

Prior Authorization Criteria

2024 MCSNP

Last Updated: 10/1/2023

## ABIRATERONE

### 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	Diagnosis of prostate cancer. One of the following: 1) Disease is metastatic, 2) Disease is regional node positive (e.g., N1), or 3) Patient is in a very-high-risk group receiving external beam radiation therapy (EBRT). 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# ABRYSVO

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## Products Affected

- Abrysvo

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 the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV). Patient has not received an RSV vaccine (i.e., Abrysvo, Arexvy) in the previous 2 years. One of the following: 1) Age greater than or equal to 60 years, OR 2) Both of the following: a) Will be used for active immunization of pregnant individuals at 32 through 36 weeks gestational age, and b) Will also be used for the prevention of severe LRTD caused by RSV in infants from birth through 6 months of age.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months (1 injection per 2 years)
Other Criteria	N/A

# ACTEMRA SC

## Products Affected

- Actemra INJ 162MG/0.9ML

- Actemra Actpen

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 of moderately to severely active RA. One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Formulary adalimumab product, Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), OR 2) for continuation of prior therapy if within the past 120 days. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. TF/C/I to a glucocorticoid (e.g., prednisone). Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. TF/C/I to one of the following conventional therapies at maximally tolerated doses: a) minimum duration of a one month trial of a nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen), b) minimum duration of a 3-month trial of methotrexate, or c) minimum duration of a 2-week trial of a systemic glucocorticoid (eg, prednisone). Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: 1) TF/C/I to two of the following: Enbrel (etanercept), Formulary adalimumab product, Orencia (abatacept), Xeljanz (tofacitinib), OR 2) for continuation of prior therapy if within the past 120 days. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (Initial): Diagnosis of SSc-ILD as documented by the following: a) Exclusion of other known causes of ILD AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD, OR ii) In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD.</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	RA, GCA, SJIA, PJIA (Initial): Prescribed by or in consultation with a rheumatologist. SSc-ILD (Initial): Prescribed by or in consultation with a pulmonologist or rheumatologist.
<b>Coverage Duration</b>	All uses (initial): 6 months. All uses (reauth): plan year.
<b>Other Criteria</b>	All indications (reauth): Patient demonstrates positive clinical response to therapy.

# 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

# AIMOVIG

## Products Affected

- Aimovig

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<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), f) Candesartan (Atacand). 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), g) Candesartan (Atacand). All Indications (initial): Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.</p>
Age Restrictions	N/A
Prescriber Restrictions	<p>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</p>
Coverage Duration	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. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.
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# ALECENSA

## Products Affected

- Alecensa

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, recurrent, or advanced NSCLC. Patient has anaplastic lymphoma kinase (ALK)-positive disease.
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.



# 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. Patient demonstrates 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
- 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 (initial): Diagnosis of congenital AAT deficiency. Diagnosis of emphysema. One of the following: Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous) or Other rare AAT disease genotypes associated with pre-treatment serum AAT level less than 11 µmol/L [eg, Pi(Malton, Malton), Pi(SZ)]. One of the following: 1) Circulating pre-treatment serum AAT level less than 11 µmol/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry), or 2) Patient has a concomitant diagnosis of necrotizing panniculitis. Continued conventional treatment for emphysema (eg, bronchodilators).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	AAT deficiency (initial, reauth): plan year
Other Criteria	AAT deficiency (reauth): Patient demonstrates positive clinical response to therapy. Continued conventional treatment for emphysema (e.g., bronchodilators).

# ALUNBRIG

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## 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, recurrent, or advanced NSCLC and tumor is anaplastic lymphoma kinase (ALK)-positive.
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

# 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

# APREPITANT

## Products Affected

- Aprepitant CAPS

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-HT3 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 aprepitant (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.

# ARANESP

## 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, 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
Required Medical Information	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. Documentation of a positive clinical response to therapy 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 receiving chemo. (Reauth): Anemia by labs (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Documentation of a positive clinical response to therapy from pre-treatment level. Patient is receiving 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. Documentation of a positive clinical response to therapy from pre-treatment level.
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	CKD(Init): 6 mo. CKD(reauth):plan yr. Chemo(init, reauth): 3 mo. MDS(init): 3 mo,(reauth): plan yr
<b>Other Criteria</b>	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.

