.

<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist except HIVN: Prescribed by or in consultation with a hematologist/oncologist or infectious disease specialist.
<b>Coverage Duration</b>	BMSCT,NDDC,CFN,SPFN, AML: 3mo or duration of tx. HIVN: 6mo. FN, ARS: 1mo.
<b>Other Criteria</b>	N/A

# LEUPROLIDE ACETATE

## Products Affected

- Leuprolide Acetate INJ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Palliative treatment of advanced prostate cancer. Central Precocious Puberty (initial): diagnosis of central precocious puberty (idiopathic or neurogenic). Onset of secondary sexual characteristics in one of the following: females less than age 8 or males less than age 9. Confirmation of diagnosis defined by one of the following: a pubertal response to a GnRH stimulation test or bone age advanced one year beyond the chronological age. (Reauthorization): Documentation of Bone age monitoring (eg, radiographic imaging).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prostate Cancer, Central Precocious Puberty (all): plan year
Other Criteria	Prostate Cancer: Approve for continuation of prior therapy if within the past 120 days.

# LIDOCAINE PATCH

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## Products Affected

- Lidocaine PTCH 5%

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Post-herpetic neuralgia: Diagnosis of post-herpetic neuralgia
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# LONSURF

## Products Affected

- Lonsurf

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Metastatic colorectal cancer (mCRC): Diagnosis of mCRC. Trial and failure, contraindication, or intolerance with all of the following: fluoropyrimidine-based chemotherapy, oxaliplatin-based chemotherapy, irinotecan-based chemotherapy, and anti-VEGF biological therapy. One of the following: a) tumor is RAS mutant-type or b) tumor is RAS wild-type and Trial and failure, contraindication or intolerance to one anti-EGFR therapy (eg, Vectibix [panitumumab], Erbitux [cetuximab]). Gastric/Gastroesophageal Junction Adenocarcinoma: Diagnosis of metastatic gastric cancer or diagnosis of metastatic gastroesophageal junction adenocarcinoma. Trial and failure, contraindication or intolerance to at least two of the following: fluoropyrimidine-based chemotherapy (e.g. fluorouracil), Platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin), Taxane (e.g., docetaxel, paclitaxel) or irinotecan-based chemotherapy, HER2/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# LORBRENA

## Products Affected

- Lorbrena

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. One of the following: A) Both of the following: 1) Disease is advanced, metastatic, or recurrent and anaplastic lymphoma kinase (ALK)-positive AND 2) Disease has progressed on at least one of the following therapies: 1) Xalkori (crizotinib) and another ALK inhibitor [e.g., Alunbrig (brigatinib)], 2) Alecensa (alectinib) as the first ALK inhibitor for metastatic disease, or 3) Zykadia (ceritinib) as the first ALK inhibitor for metastatic disease. OR B) Both of the following: 1) Disease is both of the following: i) advanced, metastatic, or recurrent and ii) ROS proto-oncogene 1 (ROS1)-positive AND 2) Disease has progressed on at least one of the following therapies: Xalkori (crizotinib), Rozlytrek (entrectinib), or Zykadia (ceritinib).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# LUPANETA

## Products Affected

- Lupaneta Pack

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Endometriosis (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or Trial and failure, contraindication, or intolerance to one NSAID and one oral contraceptive. (reauthorization): symptoms recur after one course.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Endometriosis (Initial, reauthorization): 6 months.
Other Criteria	Endometriosis (initial): History of failure, contraindication, or intolerance to Lupron Depot (3.75 mg, 11.25 mg)

# LUPRON DEPOT

## Products Affected

- Lupron Depot (1-month)
- Lupron Depot (3-month)
- Lupron Depot (4-month)
- Lupron Depot (6-month)

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer (7.5 mg, 22.5 mg, 30 mg, 45 mg): Palliative treatment of advanced prostate cancer. Endometriosis (3.75 mg, 11.25 mg) (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID and one oral contraceptive. (reauthorization): symptoms recur after one course. Used in combination with one of the following: norethindrone 5 mg daily, other "add -back" sex hormones, other bone-sparing agents. Uterine Leiomyomata (3.75 mg, 11.25 mg) (fibroids): Either for use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) Or all of the following: treatment of anemia, anemia caused by uterine leiomyomata (fibroids), and use prior to surgery.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prostate CA: plan yr. Endometrosis(all), Uterine leiomyomata (anemia): 6 mo. (fibroids): 4 mo.
Other Criteria	Prostate Cancer (7.5 mg, 22.5 mg): Approve for continuation of prior therapy if within the past 120 days. Prostate Cancer (30 mg, 45 mg): Approve for continuation of prior therapy.



## LYNPARZA (TABLETS)

### Products Affected

- Lynparza TABS

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) Both of the following (applies to maintenance tx of ovarian cancer, including BRCA-mutated or HRD-positive ovarian cancer): a) disease is advanced or recurrent AND b) patient has had a complete or partial response to platinum-based chemotherapy, or 2) All of the following: a) disease is advanced, persistent, or recurrent AND b) presence of deleterious or suspected deleterious germline BRCA-mutations AND c) trial and failure, contraindication, or intolerance to two or more prior lines of chemotherapy (e.g., paclitaxel with cisplatin). Breast cancer: Diagnosis of breast cancer. Disease is metastatic or recurrent. Presence of deleterious or suspected deleterious germline BRCA-mutations. Disease is human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) Disease is hormone receptor (HR) negative, or b) Disease is hormone receptor (HR)-positive and one of the following: i) disease has progressed on previous endocrine therapy or ii) provider attestation that treatment with endocrine therapy is inappropriate for the patient's disease. Pancreatic adenocarcinoma: Diagnosis of pancreatic adenocarcinoma. Disease is metastatic. Presence of deleterious or suspected deleterious germline BRCA-mutations. Disease has not progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen (e.g., FOLFIRINOX, FOLFOX, etc.).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	All indications (except prostate cancer): Prescribed by or in consultation with an oncologist. Prostate cancer: Prescribed by or in consultation with an oncologist or urologist.
<b>Coverage Duration</b>	Plan year

<b>Other Criteria</b>	<p>Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer. Presence of deleterious or suspected deleterious homologous recombination repair (HRR) gene mutations. Disease has progressed following prior treatment with one of the following: a) enzalutamide (Xtandi), or b) abiraterone (e.g., Zytiga, Yonsa). One of the following: 1) used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)], or 2) Patient has had bilateral orchiectomy. All indications: Approve for continuation of prior therapy if within the past 120 days.</p>
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# MAVYRET

## Products Affected

- Mavyret

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
Coverage Duration	8 to 16 weeks (168 to 336 tabs). Criteria applied consistent with current AASLD/IDSA guideline
Other Criteria	N/A

# MEKINIST

## Products Affected

- Mekinist

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable or metastatic melanoma AND cancer is BRAF V600 mutant type. Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type. Involvement of lymph nodes following complete resection. Used as adjuvant therapy. Medication is used in combination with Tafenlar (dabrafenib). Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type AND medication is used in combination with Tafenlar (dabrafenib). Anaplastic Thyroid Cancer (ATC): Diagnosis of ATC. One of the following: 1) Disease is one of the following: metastatic, locally advanced, or unresectable OR 2) Prescribed as adjuvant therapy following resection. Cancer is BRAF V600E mutant type. Medication is used in combination with Tafenlar (dabrafenib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# MEKTOVI

## Products Affected

- Mektovi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Patient is positive for BRAF V600 mutation. Used in combination with Braftovi (encorafenib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days

# MEMANTINE

## Products Affected

- Memantine Hcl Titration Pak
- Memantine Hydrochloride SOLN
- Memantine Hydrochloride TABS
- Memantine Hydrochloride Er
- Namzaric

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Age 41 or older, or diagnosis of moderate to severe dementia of the Alzheimer's type.
Age Restrictions	No Prior Authorization if patient is age 41 or older.
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# MIGLUSTAT

## Products Affected

- Miglustat

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gaucher disease: Diagnosis of mild to moderate Type 1 Gaucher disease. Patient is unable to receive enzyme replacement therapy due to one of the following conditions: allergy or hypersensitivity to enzyme replacement therapy, poor venous access, or unavailability of enzyme replacement therapy (e.g. Cerezyme, VPRIV).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# MODAFINIL

## Products Affected

- Modafinil

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Obstructive sleep apnea/hypopnea syndrome (OSAHS) (Initial): Diagnosis (dx) of OSAHS defined by one of the following: 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), and 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work sleep disorder (SWSD) (Initial):Dx of SWSD confirmed by one of the following: 1) symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). No other medical condition or medication accounts for the symptoms. Narcolepsy (initial): Dx of narcolepsy as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). MS Fatigue (initial): Dx of multiple sclerosis (MS). Patient is experiencing fatigue. Idiopathic Hypersomnia (initial): Dx of idiopathic hypersomnia as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). Depression (initial): Treatment-resistant depression defined as diagnosis of major depressive disorder (MDD) or bipolar depression, AND trial and failure, contraindication, or intolerance to at least two antidepressants from different classes (eg, SSRIs, SNRIs, bupropion). Used as adjunctive therapy.</p>
Age Restrictions	N/A



<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	OSAHS,SWSD,MS Fatigue,Hypersomnia,Depression:Initial,Reauth:6 mo.Narcolepsy:Initial,Reauth:Plan Yr
<b>Other Criteria</b>	OSAHS, Narcolepsy, Idiopathic Hypersomnia (Reauth): Documentation of positive clinical response to modafinil therapy. SWSD (Reauth): Documentation of positive clinical response to modafinil therapy. MS Fatigue (reauth): Patient is experiencing relief of fatigue with modafinil therapy. Depression (reauth): Documentation of positive clinical response to modafinil therapy. Used as adjunctive therapy.

# MYALEPT

## Products Affected

- Myalept

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of congenital or acquired generalized lipodystrophy associated with leptin deficiency. Reauth: Documentation of positive clinical response to Myalept therapy.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by an endocrinologist.
Coverage Duration	Initial, Reauth: plan year
Other Criteria	Initial: One of the following: a) Diabetes mellitus or insulin resistance with persistent hyperglycemia (HgbA1C greater than 7.0% ) despite optimized insulin therapy at maximum tolerated doses OR b) Persistent hypertriglyceridemia (TG greater than 250mg/dL) despite optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses.