# ARCALYST

## Products Affected

- Arcalyst

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cryopyrin-Associated Period Syndromes (CAPS): Diagnosis of CAPS, Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS). Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA. Patient weighs at least 10 kg. Patient is currently in remission (e.g., no fever, skin rash, and bone pain/no radiological evidence of active bone lesions/C-reactive protein [CRP] less than 5 mg/L). Recurrent Pericarditis (initial): Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart. Trial and failure, contraindication, or intolerance (TF/C/I) to at least one of the following: nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen), colchicine, or corticosteroids (e.g., prednisone).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CAPS, DIRA: plan year. Recurrent Pericarditis (initial, reauth): plan year.
Other Criteria	Recurrent Pericarditis (reauth): Patient demonstrates positive clinical response to therapy.



# AREXVY

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## Products Affected

- Arexvy

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 the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV). Patient has not received an RSV vaccine (i.e., Abrysvo, Arexvy) in the previous 2 years. Age greater than or equal to 60 years.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months (1 injection per 2 years)
Other Criteria	N/A

# ARMODAFINIL

## Products Affected

- Armodafinil

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Obstructive sleep apnea (OSA) (Initial): Diagnosis (dx) of OSA defined by one of the following: a) 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 b) 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 disorder (SWD) (Initial): Dx of SWD 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). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. Narcolepsy (initial): Dx of narcolepsy as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	OSA, SWD: Initial, Reauth: 6 mo. Narcolepsy: Initial, Reauth: Plan Year
Other Criteria	OSA, Narcolepsy (Reauth): Patient demonstrates positive clinical response to therapy. SWD (Reauth): Patient demonstrates positive clinical response to therapy.

# AUSTEDO

## Products Affected

- Austedo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Huntington's disease chorea (initial): Prescribed by a neurologist. Tardive dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist.
Coverage Duration	Plan year
Other Criteria	N/A

# 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. One of the following: 1) Patient has unresectable, recurrent, or metastatic disease after failure on one approved therapy (e.g., imatinib, sunitinib, dasatinib, regorafenib, ripretinib) OR 2) Both of the following: a) Disease is one of the following: i) unresectable, ii) metastatic, iii) recurrent, iv) persistent microscopic or gross residual disease, v) residual disease with significant morbidity, vi) limited progression, or vii) resectable with significant morbidity AND b) Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Systemic Mastocytosis: Both of the following: 1) Diagnosis of one of the following: a) advanced systemic mastocytosis (AdvSM), b) aggressive systemic mastocytosis (ASM), c) systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or d) mast cell leukemia (MCL) AND 2) platelet count is greater than $50 \times 10^9/L$ . Ayvakit 25 mg - Indolent Systemic Mastocytosis (ISM): Diagnosis of ISM. Platelet count is greater than $50 \times 10^9/L$ .
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.

# 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 (e.g., gemcitabine with cisplatin or carboplatin, dose dense methotrexate vinblastine doxorubicin cisplatin [DDMVAC] with growth factor support, etc.) or immunotherapy (e.g., avelumab, atezolizumab, etc.) OR 2) Patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (e.g., [DDMVAC] with growth factor support, gemcitabine with cisplatin, etc.).
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.

# 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)]). Lupus Nephritis (Initial): Diagnosis of active lupus nephritis. Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide). SLE, Lupus Nephritis (Reauthorization): Patient demonstrates positive clinical response to therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	SLE, Lupus Nephritis (initial, reauth): 6 months
Other Criteria	N/A

# BERINERT

## 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. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. 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 or an allergist
Coverage Duration	Plan year
Other Criteria	N/A

# BESREMI

## Products Affected

- Besremi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of polycythemia vera as confirmed by all of the following: 1) One of the following: a) Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women, b) Hematocrit greater than 49% for men or hematocrit greater than 48% for women, or c) Increased red cell mass, AND 2) Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes, AND 3) One of the following: a) Presence of JAK2 or JAK2 exon 12 mutation or b) Subnormal serum erythropoietin level. Both of the following: 1) Trial and failure, contraindication or intolerance (TF/C/I) to hydroxyurea, AND 2) TF/C/I to one interferon therapy (e.g., Intron A, Pegasys, etc.).
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.