# NATPARA

## Products Affected

- Natpara

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hypoparathyroidism (initial): Diagnosis of hypoparathyroidism. Used as adjunctive therapy at treatment initiation. Hypoparathyroidism (reauthorization): Documentation of positive clinical response to Natpara therapy.
Age Restrictions	N/A
Prescriber Restrictions	Initial authorization: Prescribed by an endocrinologist
Coverage Duration	Initial: 6 months      Reauthorization: plan year
Other Criteria	N/A

# NERLYNX

## Products Affected

- Nerlynx

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Early Stage Breast cancer: Diagnosis (dx) of early stage breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received adjuvant trastuzumab treatment. Advanced or Metastatic Breast Cancer: Dx of advanced or metastatic breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received two or more prior anti-HER2 based regimens (e.g., trastuzumab + pertuzumab + docetaxel, ado-trastuzumab emtansine, etc.). Used in combination with capecitabine.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days

# NEULASTA

## Products Affected

- Neulasta

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Neutropenia Associated with Dose Dense Chemotherapy (NDDC): Patient is receiving NCI's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, or a dose-dense regimen for which the incidence of febrile neutropenia is unknown.</p> <p>Chemotherapy-Induced Febrile Neutropenia (CFN): Patient is receiving a chemotherapy regimen associated with more than 20% incidence of febrile neutropenia, or patient is receiving chemotherapy regimen associated with 10-20% incidence of febrile neutropenia and has 1 or more risk factors associated with chemotherapy-induced infection, febrile neutropenia or neutropenia. Secondary prophylaxis of FN: For patients who are receiving myelosuppressive anticancer drugs associated with neutropenia. Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of Febrile Neutropenia (FN): For patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia . Patient has febrile neutropenia at high risk for infection-associated complications. Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	FN (treatment), ARS: 1 mo. CFN, NDDC, FN (prophylaxis): 3 mo or duration of tx.
<b>Other Criteria</b>	N/A

# NEXAVAR

## Products Affected

- Nexavar

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC and one of the following: (1) relapse following surgical excision, or (2) both of the following: medically or surgically unresectable tumor and Stage IV disease. Hepatocellular carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or disease is unresectable. Differentiated thyroid carcinoma (DTC): Diagnosis of one of the following: follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma. One of the following: metastatic disease, unresectable recurrent disease, or persistent locoregional disease. One of the following: patient has symptomatic disease or patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. Medullary thyroid carcinoma (MTC): Diagnosis of MTC and one of the following: a) disease is progressive or disease is symptomatic with distant metastases. Trial and failure, contraindication, or intolerance to one of the following: Caprelsa (vandetanib) or Cometriq (cabozantinib).
Age Restrictions	N/A
Prescriber Restrictions	DTC, MTC: Prescribed by or in consultation with an oncologist, RCC: Prescribed by or in consultation with one of the following: oncologist or nephrologist. HCC: Prescribed by or in consultation with one of the following: oncologist, hepatologist, gastroenterologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# NINLARO

## Products Affected

- Ninlaro

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Multiple myeloma: Diagnosis of multiple myeloma. One of the following: 1) Both of the following: Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)] AND Used as part of combination regimen including dexamethasone [combination regimen may include additional agents, such as Revlimid (lenalidomide)] OR 2) Both of the following: a) Used as primary therapy and b) Used in combination with dexamethasone and Revlimid (lenalidomide) OR 3) Both of the following: a) Patient is a transplant candidate and b) Patient has symptomatic disease following response to primary myeloma therapy or response or stable disease following autologous stem cell transplant
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# NORTHERA

## Products Affected

- Northera

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Neurogenic orthostatic hypotension (NOH): (Initial): Diagnosis of symptomatic NOH. NOH is caused by one of the following conditions: primary autonomic failure (eg, Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, non-diabetic autonomic neuropathy. (Reauth): Documentation of positive clinical response to therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	NOH (init): Prescribed by or in consultation with one of the following specialists: cardiologist, neurologist, nephrologist.
<b>Coverage Duration</b>	Initial: 1 month. Reauth: plan year
<b>Other Criteria</b>	Trial and failure, contraindication, or intolerance to one of the following agents: Fludrocortisone acetate, midodrine.



# NOXAFIL

## Products Affected

- Noxafil TBEC
- Posaconazole Dr

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Invasive Fungal Infections (IFI): Used as prophylaxis of invasive fungal infections caused by Aspergillus or Candida for one of the following conditions: 1) Patient is at high risk of infections due to severe immunosuppression from hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD) or hematologic malignancies with prolonged neutropenia from chemotherapy [eg, acute myeloid leukemia (AML), myelodysplastic syndrome (MDS)], OR 2) patient has a prior fungal infection requiring secondary prophylaxis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	IFI: plan year.
Other Criteria	N/A

## NUBEQA (X)

### Products Affected

- Nubeqa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-metastatic castration-resistant or castration-recurrent prostate cancer (nmCRPC): Diagnosis of non-metastatic castration-resistant (chemical or surgical) or castration-recurrent prostate cancer. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog OR 2) Patient received bilateral orchiectomy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# NUCALA

## Products Affected

- Nucala

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Severe eosinophilic asthma (initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by (1) Baseline (pre-treatment) peripheral blood eosinophil level is greater than or equal to 150 cells/microliter or (2) peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months. Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months or Patient has had any prior intubation for an asthma exacerbation or Patient has had a prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with both a high dose inhaled corticosteroid (ICS) (eg, greater than 500 mcg fluticasone propionate equivalent/day) and additional asthma controller medication (eg, leukotriene receptor antagonist, long-acting beta-2 agonist [LABA], theophylline), OR one maximally-dosed combination ICS/ LABA product (eg, Advair [fluticasone propionate/ salmeterol], Dulera [mometasone/ formoterol], Symbicort [budesonide/ formoterol]), unless there is a contraindication or intolerance to these medications. Eosinophilic Granulomatosis with Polyangiitis (EGPA) (init): Diagnosis of EGPA. Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy). Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone) unless there is a contraindication or intolerance to corticosteroid therapy.
Age Restrictions	Severe asthma initial: Age greater than or equal to 6 years
Prescriber Restrictions	Severe asthma (initial): Prescribed by or in consultation with a pulmonologist or allergy/immunology specialist. EGPA (init): Prescribed by or in consultation with a pulmonologist, rheumatologist or allergist/immunologist.
Coverage Duration	Initial, reauth: plan year

<b>Other Criteria</b>	<p>Severe asthma (reauth): Documentation of positive clinical response (eg, reduction in exacerbations). Patient is currently being treated with both a inhaled corticosteroid (ICS) and an additional asthma controller medication [eg, leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR a combination ICS/LABA product [eg, Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)], unless there is a contraindication or intolerance to these medications. EGPA (reauth): Documentation of positive clinical response to therapy (e.g., increase in remission time).</p>
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# NUEDEXTA

## Products Affected

- Nuedexta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pseudobulbar affect (PBA) (initial): Diagnosis of PBA. (Reauthorization): Documentation of clinical benefit from ongoing therapy with Nuedexta.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PBA (initial/reauth): plan year
Other Criteria	N/A

# NUPLAZID

## Products Affected

- Nuplazid CAPS
- Nuplazid TABS 10MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# Ocaliva

## Products Affected

- Ocaliva

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Primary Biliary Cholangitis (PBC) (initial): Diagnosis of PBC (aka primary biliary cirrhosis). One of the following: a) patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) AND used in combination with UDCA, OR b) history of contraindication or intolerance to UDCA. Prescriber has adjusted drug dose for patients with moderate to severe hepatic impairment (e.g., Child-Pugh class B or C).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PBC (initial): Prescribed by or in consultation with a hepatologist or gastroenterologist.
<b>Coverage Duration</b>	PBC (initial): 6 months. (reauth): Plan Year
<b>Other Criteria</b>	PBC (reauthorization): Submission of medical records (eg, laboratory values) documenting a reduction in alkaline phosphatase (ALP) level from pre-treatment baseline (ie, prior to Ocaliva therapy) while receiving Ocaliva therapy. Prescriber has adjusted drug dose for patients with moderate to severe hepatic impairment (e.g., Child-Pugh class B or C).

# OCTREOTIDE

## Products Affected

- Octreotide Acetate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Acromegaly (initial): Diagnosis of acromegaly confirmed by one of the following: serum GH level greater than 1 ng/mL after a 2-hour oral glucose tolerance test at the time of diagnosis, or elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at the time of diagnosis. One of the following: A) Inadequate response to surgery, radiotherapy, or dopamine agonist (e.g., bromocriptine, cabergoline) therapy, or B) Not a candidate for any of the following: surgery, radiotherapy, dopamine agonist (e.g., bromocriptine, cabergoline) therapy. HIV/AIDS-Related Diarrhea (initial): Diagnosis of HIV/AIDS-related diarrhea. Carcinoid tumors, symptomatic treatment of diarrhea or flushing (initial): diagnosis of metastatic carcinoid tumor, for symptomatic treatment of severe diarrhea or flushing. Vasoactive Intestinal Peptide Tumors, symptomatic treatment of diarrhea (initial): Diagnosis of metastatic vasoactive intestinal peptide tumor, for symptomatic treatment of diarrhea associated with vasoactive intestinal peptide tumor. Cancer Chemotherapy - and/or Radiation- Induced Diarrhea (initial): Diagnosis of complicated diarrhea due to concurrent cancer chemotherapy and/or radiation or uncomplicated diarrhea due to concurrent cancer chemotherapy and/or radiation. Carcinoid tumor: diagnosis of carcinoid tumor. Reauthorization (all except carcinoid tumor): Documentation of positive clinical response to therapy.</p>
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Carcinoid tumor: 6 mo. Acromegaly (initial): 6 mo, (Reauth): plan yr. Other uses (all): 6 mo.



<b>Other Criteria</b>	Uncomplicated diarrhea due to concurrent cancer chemotherapy and/or radiation (initial): Trial and failure, contraindication, or intolerance (TF/C/I) to standard therapy (e.g., loperamide). HIV/AIDS-related Diarrhea (initial): TF/C/I to standard therapy (e.g., loperamide, diphenoxylate with atropine). Carcinoid tumor: Approve for continuation of prior therapy if within the past 120 days.
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# ODOMZO

## Products Affected

- Odomzo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Advanced basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma. One of the following: cancer that has recurred following surgery or radiation therapy, or patient is not a candidate for surgery or radiation therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# OFEV

## Products Affected

- Ofev

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF, defined as exclusion of other known causes of interstitial lung disease and either the presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF in patients not subjected to lung biopsy, or HRCT and surgical lung biopsy pattern revealing IPF or probable IPF in patients subjected to a lung biopsy.</p> <p>Systemic Sclerosis-associated interstitial lung disease (SSc-ILD) (initial): Diagnosis of SSc-ILD, defined as exclusion of other known causes of interstitial lung disease (ILD) and either the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on HRCT revealing SSc-ILD or probable SSc-ILD in patients not subjected to surgical lung biopsy, or HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD in patients subjected to a lung biopsy. Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (initial): Diagnosis of chronic fibrosing ILDs. Patient has a high-resolution computed tomography (HRCT) showing at least 10% of lung volume with fibrotic features. Disease has a progressive phenotype as observed by one of the following: decline of forced vital capacity (FVC), worsening of respiratory symptoms, or increased extent of fibrosis seen on imaging. IPF, SSc-ILD, Chronic Fibrosing ILDs with a progressive phenotype (reauth): Documentation of positive clinical response to therapy.</p>
Age Restrictions	N/A
Prescriber Restrictions	(initial): Prescribed by or in consultation with a pulmonologist.
Coverage Duration	(initial, reauth): plan year

<b>Other Criteria</b>	IPF, SSc-ILD (initial, reauth): Not used in combination with Esbriet.
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# OPSUMIT

## Products Affected

- Opsumit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH: Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: plan year
Other Criteria	N/A

## ORENCIA SC (EH)

### Products Affected

- Orenzia INJ 125MG/ML, 50MG/0.4ML, 87.5MG/0.7ML

- Orenzia Clickject

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. All indications (Initial): One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Orenzia therapy if within the past 120 days.
Age Restrictions	N/A
Prescriber Restrictions	RA (initial), JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	All indications (Initial, reauth): plan year
Other Criteria	All indications (Reauth): Documentation of positive clinical response to Orenzia therapy.

# ORENITRAM

## Products Affected

- Orenitram

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH: Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: plan year
Other Criteria	N/A

# ORKAMBI

## Products Affected

- Orkambi TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic fibrosis (initial): Diagnosis of cystic fibrosis (CF). Submission of laboratory records confirming the patient is homozygous for the F508del mutation in the CFTR gene. (Reauthorization): Prescriber attests that the patient has achieved a clinically meaningful response while on Orkambi therapy to one of the following: lung function as demonstrated by percent predicted forced expiratory volume in 1 second (ppFEV1), body mass index (BMI), pulmonary exacerbations, quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score.
Age Restrictions	Patient is greater than or equal to 6 years of age
Prescriber Restrictions	CF (initial, reauthorization): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
Coverage Duration	Initial: 6 months. Reauth: plan year
Other Criteria	N/A



# ORKAMBI GRANULES

## Products Affected

- Orkambi PACK

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic fibrosis (initial): Diagnosis of cystic fibrosis (CF). Submission of laboratory records confirming the patient is homozygous for the F508del mutation in the CFTR gene. One of the following: A) Patient is 2 through 5 years of age, OR B) Both of the following: Patient is 6 years of age or greater AND Patient is unable to swallow oral tablets.
Age Restrictions	N/A
Prescriber Restrictions	CF (initial, reauthorization): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
Coverage Duration	Initial: 6 months. Reauth: plan year
Other Criteria	CF (Reauthorization): Prescriber attests that the patient has achieved a clinically meaningful response while on Orkambi therapy to one of the following: lung function as demonstrated by percent predicted forced expiratory volume in 1 second (ppFEV1), body mass index (BMI), pulmonary exacerbations, quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score. One of the following: A) Patient is 2 through 5 years of age, OR B) Both of the following: Patient is 6 years of age or greater AND Patient is unable to swallow oral tablets.

# OSPHERA

## Products Affected

- Osphena

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Dyspareunia: Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause. Vaginal dryness: Diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

## OTEZLA (EH)

### Products Affected

- Otezla

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Psoriatic arthritis (PsA, initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. PsA, plaque psoriasis (initial): Trial and failure, contraindication, or intolerance to both Humira and Enbrel, OR for continuation of prior Otezla therapy if within the past 120 days. Oral ulcers associated with Behcet's Disease (Initial): Diagnosis of Behcet's Disease. Patient has active oral ulcers.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PsA (init): Prescribed by or in consultation with one of the following specialists: dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.
<b>Coverage Duration</b>	Initial, Reauth: plan year
<b>Other Criteria</b>	Reauthorization (PsA, plaque psoriasis): Documentation of positive clinical response to Otezla therapy. Reauthorization (oral ulcers associated with Behcet's Disease): Documentation of positive clinical response to Otezla therapy (eg, reduction in pain from oral ulcers or reduction in number of oral ulcers).

# OXANDRIN

## Products Affected

- Oxandrolone TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Bone Pain: Diagnosis of bone pain due to osteoporosis. AIDS Wasting: Diagnosis of AIDS wasting or cachexia associated with AIDS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All indications: plan year
Other Criteria	N/A

# PEGASYS

## Products Affected

- Pegasys
- Pegasys Proclic INJ 180MCG/0.5ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD-IDSA guidance.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HepB: 48 wks. HepC: 20-28wks. Criteria will be applied consistent with current AASLD/IDSA guideline
Other Criteria	N/A

# PEMAZYRE

## Products Affected

- Pemazyre

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of cholangiocarcinoma. Disease is one of the following: unresectable locally advanced or metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement. Patient has been previously treated.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# PIQRAY

## Products Affected

- Piqray 200mg Daily Dose
- Piqray 250mg Daily Dose
- Piqray 300mg Daily Dose

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer (BC): Diagnosis of advanced or metastatic BC. Disease is hormone receptor (HR)-positive, and human epidermal growth factor receptor 2 (HER2)-negative. Cancer is PIK3CA-mutated as detected by an FDA-approved test (therascreen PIK3CA RGQ PCR Kit). Patient is a postmenopausal woman or male. Used in combination with fulvestrant. Disease has progressed on or after an endocrine-based regimen.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# POMALYST

## Products Affected

- Pomalyst

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma: Diagnosis of multiple myeloma. Trial and failure, contraindication or intolerance to both an immunomodulatory agent [eg, Revlimid (lenalidomide)] and a proteasome inhibitor [eg, Velcade (bortezomib)]. Kaposi sarcoma (KS): One of the following: 1) Both of the following: a) Diagnosis of AIDS-related KS and b) Patient has failed highly active antiretroviral therapy (HAART), OR 2) Both of the following: a) Diagnosis of KS and b) Patient is HIV -negative.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# PRALUENT

## Products Affected

- Praluent

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: One of the following diagnoses: A) HeFH as confirmed by one of the following: (1) Both of the following: a) Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult, AND b) One of the following: i) Family history (hx) of tendinous xanthomas and/or arcus cornealis in 1st degree relative, or 2nd degree relative, ii)Hx of myocardial infarction (MI) in 1st-degree relative less than 60 years of age, iii) Family hx of MI in 2nd-degree relative less than 50 years of age, iv) Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, v) Family hx of FH in 1st- or 2nd-degree relative, or (2) Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult AND one of the following: presence of tendinous xanthoma in pt, arcus cornealis before age 45, or functional mutation in the LDL receptor, ApoB, or PCSK9 gene. OR B) Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin. OR C) Primary Hyperlipidemia.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Reauth: plan year

<b>Other Criteria</b>	<p>Initial, continued: One of the following LDL-C values while on maximally tolerated statin tx within the last 120 days: (1) LDL-C greater than or equal to 70 mg/dL with ASCVD. (2) LDL-C greater than or equal to 100 mg/dL without ASCVD. AND One of the following: i) Pt has been receiving at least 12 weeks of one maximally-tolerated statin tx and will continue to receive a statin at maximally tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times ULN, iii) patient has a labeled contraindication to all statins, or iv) Pt has experienced rhabdomyolysis or muscle symptoms with statin tx with CK elevations greater than 10 times ULN on one statin tx. Reauth: Pt continues to receive statin at the maximally tolerated dose (unless pt has documented inability to take statins). Patient has experienced LDL-C reduction while on Praluent therapy. Initial, reauth: Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. All indications (initial/reauth): Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.</p>
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# PRILOSEC POWDER

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## Products Affected

- Prilosec PACK

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Trial and failure, contraindication, or intolerance to Nexium granules.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# PROMACTA

## Products Affected

- Promacta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic idiopathic thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: chronic ITP or relapsed/refractory ITP. Baseline platelet count is less than 30,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. ITP (reauthorization): Documentation of positive clinical response to Promacta therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding. Chronic Hepatitis C-associated thrombocytopenia (initial): Diagnosis of chronic hepatitis C-associated thrombocytopenia. One of the following: planning to initiate and maintain interferon-based treatment or currently receiving interferon-based treatment. First-line for severe aplastic anemia (SAA): Diagnosis of SAA. Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy with any equine antithymocyte globulin plus cyclosporine, alemtuzumab, or high dose cyclophosphamide). Used in combination with standard immunosuppressive therapy (e.g., Atgam [antithymocyte globulin equine] and cyclosporine). Patient meets at least two of the following: 1) absolute neutrophil count less than 500/mcL, 2) platelet count less than 20,000/mcL, 3) absolute reticulocyte count less than 60,000/mcL. Refractory SAA (initial): Diagnosis of refractory SAA. Patient has a platelet count less than 30,000/mcL. SAA (reauthorization): Documentation of positive clinical response to Promacta therapy.
Age Restrictions	N/A
Prescriber Restrictions	Chronic ITP and SAA: Prescribed by or in consultation with a hematologist/oncologist. Chronic hepatitis C associated thrombocytopenia: Prescribed by or in consultation with a hematologist/oncologist, gastroenterologist, hepatologist, infectious disease specialist, or HIV specialist certified through the American Academy of HIV Medicine.