# BEXAROTENE

## Products Affected

- Bexarotene

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.

# BOSENTAN

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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

# 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	N/A
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	N/A
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.

# BRONCHITOL

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## Products Affected

- Bronchitol

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. Patient has passed the Bronchitol Tolerance Test (BTT).
Age Restrictions	CF (initial): Patient is 18 years of age or older.
Prescriber Restrictions	CF (initial): Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center.
Coverage Duration	CF (initial): 6 months. CF (reauth): Plan year.
Other Criteria	CF (reauth): Patient demonstrates positive clinical response to therapy.

# 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	Mantle Cell Lymphoma (MCL): Diagnosis of MCL. Patient has received at least one prior therapy for MCL. Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. Disease is relapsed or refractory. Patient has received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab). Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL.
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.

# 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 thrombotic 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	N/A
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 advanced RCC. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: a) Trial and failure, contraindication, 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. Differentiated Thyroid Cancer (DTC): Diagnosis of DTC. Disease is one of the following: a) locally advanced or b) metastatic. Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib]). Disease is radioactive iodine-refractory or ineligible.
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.

# 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). Trial and failure, contraindication, or intolerance to Brukinsa (zanubrutinib). Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. Trial and failure, contraindication, or intolerance to Brukinsa (zanubrutinib) or Imbruvica (ibrutinib).
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.

# CAPLYTA

## Products Affected

- Caplyta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Schizophrenia: Diagnosis of schizophrenia. Trial and failure, contraindication, or intolerance to two of the following oral, single-ingredient, formulary, generic atypical antipsychotics: asenapine, aripiprazole, paliperidone, olanzapine, quetiapine (IR or ER), risperidone, or ziprasidone. Bipolar disorder: Diagnosis of bipolar I or II disorder (bipolar depression). Patient has depressive episodes associated with bipolar disorder. Used as monotherapy or as adjunctive therapy with lithium or valproate.
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.

# CAYSTON

## 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 Pseudomonas aeruginosa infection.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# CHENODAL

## Products Affected

- Chenodal

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of radiolucent gallstones. Patient has a well-opacifying gallbladder visualized by oral cholecystography. Trial and failure, contraindication or intolerance to ursodiol. Patient is not a candidate for surgery. Stones are not calcified (radiopaque) or radiolucent bile pigment stones.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, reauth: Plan year
Other Criteria	Reauth: Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment as evidenced by Oral cholecystograms or ultrasonograms.

# CHOLBAM

## Products Affected

- Cholbam

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>	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) Will be used as an adjunctive treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial: Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.
<b>Coverage Duration</b>	Initial: 3 months Reauth: Plan year
<b>Other Criteria</b>	All uses (reauth): Patient demonstrates positive clinical response to therapy.

# CIMZIA

## Products Affected

- Cimzia

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): Diagnosis (dx) of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinib), OR for continuation of prior therapy if within the past 120 days. Crohn's Disease (CD): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. One of the following: TF/C/I to two of the following: Humira, Skyrizi (risankizumab-rzaa), or Stelara (ustekinumab), OR for continuation of prior therapy if within the past 120 days. Psoriatic Arthritis (PsA): Dx of active psoriatic arthritis. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. TF/C/I to two agents from the following different mechanisms of action: TNF [ie, Enbrel or Humira], IL-17 [ie, Cosentyx (secukinumab)], IL-23 [ie, Stelara or Skyrizi], JAK [ie, Xeljanz/Xeljanz XR or Rinvoq], PDE4 [ie, Otezla (apremilast)], OR for continuation of prior therapy if within the past 120 days. Ankylosing Spondylitis (AS): Dx of active AS. TF/C/I to two agents from the following different mechanisms of action: TNF [ie, Enbrel or Humira], IL-17 [ie, Cosentyx], JAK [ie, Rinvoq or Xeljanz/Xeljanz XR], OR for continuation of prior therapy if within the past 120 days. Plaque Psoriasis (initial): Dx of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. TF/C/I to two agents from the following different mechanisms of action: TNF [ie, Enbrel or Humira], IL-17 [ie, Cosentyx], IL-23 [ie, Stelara or Skyrizi], PDE4 [ie, Otezla].</p>
Age Restrictions	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): 6 months, (reauth): plan year
<b>Other Criteria</b>	Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of nr-axSpA with signs of inflammation. Minimum duration of a one-month TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, naproxen) at maximally tolerated doses. All indications (reauth): Patient demonstrates positive clinical response to 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. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For prophylaxis against HAE attacks. Not used in combination with other approved treatments for prophylaxis against HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE (prophylaxis): Prescribed by or in consultation with an immunologist or an allergist
Coverage Duration	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 Hydrochloride 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

## 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 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.].
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.