<b>Coverage Duration</b>	1stline SAA:6mo.HepC (init):3mo.RefractSAA(init):16wk.ITP,HepC(reauth),RefractSAA(reauth):plan yr
<b>Other Criteria</b>	Chronic ITP: Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids, immunoglobulins, or splenectomy. Chronic Hepatitis C-associated thrombocytopenia (Reauthorization): One of the following criteria: For patients that started treatment with Promacta prior to initiation of treatment with interferon, Promacta will be approved when both of the following are met: currently on antiviral interferon treatment for treatment of chronic hepatitis C and documentation that patient reached threshold platelet count that allows initiation of antiviral interferon therapy with Promacta treatment by week 9. OR for patients that started treatment with Promacta while on concomitant treatment with interferon, Promacta will be approved based on the following criterion: currently on antiviral interferon therapy for treatment of chronic hepatitis C. Refractory SAA: Trial and failure, contraindication, or intolerance to at least one course of immunosuppressive therapy (eg, Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine).

# PURIXAN

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## Products Affected

- Purixan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	One of the following: History of contraindication or intolerance to generic mercaptopurine tablets OR patient is unable to swallow tablets.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# QINLOCK

## Products Affected

- Qinlock

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gastrointestinal Stromal Tumor (GIST): Diagnosis of gastrointestinal stromal tumor (GIST). Disease is one of the following: a) advanced, b) metastatic, or c) unresectable. Trial and failure, contraindication, or intolerance to all of the following: imatinib (Gleevec), Sutent (sunitinib), and Stivarga (regorafenib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# QUININE

## Products Affected

- Quinine Sulfate CAPS 324MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Excluded if used solely for treatment or prevention of nocturnal leg cramps.
Required Medical Information	Diagnosis (dx) of uncomplicated malaria and one of the following: treatment in areas of chloroquine-sensitive malaria or treatment in areas of chloroquine-resistant malaria.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	Chloroquine-sensitive malaria: Failure, contraindication or intolerance to chloroquine or hydroxychloroquine.



# RASUVO

## Products Affected

- Rasuvo INJ 10MG/0.2ML, 12.5MG/0.25ML, 15MG/0.3ML, 17.5MG/0.35ML, 20MG/0.4ML, 22.5MG/0.45ML, 25MG/0.5ML, 30MG/0.6ML, 7.5MG/0.15ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA): Diagnosis of severe, active RA. Polyarticular juvenile idiopathic arthritis (PJIA): Diagnosis of active PJIA. Psoriasis: Diagnosis of severe psoriasis.
Age Restrictions	N/A
Prescriber Restrictions	RA, PJIA: Prescribed by or in consultation with a rheumatologist. Psoriasis: Prescribed by or in consultation with a dermatologist.
Coverage Duration	Plan year
Other Criteria	N/A

# REGRANEX

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## Products Affected

- Regranex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diabetic Neuropathic Ulcers: Patient has a lower extremity diabetic neuropathic ulcer. Treatment will be given in combination with ulcer wound care (eg, debridement, infection control, and/or pressure relief).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Diabetic Neuropathic Ulcers: 5 months.
Other Criteria	N/A

## RELISTOR (NON - PREFERRED)

### Products Affected

- Relistor INJ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Opioid-induced Constipation (OIC) (advanced illness or pain caused by active cancer): Diagnosis of OIC. Patient has advanced illness, or pain caused by active cancer. OIC (non-cancer pain, pain related to prior cancer or its treatment): Diagnosis of OIC. Patient has chronic non-cancer pain, or patient has chronic pain related to prior cancer or its treatment.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	OIC (advanced illness or pain caused by active cancer, non-cancer pain, pain related to prior cancer or its treatment): Trial and failure, contraindication, or intolerance to an osmotic laxative [eg, Constulose (lactulose)]. TF/C/I to Amitiza (lubiprostone).

## RELISTOR TABLETS (NON - PREFERRED)

### Products Affected

- Relistor TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Opioid-induced Constipation (OIC) (non-cancer pain, pain related to prior cancer or its treatment): Diagnosis of OIC. Patient has chronic non-cancer pain, or patient has chronic pain related to prior cancer or its treatment.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	OIC (non-cancer, pain related to prior cancer or its treatment): Trial and failure, contraindication, or intolerance (TF/C/I) to an osmotic laxative [e.g., Constulose (lactulose)]. TF/C/I to Amitiza (lubiprostone).

# REPATHA

## Products Affected

- Repatha
- Repatha Pushttronex System
- Repatha Sureclick

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>HeFH/ASCVD/Primary HLD(init): One of the following dx: A) HeFH as confirmed by one of the following: (1) Both of the following: a) Untreated/pre-treatment LDL greater than 190 mg/dL in an adult, AND b) One of the following: i) Family hx of tendinous xanthomas and/or arcus cornealis in 1st degree relative, or 2nd degree relative, ii) Hx of myocardial infarction (MI) in 1st-degree relative less than 60 years of age, iii) Family hx of MI in 2nd-degree relative less than 50 years of age, iv) Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, v) Family hx of FH in 1st- or 2nd-degree relative, or (2) Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult AND one of the following: presence of tendinous xanthoma in pt, arcus cornealis before age 45, or functional mutation in the LDL receptor, ApoB, or PCSK9 gene. OR B) ASCVD as confirmed by ACS, hx of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin. OR C) Primary hyperlipidemia (HLD). HoFH (initial): dx of HoFH as confirmed by one of the following: (1) Gen confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or (2) either untreated LDL greater than 500 or treated LDL greater than 300, AND either xanthoma before 10 yo or evidence of HeFH in both parents.</p>
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Reauth: plan year

<b>Other Criteria</b>	<p>HeFH/ASCVD/Primary HLD (init): One of the following LDL values while on max tolerated statin tx w/in the last 120 days: (1) LDL greater than or equal to 70 mg/dL w/ ASCVD. (2) LDL greater than or equal to 100 mg/dL w/o ASCVD. AND One of the following: i) Pt has been receiving at least 12 wks of one max-tolerated statin tx and will continue to receive a statin at max tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN, iii) patient has a labeled contraindication to all statins, or iv) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin tx w/ CK elevations greater than 10 times ULN on one statin tx. HoFH (init): Pt is receiving other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD (reauth): Pt continues to receive statin at max tolerated dose (unless pt has documented inability to take statins). HoFH (reauth): Pt continues to receive other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD/HoFH (reauth): Pt has experienced LDL reduction while on Repatha tx. HeFH/ASCVD/Primary HLD/HoFH (Init, reauth): Not used in combination w/ another PCSK9 inhibitor. Prescriber attests that the info provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical info necessary to verify the accuracy of the info provided. HoFH (Init, reauth): Not used in combo w/ Juxtapid.</p>
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# RETEVMO

## Products Affected

- Retevmo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lung cancer: Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: a) recurrent, b) advanced, or c) metastatic. Presence of RET gene fusion-positive or RET arrangement positive tumor(s). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is advanced or metastatic. Disease has presence of RET gene mutation. Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is advanced or metastatic. Disease is RET gene fusion-positive. Disease requires treatment with systemic therapy. Patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate.
Age Restrictions	N/A
Prescriber Restrictions	Lung Cancer, MTC: Prescribed by or in consultation with an oncologist. Thyroid Cancer: Prescribed by or in consultation with an endocrinologist or an oncologist.
Coverage Duration	Lung Cancer, MTC, Thyroid Cancer: Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# REVLIMID

## Products Affected

- Revlimid

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Myeloma: Diagnosis of multiple myeloma. Myelodysplastic syndrome (MDS) with a deletion 5q: Diagnosis of symptomatic anemia due to MDS associated with a deletion 5q. MDS without deletion 5q: Diagnosis of anemia due to MDS without deletion 5q and one of the following: A) serum erythropoietin levels greater than 500 mU/mL, OR B) All of the following: 1) serum erythropoietin levels less than or equal to 500 mU/mL and 2) ring sideroblasts less than 15% and 3) One of the following: a) Revlimid therapy is in combination with an erythropoietin agent [eg, Aranesp (darbepoetin), Epogen or Procrit (epoetin alfa)] OR b) trial and failure, contraindication, or intolerance to at least one erythropoietin agent [eg, Aranesp (darbepoetin), Epogen or Procrit (epoetin alfa)]. Mantle Cell Lymphoma (MCL): Diagnosis of MCL. Follicular Lymphoma (FL): Diagnosis of FL that has been previously treated. Used in combination with a rituximab product. Marginal Zone Lymphoma (MZL): Diagnosis of MZL that has been previously treated. Used in combination with a rituximab product.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# ROZLYTREK

## Products Affected

- Rozlytrek

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic non-small cell lung cancer (NSCLC). Patient has ROS1 rearrangement positive tumor(s). Solid Tumors: Patient has solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.). Disease is without a known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions). Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) or disease has no satisfactory alternative treatments.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# RUBRACA

## Products Affected

- Rubraca

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Ovarian cancer: Diagnosis of ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) Both of the following: a) Presence of deleterious BRCA mutation and b) Trial and failure, contraindication, or intolerance to two or more chemotherapies (e.g., cisplatin, carboplatin), OR 2) Both of the following: a) Disease is recurrent and b) Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer. Presence of deleterious BRCA mutation. Patient has received previous treatment with both of the following: 1) Androgen receptor-directed therapy [e.g., Erleada (apalutamide), Xtandi (enzalutamide), Zytiga (abiraterone)], AND 2) A taxane-based chemotherapy [e.g., docetaxel, Jevtana (cabazitaxel)]. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin)], OR 2) Patient received bilateral orchiectomy.
Age Restrictions	N/A
Prescriber Restrictions	Ovarian cancer: Prescribed by or in consultation with an oncologist. Prostate cancer: Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days

# RUCONEST

## Products Affected

- Ruconest

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	Plan year
Other Criteria	N/A

# RYDAPT

## Products Affected

- Rydapt

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute Myeloid Leukemia (AML): Diagnosis of acute myeloid leukemia (AML), AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive, Rydapt will be used in combination with standard induction and consolidation therapy. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), Mast Cell Leukemia (MCL): Diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).
Age Restrictions	N/A
Prescriber Restrictions	All indications: Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days

# SECUADO

## Products Affected

- Secuado

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of schizophrenia. Both of the following: 1) Trial and failure of Saphris (asenapine) and 2) Trial and failure, contraindication, or intolerance to one of the following generic atypical antipsychotic agents: olanzapine, quetiapine, risperidone, or ziprasidone.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# SEROSTIM

## Products Affected

- Serostim INJ 4MG, 5MG, 6MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	HIV wasting (Initial): Diagnosis of HIV-associated wasting syndrome or cachexia, and one of the following: unintentional weight loss greater than 10% over the last 12 months, or unintentional weight loss greater than 7.5% over the last 6 months, or loss of 5% body cell mass (BCM) within 6 months, or body mass index (BMI) less than 20 kg/m <sup>2</sup> , or patient is male and has BCM less than 35% of total body weight (TBW) and BMI less than 27 kg/m <sup>2</sup> , or patient is female and has BCM less than 23% of TBW and BMI less than 27 kg/m <sup>2</sup> . Nutritional evaluation since onset of wasting first occurred. Anti-retroviral tx has been optimized to decrease the viral load. Patient has not had weight loss as a result of other underlying treatable conditions (eg, depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes). HIV wasting (reauthorization): Evidence of positive response to therapy. One of the following targets or goals has not been achieved: weight, BCM, BMI.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months, Reauth: 6 months
Other Criteria	N/A

# SHINGRIX

## Products Affected

- Shingrix

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Vaccine is being used for prevention of herpes zoster (shingles).
Age Restrictions	Approve for age 50 and older.
Prescriber Restrictions	N/A
Coverage Duration	6 months (2 injections per lifetime)
Other Criteria	N/A

# SIGNIFOR

## Products Affected

- Signifor

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cushing's disease: Diagnosis of endogenous Cushing's disease (i.e, hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Either pituitary surgery has not been curative for the patient OR patient is not a candidate for pituitary surgery.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Plan year
Other Criteria	N/A



# SILDENAFIL

## Products Affected

- Sildenafil Citrate TABS 20MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH: Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: plan year
Other Criteria	N/A

## SIMPONI (EH)

### Products Affected

- Simponi

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Rheumatoid Arthritis (RA) (initial): Diagnosis of moderately to severely active rheumatoid arthritis. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall) OR Trial and failure, contraindication, or intolerance (TF/C/I) to methotrexate (Rheumatrex/Trexall). One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior therapy if within the past 120 days. Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior therapy if within the past 120 days. Ankylosing Spondylitis (AS) (initial): Diagnosis of active AS. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior therapy if within the past 120 days. Ulcerative Colitis (UC) (initial): Diagnosis of moderately to severely active UC. Patient is corticosteroid dependent (ie, an inability to successfully taper corticosteroids without a return of the symptoms of UC), OR TF/C/I to one of the following: oral aminosalicylate, oral corticosteroid, azathioprine, 6-mercaptopurine. One of the following: TF/C/I to Humira (adalimumab), OR for continuation of prior Simponi therapy if within the past 120 days.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. UC (Initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	UC (Initial): 12 weeks. UC (Reauthorization): plan year. RA, AS, PsA (initial, reauth): plan year
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to Simponi therapy.

# SIRTURO

## Products Affected

- Sirturo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of pulmonary multidrug resistant tuberculosis (MDR-TB), adverse reactions or resistance to standard drugs used to treat MDR-TB, and one of the following: Sirturo is being used in combination with at least 3 other medications to which the patient's MDR-TB isolate has been shown to be susceptible in vitro, or if in vitro testing results are unavailable Sirturo is being used in combination with at least 4 other medications to which the patient's MDR-TB isolate is likely to be susceptible.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	24 weeks
Other Criteria	N/A

# SOMAVERT

## Products Affected

- Somavert

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Acromegaly (Initial): Diagnosis of acromegaly by one of the following: serum growth hormone (GH) level greater than 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis, or elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis. Inadequate response to one of the following: surgery, radiotherapy, or dopamine agonist (e.g., bromocriptine, cabergoline) therapy or not a candidate for surgery, radiotherapy or dopamine agonist (eg, bromocriptine, cabergoline) therapy. Trial and failure, contraindication, or intolerance to one of the following somatostatin analogs: Sandostatin (octreotide) or Sandostatin LAR (octreotide) or Somatuline Depot (lanreotide) , or Patient has extremely high IGF-1 values defined as greater than 900 ng/mL.</p> <p>Acromegaly (Reauth): Documentation of positive clinical response to Somavert therapy.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Acromegaly (Initial): 12 weeks. Reauth: plan year
<b>Other Criteria</b>	N/A

## SOVALDI (EM)

### Products Affected

- Sovaldi PACK

- Sovaldi TABS 400MG

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C. All GT1 and GT4: 1) trial and failure, intolerance or contraindication (TF/I/C) to both of the following: a) sofosbuvir/velpatasvir OR Epclusa (brand) and b) Mavyret OR 2) For continuation of prior Sovaldi therapy within the past 120 days. For GT2 or GT3 patients (12 years of age or older or weighing at least 45 kg), using Sovaldi plus ribavirin: TF/I/C to a) Epclusa (brand) OR sofosbuvir/velpatasvir AND Mavyret OR b) for continuation of prior Sovaldi therapy. For pediatric patients 6 to 11 years of age or older or weighing at least 17 kg, using Sovaldi plus ribavirin with either GT 2 or GT3: TF/I/C to Epclusa (brand) OR sofosbuvir/velpatasvir, OR for continuation of prior Sovaldi therapy within the past 120 days.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine.
<b>Coverage Duration</b>	12 to 48 wks (84-336 tabs). Criteria will be applied consistent with current AASLD/IDSA guideline.
<b>Other Criteria</b>	N/A

# SPRYCEL

## Products Affected

- Sprycel

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Myeloid Leukemia (CML): Diagnosis (dx) of Philadelphia chromosome-positive/BCR ABL-positive chronic myeloid leukemia (Ph+/BCR ABL+ CML). Acute Lymphoblastic Leukemia (ALL): Diagnosis of Philadelphia chromosome-positive/BCR ABL-positive acute lymphoblastic leukemia (Ph+/BCR ABL+ ALL).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

## STELARA (EH)

### Products Affected

- Stelara INJ 45MG/0.5ML, 90MG/ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. Crohn's disease (CD): Diagnosis of moderately to severely active Crohn's disease. Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Plaque psoriasis (Initial): One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept) OR Humira (adalimumab) OR b) for continuation of prior Stelara therapy if within the past 120 days. PsA (Initial): One of the following: a) TF/C/I to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept) or Humira (adalimumab) OR b) for continuation of prior Stelara therapy if within the past 120 days. CD (Initial): One of the following: a) TF/C/I to Humira (adalimumab), b) TF/C/I to treatment with at least one immunomodulator or corticosteroid [e.g., Purinethol (6-mercaptopurine), Imuran (azathioprine), Sandimmune (cyclosporine A), Prograf (tacrolimus), MTX (methotrexate)], OR c) For continuation of prior Stelara therapy if within the past 120 days. UC (Initial): One of the following: a) TF/C/I to Humira (adalimumab) OR b) TF/C/I to treatment with at least one immunomodulator or corticosteroid (e.g., Purinethol [6-mercaptopurine], Imuran [azathioprine], aminosaliclates [e.g., mesalamine {Asacol, Pentasa, Rowasa}, olsalazine {Dipentum}, sulfasalazine {Azulfidine, Sulfazine}]), OR c) for continuation of prior Stelara therapy if within the past 120 days.</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD and UC (initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	All indications (initial and reauth): plan year
<b>Other Criteria</b>	Reauthorization (all indications): Documentation of positive clinical response to Stelara therapy.



# STIVARGA

## Products Affected

- Stivarga

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Metastatic Colorectal Cancer (mCRC): Diagnosis of advanced or metastatic colorectal cancer. One of the following: a) Trial and failure, contraindication, or intolerance to FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan)], OR b) Trial and failure, contraindication, or intolerance to oxaliplatin-based chemotherapy and irinotecan-based chemotherapy, OR c) disease that has progressed through all available regimens. Gastrointestinal stromal tumor (GIST): Diagnosis of progressive, locally advanced, unresectable or metastatic GIST. Trial and failure, contraindication, or intolerance to imatinib mesylate or Sutent (sunitinib malate). Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Trial and failure or intolerance to Nexavar (sorafenib tosylate).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	mCRC, GIST: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# SUTENT

## Products Affected

- Sutent

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. Trial and failure, contraindication, or intolerance to imatinib. Renal Cell Carcinoma (RCC): Diagnosis of RCC and one of the following: (1) Disease has relapsed, or (2) both of the following: medically or surgically unresectable tumor and diagnosis of Stage IV disease, or (3) both of the following: used in adjuvant setting and patient has a high risk of recurrence following nephrectomy. Islet Cell Tumors/Pancreatic Neuroendocrine Tumors (pNET): Diagnosis of islet cell tumors/progressive pNET.
Age Restrictions	N/A
Prescriber Restrictions	pNET: Prescribed by or in consultation with an oncologist or neuro-oncologist. GIST, RCC: Prescribed by or in consultation with an oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# SYMLIN

## Products Affected

- Symlinpen 120
- Symlinpen 60

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diabetes Mellitus (DM): Type 1 or type 2 diabetes. Patient has failed to achieve desired glucose control despite optimal insulin therapy. Patient is taking concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog). Reauth: Patient has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline. Patient is receiving concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# SYMPAZAN

## Products Affected

- Sympazan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lennox-Gastaut syndrome: Diagnosis of Lennox-Gastaut syndrome. Used for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome. Dravet syndrome: Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with Diacomit.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# SYNRIBO

## Products Affected

- Synribo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic myeloid leukemia (CML): One of the following: 1) Diagnosis of advanced phase CML with progression to accelerated phase, 2) Diagnosis of chronic phase CML or accelerated phase CML and Trial and failure, contraindication, or intolerance to two prior tyrosine kinase inhibitor therapies [eg, imatinib, Sprycel (dasatinib), Tasigna (nilotinib), Bosulif (bosutinib), Iclusig (ponatinib)], or 3) Diagnosis of post-transplant relapse or refractory chronic or accelerated phase CML.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

## TABLOID

### Products Affected

- Tabloid

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of acute myeloid leukemia
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# TABRECTA

## Products Affected

- Tabrecta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: recurrent, advanced, metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

## TADALAFIL (PAH)

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### Products Affected

- Alyq
- Tadalafil TABS 20MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH: Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: plan year
Other Criteria	N/A



# TAFAMIDIS

## Products Affected

- Vyndamax

- Vyndaqel

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) (initial): Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM). One of the following: 1) Patient has a transthyretin (TTR) mutation (e.g., V122I), 2) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits, OR 3) All of the following: i) echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis, ii) scintigraphy scan suggestive of cardiac TTR amyloidosis, and iii) absence of light-chain amyloidosis. One of the following: 1) History of heart failure (HF), with at least one prior hospitalization for HF, OR 2) Presence of clinical signs and symptoms of HF (e.g., dyspnea, edema). Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	ATTR-CM (initial, reauth): Plan year
<b>Other Criteria</b>	ATTR-CM (reauth): Documentation of positive clinical response to therapy. Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure.