# 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	<p>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. Patient has been hospitalized for worsening HF in the previous 12 months. Trial and failure, contraindication, or intolerance to two of the following at a maximally tolerated dose: A) One of the following: 1) ACE inhibitor (e.g., captopril, enalapril, lisinopril), 2) ARB (e.g., candesartan, losartan, valsartan), or 3) ARNI (e.g., Entresto [sacubitril and valsartan]), B) One of the following: 1) bisoprolol, 2) carvedilol, or 3) metoprolol succinate extended release, C) Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)], or D) Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]. 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).</p>
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CHF, DCM (Initial, reauth): plan year
Other Criteria	CHF, DCM (reauth): Patient demonstrates positive clinical response to therapy.

# COSENTYX

## Products Affected

- Cosentyx INJ 150MG/ML, 75MG/0.5ML
- Cosentyx Sensoready Pen

- Cosentyx Unoready

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance (TF/C/I) to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one non-steroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with signs of inflammation. Minimum duration of a one-month TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, naproxen) at maximally tolerated doses.
Age Restrictions	N/A
Prescriber Restrictions	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, ERA (initial): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	All uses (Initial): 6 months. All uses (Reauth): plan year.

<b>Other Criteria</b>	Enthesitis-Related Arthritis (ERA) (Initial): Diagnosis of active ERA. Minimum duration of a one-month TF/C/I to two NSAIDs (eg, ibuprofen, naproxen) at maximally tolerated doses. All indications (Reauth): Patient demonstrates positive clinical response to therapy.
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# 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). Histiocytic Neoplasm: Diagnosis of one of the following: 1) Langerhans Cell Histiocytosis, 2) Erdheim-Chester Disease, or 3) Rosai-Dorfman Disease. One of the following: 1) Mitogen-activated protein (MAP) kinase pathway mutation, 2) No detectable mutation, or 3) Testing not available.
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.

# 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

# 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 (e.g., glipizide, glimepiride), thiazolidinedione (e.g., pioglitazone), DPP-4 Inhibitor [e.g., Tradjenta (linagliptin)], SGLT2 inhibitor [e.g., Jardiance (empagliflozin)], GLP-1 receptor agonist [e.g., Trulicity (dulaglutide), Victoza (liraglutide)], or basal insulin (e.g., insulin glargine).
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.

# CYLTEZO

## Products Affected

- Cyltezo

- Cyltezo Starter Package For Crohns Disease/uc/hs
- Cyltezo Starter Package For Psoriasis

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. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate (MTX), leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Dx of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (PsO) (Initial): Dx of moderate to severe chronic PSO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week TF/C/I to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Ankylosing Spondylitis (AS) (Initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine (6-MP), azathioprine, corticosteroid (eg, prednisone), MTX.</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. PsO, HS (Initial): Prescribed by or in consultation with a dermatologist. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	UC (Initial): 12 wks. Other uses (initial): 6 months. All uses (reauth): plan year.
<b>Other Criteria</b>	Ulcerative Colitis (UC) (Initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-MP, azathioprine, corticosteroid (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine). Hidradenitis suppurativa (HS) (Initial): Dx of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA, PsA, AS, PsO, CD, HS (Reauth): Patient demonstrates positive clinical response to therapy. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Patient has clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Patient demonstrates positive clinical response to therapy.

# 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# DEFERASIROX

## Products Affected

- Deferasirox

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): Patient demonstrates positive clinical response to therapy.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by a hematologist/oncologist or hepatologist.
Coverage Duration	Plan year
Other Criteria	N/A

# DEFERIPRONE

## Products Affected

- Deferiprone

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Transfusional iron overload: Diagnosis of transfusional iron overload due to one of the following: thalassemia syndromes, sickle cell disease, other transfusional-dependent anemia. Absolute Neutrophil Count (ANC) greater than $1.5 \times 10^9/L$ . One of the following: A) Trial and failure to one chelation therapy (e.g., generic deferasirox) OR B) History of contraindication or intolerance to one chelation therapy (e.g., generic deferasirox).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	All uses (reauth): Patient demonstrates positive clinical response to therapy. ANC greater than $1.5 \times 10^9/L$ .