# TAFINLAR

## Products Affected

- Tafinlar

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma AND cancer is BRAFV600 mutant type. Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type. Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Mekinist (trametinib). Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type AND medication is used in combination with Mekinist (trametinib). Anaplastic Thyroid Cancer (ATC): Diagnosis of anaplastic thyroid cancer. One of the following: 1) Disease is one of the following: metastatic, locally advanced, or unresectable OR 2) Prescribed as adjuvant therapy following resection. Cancer is BRAF V600E mutant type. Medication is used in combination with Mekinist (trametinib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# TAGRISSO

## Products Affected

- Tagrisso

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is recurrent or metastatic. One of the following: 1) Used as first-line therapy AND One of the following: a) Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions, or b) Tumors are positive for EGFR exon 21 L858R mutations, or c) Disease is sensitizing EGFR mutation positive, OR 2) Tumors are positive for EGFR T790M mutation AND Trial and failure, contraindication, or intolerance to at least one prior EGFR tyrosine kinase inhibitor (TKI) therapy [e.g., Iressa (gefitinib), Tarceva (erlotinib), Gilotrif (afatinib)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# TALZENNA

## Products Affected

- Talzenna

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) locally advanced or b) metastatic. Presence of deleterious or suspected deleterious germline BRCA-mutations as detected by the FDA-approved companion diagnostic for Talzenna. Disease is human epidermal growth factor receptor 2 (HER2)-negative.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# TARCEVA

## Products Affected

- Erlotinib Hydrochloride

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-Small Cell Lung Cancer (NSCLC): 1) Diagnosis of NSCLC. Disease is metastatic or recurrent. Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletion mutations or exon 21 (L858R) substitution mutations or a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation). Pancreatic cancer: Diagnosis of locally advanced, unresectable or metastatic pancreatic cancer. Used in combination with Gemzar (gemcitabine).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# TASIGNA

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## Products Affected

- Tasigna

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Myeloid Leukemia (CML): Diagnosis of Philadelphia chromosome-positive/BCR ABL-positive chronic myeloid leukemia (Ph+/BCR ABL+ CML).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# TAZORAC

## Products Affected

- Tazarotene CREA
- Tazorac CREA 0.05%
- Tazorac GEL

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	All indications: Excluded if treatment for cosmetic purposes.
Required Medical Information	Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne). Psoriasis: Diagnosis of psoriasis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# TAZVERIK

## Products Affected

- Tazverik

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Epithelioid sarcoma: Diagnosis of epithelioid sarcoma. Disease is one of the following: metastatic or locally advanced. Patient is not eligible for complete resection. Follicular lymphoma: Diagnosis of follicular lymphoma. Disease is one of the following: relapsed or refractory.
Age Restrictions	N/A
Prescriber Restrictions	Epithelioid sarcoma: Prescribed by or in consultation with an oncologist. Follicular lymphoma: Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# TEGSEDI

## Products Affected

- Tegsedi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) (initial): Diagnosis of hATTR amyloidosis with polyneuropathy. Patient has a transthyretin (TTR) mutation (e.g., V30M). One of the following: 1) Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb, 2) Patient has baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2, OR 3) Patient has a baseline neuropathy impairment score (NIS) between 10 and 130. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy).
Age Restrictions	N/A
Prescriber Restrictions	hATTR amyloidosis (initial): Prescribed by or in consultation with a neurologist
Coverage Duration	hATTR amyloidosis (initial, reauth): Plan year
Other Criteria	hATTR amyloidosis (reauth): Patient has demonstrated a benefit from therapy (e.g., improved neurologic impairment, slowing of disease progression, quality of life assessment). One of the following: 1) Patient continues to have a PND score less than or equal to IIIb, 2) Patient continues to have a FAP stage of 1 or 2, OR 3) Patient continues to have a NIS between 10 and 130.

# TERIPARATIDE

## Products Affected

- Teriparatide

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Postmenopausal osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia: Diagnosis of one of the following: a) postmenopausal osteoporosis or osteopenia or b) primary or hypogonadal osteoporosis or osteopenia. One of the following: Set I) Both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) Both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All indications: plan year (up to 24 months per lifetime).

<b>Other Criteria</b>	<p>Glucocorticoid-Induced Osteoporosis: Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: 1) BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site), or 2) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions, or 3) History of one of the following fractures resulting from minimal trauma: vertebral compression fx, fx of the hip, fx of the distal radius, fx of the pelvis, or fx of the proximal humerus. TF/C/I to one bisphosphonate (e.g., alendronate). Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos (abaloparatide)) has not exceeded a total of 24 months during the patient's lifetime.</p>
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# TETRABENAZINE

## Products Affected

- Tetrabenazine

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Huntington's Disease: Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia: Diagnosis of tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication or 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Tourette's syndrome: Patient has tics associated with Tourette's syndrome. Trial and failure, contraindication, or intolerance to Haldol (haloperidol).
<b>Age Restrictions</b>	Tardive dyskinesia: Age greater than or equal to 18 years.
<b>Prescriber Restrictions</b>	Huntington's: Prescribed by a neurologist. Tardive dyskinesia, Tourette's: Prescribed by a neurologist or psychiatrist.
<b>Coverage Duration</b>	Plan year.
<b>Other Criteria</b>	N/A

# THALOMID

## Products Affected

- Thalomid

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Erythema Nodosum Leprosum (ENL): Diagnosis (Dx) of moderate to severe ENL. One of the following: used for acute treatment OR used as maintenance therapy for prevention & suppression of cutaneous manifestations of ENL recurrence. Multiple Myeloma (MM): Dx of multiple myeloma.
Age Restrictions	N/A
Prescriber Restrictions	MM: Prescribed by or in consultation with an oncologist/ hematologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# TIBSOVO

## Products Affected

- Tibsovo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Relapsed or refractory Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. AML is isocitrate dehydrogenase-1 (IDH1) mutation-positive. Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. AML is isocitrate dehydrogenase-1 (IDH1) mutation-positive. One of the following: 1) Patient is greater than or equal to 75 years old OR 2) Patient has comorbidities that preclude the use of intensive induction chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# TOBI PODHALER

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## Products Affected

- Tobi Podhaler

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# TOPICAL RETINOIDS

## Products Affected

- Tretinoin CREA
- Tretinoin GEL 0.01% , 0.025%
- Tretinoin Microsphere

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	All indications: Excluded if treatment for cosmetic purposes.
Required Medical Information	Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A



# TRACLEER

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## Products Affected

- Bosentan

- Tracleer TBSO

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH
Age Restrictions	N/A
Prescriber Restrictions	PAH: Prescribed by or in consultation with a pulmonologist or cardiologist
Coverage Duration	PAH: Plan year
Other Criteria	N/A

# TRELSTAR

## Products Affected

- Trelstar Mixject

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Palliative treatment of advanced prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Prostate Cancer: Trial and failure, contraindication, or intolerance to any brand Lupron formulation. 22.5 mg: Approve for continuation of prior therapy. All other strengths: Approve for continuation of prior therapy if within the past 120 days.

# TRIENTINE

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## Products Affected

- Clovique
- Trientine Hydrochloride

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration). Trial and failure, contraindication, or intolerance to a penicillamine product (e.g., Depen, Cuprimine)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# TUKYSA

## Products Affected

- Tukysa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) advanced unresectable or b) metastatic. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Used in combination with trastuzumab and capecitabine. Patient has been previously treated with an anti-HER2-based regimen (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine) in the metastatic setting.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# TURALIO

## Products Affected

- Turalio

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Tenosynovial Giant Cell Tumor (TGCT): Diagnosis of TGCT. Patient is symptomatic. Patient is not a candidate for surgery due to worsening functional limitation or severe morbidity with surgical removal.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# TYKERB

## Products Affected

- Tykerb

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer: One of the following: A) Diagnosis of recurrent or stage IV hormone receptor positive (HR+), human epidermal growth factor receptor 2-positive (HER2+) breast cancer. Used in combination with an aromatase inhibitor [eg, Aromasin (exemestane), Femara (letrozole), Arimedex (anastrozole)]. OR B) Diagnosis of recurrent or metastatic HER2+ breast cancer. Used in combination with trastuzumab or Xeloda (capecitabine).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# TYMLOS

## Products Affected

- Tymlos

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of postmenopausal osteoporosis or osteopenia. One of the following: Set I) Both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) Both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) one of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: a) major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Treatment duration of parathyroid hormones (e.g., Forteo [teriparatide], Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year (up to 24 months per lifetime)
Other Criteria	N/A

# UDENYCA

## Products Affected

- Udenyca

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Neutropenia Associated with Dose Dense Chemotherapy (NDDC): Patient is receiving NCI's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, or a dose-dense regimen for which the incidence of febrile neutropenia is unknown.</p> <p>Chemotherapy-Induced Febrile Neutropenia (CFN): Patient is receiving a chemotherapy regimen associated with more than 20% incidence of febrile neutropenia, or patient is receiving chemotherapy regimen associated with 10-20% incidence of febrile neutropenia and has 1 or more risk factors associated with chemotherapy-induced infection, febrile neutropenia or neutropenia. Secondary prophylaxis of FN: For patients who are receiving myelosuppressive anticancer drugs associated with neutropenia. Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of Febrile Neutropenia (FN): For patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia . Patient has febrile neutropenia at high risk for infection-associated complications. Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist/oncologist.
<b>Coverage Duration</b>	FN (treatment), ARS: 1 mo. CFN, NDDC, FN (prophylaxis): 3 mo or duration of tx.
<b>Other Criteria</b>	N/A



# VALCHLOR

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## Products Affected

- Valchlor

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Mycosis fungoides (MF)/Sezary Syndrome (SS): Diagnosis of MF or SS. Disease is not stage IVA1, IVA2 or IVB.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

## VANDETANIB

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### Products Affected

- Caprelsa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Thyroid Cancer: Diagnosis of unresectable locally advanced or metastatic medullary thyroid cancer
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# VENCLEXTA

## Products Affected

- Venclexta

- Venclexta Starting Pack

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL. Acute Myeloid Leukemia (AML): One of the following: 1) Diagnosis of newly diagnosed AML. Used in combination with azacitidine, or decitabine, or low-dose cytarabine. One of the following: age 60 years or older OR comorbidities that preclude use of intensive induction chemotherapy. 2) Diagnosis of relapsed/refractory acute myeloid leukemia (AML). Relapse is greater than or equal to 12 months from most recent disease remission. Venclexta therapy to be given in combination with the patients previous initial successful induction regimen (e.g., azacitidine, decitabine, low-dose cytarabine, etc.)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# VENTAVIS

## Products Affected

- Ventavis

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH: Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: plan year
Other Criteria	Subject to Part B vs D review.