# 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%

### 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): Patient demonstrates positive clinical response to 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

# DIHYDROERGOTAMINE NASAL

## Products Affected

- Dihydroergotamine Mesylate NASAL SOLN

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of migraine headaches with or without aura. Will be used for the acute treatment of migraine. One of the following: Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or contraindication to all triptans.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with one of the following specialists with expertise in the treatment of migraine: neurologist, pain specialist, headache specialist.
Coverage Duration	Plan year
Other Criteria	Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea).

# DOPTELET

## Products Affected

- Doptelet

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Thrombocytopenia Prior to Planned Procedure (TPPP): Diagnosis (dx) of thrombocytopenia. Patient has chronic liver disease and is scheduled to undergo a procedure. Baseline platelet count is less than 50,000/mcL. Chronic Immune Thrombocytopenia (ITP) (initial): Diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) or relapsed/refractory ITP. Baseline platelet count is less than 30,000/mcL. Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	TPPP: 1 month. ITP (initial, reauth): Plan year
Other Criteria	ITP (reauth): Patient demonstrates positive clinical response to therapy.

# 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
<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>	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.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	CINV: 6 months. AIDS anorexia: 3 months.
<b>Other Criteria</b>	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.

# DROXIDOPA

## Products Affected

- Droxidopa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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): Patient demonstrates positive clinical response to therapy.
Age Restrictions	N/A
Prescriber Restrictions	NOH (init): Prescribed by or in consultation with one of the following specialists: cardiologist, neurologist, nephrologist.
Coverage Duration	Initial: 1 month. Reauth: plan year
Other Criteria	Trial and failure, contraindication, or intolerance to one of the following agents: Fludrocortisone acetate, midodrine.

# DUPIXENT

## Products Affected

- Dupixent

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Atopic Dermatitis (AD) (initial): Diagnosis (dx) of moderate-to-severe AD. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance to at least one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. Eosinophilic Asthma (EA) (initial): Dx of moderate to severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter. One of the following: 1) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (eg, prednisone) within the past 12 mo, or 2) Prior asthma-related hospitalization within the past 12 mo. Corticosteroid Dependent Asthma (CDA) (initial): Dx of moderate to severe asthma. Patient is currently dependent on oral corticosteroids for the treatment of asthma. EA, CDA (initial): Patient is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications: 1) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and additional asthma controller medication [e.g., leukotriene receptor antagonist (eg, montelukast), long-acting beta-2 agonist (LABA) (eg, salmeterol), tiotropium] OR 2) One max-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta (fluticasone/vilanterol)). Prurigo nodularis (PN) (init): Diagnosis of PN. Trial and failure, contraindication, or intolerance to one medium or higher potency topical corticosteroid.
Age Restrictions	Asthma (initial): Patient is 6 years of age or older. AD (initial): Patient is 6 months of age or older. CRSwNP, PN: no age restriction. EoE (initial): Patient is 12 years of age or older.



<b>Prescriber Restrictions</b>	AD, PN (init): Prescribed by or in consultation with a dermatologist or allergist/immunologist. Asthma (init): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (initial): Prescribed by or in consultation with an otolaryngologist, allergist/immunologist, or pulmonologist. EoE (initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	CRSwNP, EoE (Init/Reauth): Plan year. Asthma, AD, PN (Init): 6 mo. Asthma, AD, PN (reauth): Plan yr.
<b>Other Criteria</b>	Eosinophilic esophagitis (EoE) (initial): Dx of EoE. Patient weighs at least 40 kg. Trial and failure, contraindication, or intolerance to one of the following: a) proton pump inhibitors (eg, pantoprazole, omeprazole) or b) topical (esophageal) corticosteroids (eg, budesonide, fluticasone). AD (reauth): Patient demonstrates positive clinical response to therapy. Chronic rhinosinusitis with nasal polypsis (CRSwNP) (initial): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (eg, fluticasone, mometasone). Used in combination with another agent for CRSwNP. EA (reauth): Patient demonstrates positive clinical response to therapy. CDA (reauth): Patient demonstrates positive clinical response to therapy. EA, CDA (reauth): Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. CRSwNP (reauth): Patient demonstrates positive clinical response to therapy. Used in combination with another agent for CRSwNP. EoE, PN (reauth): Patient demonstrates positive clinical response to therapy.