# VERZENIO

## Products Affected

- Verzenio

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer: Diagnosis of advanced, recurrent, or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane), OR b) used in combination with Faslodex (fulvestrant) OR c) used as monotherapy and disease has progressed following endocrine therapy and patient has already received at least one prior chemotherapy regimen.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# VIGABATRIN

## Products Affected

- Vigabatrin

- Vigadrone

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Complex Partial Seizures (CPS): For use as adjunctive therapy. Infantile Spasms (IS): Diagnosis of infantile spasms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days. CPS: Trial and failure, contraindication, or intolerance (TF/C/I) to two formulary anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)].

# VITRAKVI

## Products Affected

- Vitrakvi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Presence of solid tumors (e.g., salivary gland, soft tissue sarcoma, infantile fibrosarcoma, thyroid cancer, lung, melanoma, colon, etc.).</p> <p>Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.).</p> <p>Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]. Disease is one of the following: metastatic or unresectable. One of the following: Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy) OR Disease has no satisfactory alternative treatments.</p>
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# VIZIMPRO

## Products Affected

- Vizimpro

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Disease is positive for one of the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletion or exon 21 L858R substitution.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# VOSEVI

## Products Affected

- Vosevi

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and patient is not receiving Vosevi in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine.
<b>Coverage Duration</b>	12 weeks (84 tabs). Criteria will be applied consistent with current AASLD/IDSA guideline.
<b>Other Criteria</b>	N/A

# VOTRIENT

## Products Affected

- Votrient

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renal Cell Carcinoma (RCC): Diagnosis of RCC. Soft tissue sarcoma (STS): Diagnosis of advanced STS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# XALKORI

## Products Affected

- Xalkori

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small Cell Lung Cancer (NSCLC): Diagnosis of metastatic or recurrent NSCLC
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# XATMEP

## Products Affected

- Xatmep

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute lymphoblastic leukemia (ALL): Diagnosis of acute lymphoblastic leukemia (ALL). Polyarticular juvenile idiopathic arthritis (pJIA) (initial): Diagnosis of active polyarticular juvenile idiopathic arthritis, trial and failure, contraindication, or intolerance to an adequate trial of at least one nonsteroidal anti-inflammatory drug (NSAID).
Age Restrictions	ALL: Patient is 18 years of age or younger. pJIA (initial): Patient is 18 years of age or younger.
Prescriber Restrictions	ALL: Prescribed by or in consultation with a hematologist or oncologist. pJIA (initial): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	ALL: plan year. pJIA (initial, reauth): plan year
Other Criteria	ALL: Approve for continuation of prior therapy if within the past 120 days. pJIA (reauth): Documentation of positive clinical response to Xatmep therapy

# XCOPRI

## Products Affected

- Xcopri

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of partial onset seizures.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

## XELJANZ (EH)

### Products Affected

- Xeljanz

- Xeljanz Xr

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Xeljanz/Xeljanz XR: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. RA/PsA (initial): Trial and failure, contraindication, or intolerance (TF/C/I) to both Enbrel (etanercept) and Humira (adalimumab) or patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR F40.2 for specific phobia diagnostic criteria) or for continuation of prior tofacitinib therapy if within the past 120 days. Xeljanz/Xeljanz XR: Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Trial and failure, contraindication or intolerance to one of the following conventional therapies: 6-mercaptopurine (Purinethol), aminosaliclate [e.g., mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)], azathioprine (Imuran), or corticosteroids (e.g., prednisone, methylprednisolone). Trial and failure, contraindication, or intolerance to Humira (adalimumab), OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR F40.2 for specific phobia diagnostic criteria), OR for continuation of prior tofacitinib therapy if within the past 120 days. All Indications: (initial and reauth): Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.

<b>Coverage Duration</b>	RA/PsA (initial/reauth): plan year. UC (init): 4 mo. UC (reauth): plan year.
<b>Other Criteria</b>	All Indications (Reauthorization): Documentation of positive clinical response to tofacitinib therapy.

# XGEVA

## Products Affected

- Xgeva

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prevention of skeletal-related events in patients with multiple myeloma (MM) and bone metastases from solid tumors (BMST): One of the following: 1) Diagnosis of multiple myeloma OR 2) Diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) and documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Diagnosis of giant cell tumor of bone. Tumor is unresectable or surgical resection is likely to result in severe morbidity. Hypercalcemia of malignancy (HCM) (initial): Diagnosis of hypercalcemia of malignancy and refractory to bisphosphonate therapy. Hypercalcemia of malignancy (reauthorization): Documentation of positive clinical response to Xgeva therapy.
Age Restrictions	N/A
Prescriber Restrictions	GCTB, Hypercalcemia of malignancy (initial): Prescribed by or in consultation with an oncologist
Coverage Duration	MM/BMST: plan year. GCTB: 6 mo. HCM (all): 2 mo.
Other Criteria	Giant cell tumor of bone : Approve for continuation of prior therapy if within the past 120 days.



# XIFAXAN

## Products Affected

- Xifaxan

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Traveler's Diarrhea (TD) (only 200 mg strength): Diagnosis of traveler's diarrhea. Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin). Prophylaxis of Hepatic Encephalopathy (HE) (only 550 mg strength): Used for the prophylaxis of hepatic encephalopathy recurrence. Trial and failure, contraindication, or intolerance to lactulose. Treatment of HE: Diagnosis of HE. Used for the treatment of HE. Trial and failure, contraindication, or intolerance to lactulose. Irritable Bowel Syndrome with Diarrhea (Initial) (only 550 mg strength): Diagnosis of irritable bowel syndrome with diarrhea (IBS-D). Trial and failure, contraindication or intolerance to an antidiarrheal agent (e.g., loperamide).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	TD: 14 days (one treatment course). HE (Prophylaxis, Tx): plan year. IBS-D (initial/reauth): 2 wks
<b>Other Criteria</b>	IBS-D Reauthorization (only 550 mg strength): Patient experiences IBS-D symptom recurrence.

# XOLAIR

## Products Affected

- Xolair

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Asthma (Initial): Diagnosis of moderate to severe persistent asthma. Baseline (pre-Xolair treatment) serum total IgE level greater than or equal to 30 IU/mL and less than or equal to 700 IU/mL for patients 12 years of age and older OR greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL for patients 6 years to less than 12 years of age. Positive skin test or in vitro reactivity to a perennial aeroallergen. Chronic Idiopathic Urticaria (CIU) (Initial): Diagnosis of CIU. Asthma, CIU (Reauthorization): Documentation of positive clinical response to Xolair therapy.
Age Restrictions	N/A
Prescriber Restrictions	Asthma (Initial): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CIU (Initial): Prescribed by or in consultation with an allergist/immunologist, or dermatologist.
Coverage Duration	Asthma (Init): 6 months. Asthma (Reauth): plan year. CIU (Init): 3 months. CIU (Reauth): 6 months

<b>Other Criteria</b>	<p>Asthma (Initial): Failure of one of the following, unless there is a contraindication or intolerance to these medications: one combination inhaled corticosteroid/long-acting beta2-agonist [eg, Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)] or combination therapy with one inhaled corticosteroid at the maximum dosage [eg, Flovent (fluticasone propionate), Pulmicort (budesonide), QVAR (beclomethasone dipropionate)] and one additional asthma controller medication {e.g., leukotriene receptor antagonist, long-acting beta2-agonist [eg, Foradil (formoterol fumarate), Serevent (salmeterol xinafoate)], tiotropium}. CIU (Initial): Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to a) two H1 -antihistamines [eg, Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)] OR b) both of the following taken in combination: Second generation H1 -antihistamine [eg, Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)] AND one of the following: Different second generation H1 -antihistamine [eg, Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)], or first generation H1 -antihistamine [eg, Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)], or H2-antihistamine [eg, Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)], or Leukotriene modifier [eg, Accolate (zafirlukast), Singulair (montelukast), Zflo (zileuton)].</p>
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# XOSPATA

## Products Affected

- Xospata

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of acute myeloid leukemia (AML). AML is FMS-like tyrosine kinase (FLT3) mutation-positive. Disease is relapsed or refractory.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# XPOVIO

## Products Affected

- Xpovio 100 Mg Once Weekly
- Xpovio 40 Mg Once Weekly
- Xpovio 40 Mg Twice Weekly
- Xpovio 60 Mg Once Weekly
- Xpovio 60 Mg Twice Weekly
- Xpovio 80 Mg Once Weekly
- Xpovio 80 Mg Twice Weekly

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma (MM): Diagnosis of relapsed or refractory multiple myeloma (RRMM). Patient has received at least four prior therapies. Disease is refractory to all of the following: 1) Two proteasome inhibitors (e.g., bortezomib, carfilzomib), 2) Two immunomodulatory agents (e.g., lenalidomide, thalidomide), and 3) An anti-CD38 monoclonal antibody (e.g. daratumumab). Used in combination with dexamethasone. Diffuse large B-cell lymphoma (DLBCL): Diagnosis of one of the following: 1) Relapsed or refractory DLBCL not otherwise specified OR 2) Relapsed or refractory DLBCL arising from follicular lymphoma. Patient has previously received at least two lines of systemic therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	Plan Year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

## XTANDI (PREFERRED)

### Products Affected

- Xtandi

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Metastatic castration-resistant or recurrent prostate cancer (mCRPC): Diagnosis of castration-resistant or castration-recurrent prostate cancer. Disease is metastatic. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] or 2) Patient received bilateral orchiectomy. Non-metastatic CRPC: Diagnosis of prostate cancer. Disease is non-metastatic, castration-resistant or recurrent. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] or 2) Patient received bilateral orchiectomy. Metastatic castration-sensitive prostate cancer (mCSPC): Diagnosis of metastatic castration-sensitive prostate cancer. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] or 2) Patient received bilateral orchiectomy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Approve for continuation of prior therapy if within the past 120 days.