# EMGALITY

## Products Affected

- Emgality

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Episodic Migraines (EM) (120 mg/mL strength only) (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), f) Candesartan (Atacand). Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. Chronic Migraines (CM) (120 mg/mL strength only) (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), g) Candesartan (Atacand). Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. Episodic Cluster Headaches (ECH) (100 mg/mL strength only) (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. Medication will not be used in combination with another injectable CGRP inhibitor.</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	EM, CM, ECH (initial, reauth): Plan year.
<b>Other Criteria</b>	ECH (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Medication will not be used in combination with another injectable CGRP inhibitor. EM, CM (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.

# ENBREL

## Products Affected

- Enbrel INJ 25MG/0.5ML, 50MG/ML
- Enbrel Mini
- Enbrel Sureclick

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 of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week TF/C/I to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses.</p>
Age Restrictions	N/A
Prescriber Restrictions	<p>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.</p>

<b>Coverage Duration</b>	All indications (initial): 6 months, (reauth): plan year
<b>Other Criteria</b>	All indications (Reauth): Patient demonstrates positive clinical response to therapy.

# ENDARI

## Products Affected

- Endari

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Sickle cell disease (initial): Diagnosis of sickle cell disease. Used to reduce acute complications of sickle cell disease. Patient has had 2 or more painful sickle cell crises within the past 12 months.
Age Restrictions	N/A
Prescriber Restrictions	Sickle cell disease (initial): Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Sickle cell disease (initial, reauth): plan year
Other Criteria	Sickle cell disease (reauth): Patient demonstrates positive clinical response to therapy.

# EPCLUSA

## Products Affected

- Epclusa

- Sofosbuvir/velpatasvir

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. 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. Tuberous sclerosis complex (TSC): Diagnosis of seizures associated with TSC.
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.



## 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	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. Documentation of a positive clinical response to therapy from pre-treatment level. 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. Documentation of a positive clinical response to therapy from pre-treatment level. 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 receiving chemo. (Reauth): Anemia by labs (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 wks of request. Documentation of a positive clinical response to therapy from pre-treatment level. Patient is receiving chemo.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	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. Patient demonstrates positive clinical response to therapy 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 or unavailability of Retacrit OR B) History of intolerance, adverse event, or contraindication to Retacrit.</p>
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## 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. Documentation of a positive clinical response to therapy from pre-treatment level. 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. Documentation of a positive clinical response to therapy from pre-treatment level. 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 receiving chemo. (Reauth): Anemia by labs (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 wks of request. Documentation of a positive clinical response to therapy from pre-treatment level. Patient is receiving chemo.</p>
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	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. Patient demonstrates positive clinical response to therapy 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>
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# 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# ERLEADA

## Products Affected

- Erleada

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 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 (e.g., Zoladex [goserelin], Vantas [histrelin], Lupron [leuprolide], Trelstar [triptorelin]) OR 2) Patient received a bilateral orchiectomy. 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.
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

# ERLOTINIB

## Products Affected

- Erlotinib Hydrochloride TABS

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 one of the following: a) advanced, b) metastatic, or c) 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# EVEROLIMUS

## Products Affected

- Everolimus TABS 10MG, 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	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/Kidney Cancer: Dx of advanced renal cell cancer/kidney cancer. Disease is one of the following: (1) relapsed or (2) stage IV disease. 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year



<b>Other Criteria</b>	All uses: Approve for continuation of prior therapy if within the past 120 days.
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# EVEROLIMUS SOLUTION

## Products Affected

- Everolimus TBSO

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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/Kidney Cancer: Dx of advanced renal cell cancer/kidney cancer. Disease is one of the following: (1) relapsed or (2) stage IV disease. 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year

<b>Other Criteria</b>	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.
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## EXKIVITY

### Products Affected

- Exkivity

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: a) locally advanced or b) metastatic. Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive. Used as subsequent therapy for disease that has progressed on or after platinum-based chemotherapy (e.g., carboplatin, cisplatin).
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.