# XYREM

## Products Affected

- Xyrem

PA Criteria	Criteria Details
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are present, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are absent, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present, AND Trial and failure, contraindication, or intolerance to both of the following: 1) modafinil, AND 2) methylphenidate-based stimulant.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Reauth: plan year
<b>Other Criteria</b>	Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with Xyrem therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy.

# ZEJULA

## Products Affected

- Zejula

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of advanced epithelial ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to first-line platinum-based chemotherapy (e.g., cisplatin, carboplatin). Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Treatment of advanced ovarian cancer after three or more chemotherapies: Diagnosis of advanced ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Patient has been treated with three or more prior chemotherapy regimens. Patient's cancer is associated with homologous recombination deficiency (HRD) positive status defined by one of the following: (a) a deleterious or suspected deleterious BRCA mutation or (b) both of the following: (1) genomic instability and (2) cancer has progressed more than 6 months after response to the last platinum-based chemotherapy (e.g., cisplatin, carboplatin).</p>
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days



# ZELBORAF

## Products Affected

- Zelboraf

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable or metastatic melanoma. Patient is positive for BRAF V600 mutation. Erdheim-Chester Disease: Diagnosis of Erdheim-Chester disease AND Disease is BRAFV600 mutant type (MT).
Age Restrictions	N/A
Prescriber Restrictions	Melanoma: Prescribed by or in consultation with an oncologist. Erdheim-Chester Disease: Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# ZERBAXA

## Products Affected

- Zerbaxa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Complicated intra-abdominal infection (cIAI): Diagnosis of cIAI. Infection caused by <i>Enterobacter cloacae</i>, <i>Escherichia coli</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i>, <i>Proteus mirabilis</i>, <i>Pseudomonas aeruginosa</i>, <i>Bacteroides fragilis</i>, <i>Streptococcus anginosus</i>, <i>Streptococcus constellatus</i>, or <i>Streptococcus salivarius</i> documented by culture and sensitivity report. Used in combination with metronidazole. Trial and failure to one of the following or history of resistance, contraindication, or intolerance to all of the following antibiotics: carbapenem, piperacillin-tazobactam, tigecycline, cephalosporin in combination with metronidazole, fluoroquinolone in combination with metronidazole.</p> <p>Complicated urinary tract infection (cUTI): Diagnosis of cUTI. Infection caused by <i>Escherichia coli</i>, <i>Klebsiella pneumoniae</i>, <i>Proteus mirabilis</i>, or <i>Pseudomonas aeruginosa</i> documented by culture and sensitivity report. Trial and failure to one of the following or history of resistance, contraindication, or intolerance to all of the following antibiotics: piperacillin-tazobactam, carbapenem, cephalosporin, fluoroquinolone (except moxifloxacin). Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP): Diagnosis of HABP or VABP. Infection caused by one of the following susceptible Gram-negative microorganisms: <i>Enterobacter cloacae</i>, <i>Escherichia coli</i>, <i>Haemophilus influenzae</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i>, <i>Proteus mirabilis</i>, <i>Pseudomonas aeruginosa</i> or <i>Serratia marcescens</i> documented by culture and sensitivity report. One of the following: 1) trial and failure to one of the following antibiotics: Piperacillin-tazobactam, Carbapenem, Cephalosporin, Fluoroquinolone (ciprofloxacin or levofloxacin) OR 2) History of resistance, contraindication, or intolerance to all of the following antibiotics: Piperacillin-tazobactam, Carbapenem, Cephalosporin, Fluoroquinolone (ciprofloxacin or levofloxacin).</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist.
<b>Coverage Duration</b>	cIAI: 14 days. cUTI: 7 days. HABP/VABP: 14 days.
<b>Other Criteria</b>	cIAI, cUTI, HABP, VABP: For continuation of therapy upon hospital discharge.

## ZOLINZA

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### Products Affected

- Zolinza

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Trial and failure, contraindication, or intolerance to at least two systemic therapies.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

## ZORBTIVE

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### Products Affected

- Zorbtive

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Short Bowel Syndrome (SBS): Diagnosis of SBS. Patient is currently receiving specialized nutritional support (eg, intravenous parenteral nutrition, fluid, and micronutrient supplements). Patient has not previously received 4 weeks of treatment with Zorbtive.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	SBS: 4 weeks.
Other Criteria	N/A

# ZYCLARA

## Products Affected

- Imiquimod Pump
- Zyclara Pump

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Zyclara 2.5%: Diagnosis (Dx) of actinic keratosis (AK). Imiquimod 3.75%: Dx of AK OR external genital or perianal warts (condyloma acuminata).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	AK (2.5% and 3.75% strengths): Trial and failure, contraindication, or intolerance to Picato gel.

# ZYDELIG

## Products Affected

- Zydelig

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL, disease has relapsed or is refractory. Follicular B-cell non-Hodgkin Lymphoma (FL): Diagnosis of follicular B-cell non-Hodgkin lymphoma (FL).Not used as first-line therapy.
Age Restrictions	N/A
Prescriber Restrictions	All indications: Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# ZYKADIA

## Products Affected

- Zykadia TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC), tumor is anaplastic lymphoma kinase (ALK)-positive or ROS1-positive.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# ZYTIGA

## Products Affected

- Abiraterone Acetate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Metastatic Castration-Resistant Prostate Cancer (mCRPC): Diagnosis of metastatic castration-resistant or castration-recurrent prostate cancer. Used in combination with prednisone. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] or 2) Patient received bilateral orchiectomy. Metastatic Castration-Sensitive Prostate Cancer (mCSPC): Diagnosis of metastatic high-risk castration-sensitive prostate cancer. Used in combination with prednisone. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)] or 2) Patient received bilateral orchiectomy.
Age Restrictions	N/A
Prescriber Restrictions	mCRPC, mCSPC: Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	mCRPC, mCSPC: Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

## PART B VERSUS PART D

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### Products Affected

- Abelcet
- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU
- Ambisome
- Aminosyn II INJ 107.6MEQ/L; 1490MG/100ML; 1527MG/100ML; 1050MG/100ML; 1107MG/100ML; 750MG/100ML; 450MG/100ML; 990MG/100ML; 1500MG/100ML; 1575MG/100ML; 258MG/100ML; 447MG/100ML; 1083MG/100ML; 795MG/100ML; 50MEQ/L; 600MG/100ML; 300MG/100ML; 405MG/100ML; 750MG/100ML; 71.8MEQ/L; 993MG/100ML; 1018MG/100ML; 700MG/100ML; 738MG/100ML; 500MG/100ML; 300MG/100ML; 660MG/100ML; 1000MG/100ML; 1050MG/100ML; 172MG/100ML; 298MG/100ML; 722MG/100ML; 530MG/100ML; 38MEQ/L; 400MG/100ML; 200MG/100ML; 270MG/100ML; 500MG/100ML
- Aminosyn-pf 7%
- Amphotericin B INJ
- Azathioprine TABS
- Bethkis
- Budesonide SUSP
- Calcitriol CAPS
- Calcitriol ORAL SOLN
- Cinacalcet Hydrochloride
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclosporine CAPS
- Cyclosporine Modified
- Dextrose 5%
- Dextrose 5%/nacl 0.9%
- Doxercalciferol CAPS
- Engerix-b
- Envarsus Xr
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG
- Freamine Hbc 6.9%
- Furosemide INJ
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hcl TABS
- Heparin Sodium INJ 1000UNIT/ML
- Hepatamine
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/100ML, 30GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Levalbuterol NEBU
- Levalbuterol Hydrochloride
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nebupent
- Nephramine
- Nutrilipid
- Ondansetron Hcl SOLN
- Ondansetron Hcl TABS 24MG
- Ondansetron Hydrochloride TABS
- Ondansetron Odt
- Paricalcitol CAPS
- Pentamidine Isethionate INHALATION SOLR
- Perforomist
- Plenamine
- Potassium Chloride INJ 10MEQ/100ML, 20MEQ/100ML, 2MEQ/ML, 40MEQ/100ML
- Potassium Chloride/dextrose INJ 5%; 20MEQ/L
- Potassium Chloride/sodium Chloride INJ 20MEQ/L; 0.45%, 20MEQ/L; 0.9%, 40MEQ/L; 0.9%

- Premasol INJ 52MEQ/L;  
1760MG/100ML; 880MG/100ML;  
34MEQ/L; 1760MG/100ML;  
372MG/100ML; 406MG/100ML;  
526MG/100ML; 492MG/100ML;  
492MG/100ML; 526MG/100ML;  
356MG/100ML; 356MG/100ML;  
390MG/100ML; 34MG/100ML;  
152MG/100ML
- Procalamine
- Prograf PACK
- Prosol
- Pulmozyme
- Rabavert
- Recombivax Hb
- Sandimmune SOLN
- Sirolimus SOLN
- Sirolimus TABS
- Sodium Chloride INJ 0.9%, 3%, 5%
- Tacrolimus CAPS
- Tobramycin NEBU 300MG/5ML
- Travasol INJ 52MEQ/L;  
1760MG/100ML; 880MG/100ML;  
34MEQ/L; 1760MG/100ML;  
372MG/100ML; 406MG/100ML;  
526MG/100ML; 492MG/100ML;  
492MG/100ML; 526MG/100ML;  
356MG/100ML; 500MG/100ML;  
356MG/100ML; 390MG/100ML;  
34MG/100ML; 152MG/100ML
- Trophamine INJ 97MEQ/L;  
0.54GM/100ML; 1.2GM/100ML;  
0.32GM/100ML; 0; 0; 0.5GM/100ML;  
0.36GM/100ML; 0.48GM/100ML;  
0.82GM/100ML; 1.4GM/100ML;  
1.2GM/100ML; 0.34GM/100ML;  
0.48GM/100ML; 0.68GM/100ML;  
0.38GM/100ML; 5MEQ/L;  
0.025GM/100ML; 0.42GM/100ML;  
0.2GM/100ML; 0.24GM/100ML;  
0.78GM/100ML
- 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.