# 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 (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: a) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months, OR b) 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 [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)].
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	Initial: 6 mo, Reauth: Plan year
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy. Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications.

## 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

# FINTEPLA

## Products Affected

- Fintepla

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: 1) Diagnosis of seizures associated with Dravet syndrome, OR 2) Diagnosis of seizures associated with Lennox-Gastaut 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.

# FLECTOR

## Products Affected

- 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



# FOTIVDA

## Products Affected

- Fotivda

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of renal cell carcinoma. Disease is one of the following: relapsed or refractory. Patient has received two or more prior systemic therapies (e.g., cabozantinib + nivolumab, lenvatinib + pembrolizumab, etc.).
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.

# GAVRETO

## Products Affected

- Gavreto

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 one of the following: recurrent, advanced, or metastatic. Presence of RET (rearranged during transfection) gene fusion-positive or RET rearrangement positive tumors. Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene mutation. Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is one of the following: advanced or metastatic. Disease is rearranged during transfection (RET) gene fusion-positive. Disease requires treatment with systemic therapy. One of the following: patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate.
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

# 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 (e.g., cisplatin, carboplatin) OR 3) tumors are positive for a known sensitizing EGFR mutation.
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.

# GLP1

## Products Affected

- Bydureon Bcise
- Byetta
- Mounjaro
- Ozempic INJ 2MG/3ML, 4MG/3ML, 5.5MG/ML; 14MG/ML; 8MG/3ML
- Rybelsus
- Soliqua 100/33
- Trulicity

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Excluded if used for weight loss only.
Required Medical Information	Diabetes Mellitus (DM): 1) Diagnosis of type 2 DM, OR 2) Trial of one product from any of the following drugs/classes: alpha-glucosidase inhibitors, amylin analogs, biguanides, Cycloset (bromocriptine 0.8 mg), DPP-4 inhibitors, DPP-4 inhibitor combinations, glycemic agents (e.g., glucagon), insulins, meglitinides, SGLT2 inhibitors, SGLT2 inhibitor combinations, sulfonylureas, or thiazolidinediones.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# GLYCOPYRROLATE ORAL SOLUTION

## Products Affected

- Glycopyrrolate ORAL SOLN

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

# GROWTH HORMONES

## Products Affected

- Genotropin

- Genotropin Miniquick

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)]. 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>
Age Restrictions	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
<b>Other Criteria</b>	<p>AGHD(initial):dx of AGHD as a result of clin records supportng 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 1GH stim test (insulin tolerance test [ITT],glucagon,macimorelin) to confirm adult GHD w/corresponding peak GH values ([ITT at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IGF-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,glucagon,macimorelin) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [glucagon at or below 3mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin], 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, glucagon, macimorelin) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [glucagon at or below 3mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin]. 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 after 2 GH stim tests(ITT,glucagon,macimorelin) w/ 2 corresponding peak GH values [ITT at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin less than 2.8 ng/mL 30,45,60,90 mins after admin].</p>

# 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. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For prophylaxis against HAE attacks. Not used in combination with other approved treatments for prophylaxis against HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE (prophylaxis): Prescribed by or in consultation with an immunologist or an allergist
Coverage Duration	HAE (prophylaxis): plan year
Other Criteria	N/A



# HUMIRA

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## Products Affected

- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pediatric Crohns Disease Starter Pack INJ 0, 80MG/0.8ML
- Humira Pen
- Humira Pen-cd/uc/hs Starter
- Humira Pen-pediatric Uc Starter Pack
- Humira Pen-ps/uv Starter

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

<b>Required Medical Information</b>	<p>Rheumatoid Arthritis (RA) (Initial): Diagnosis (Dx) of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate (MTX), leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Dx of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (PsO) (Initial): Dx of moderate to severe chronic PSO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week TF/C/I to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Ankylosing Spondylitis (AS) (Initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine (6-MP), azathioprine, corticosteroid (eg, prednisone), MTX. Uveitis (UV) (Initial): Dx of non-infectious uveitis classified as intermediate, posterior, or panuveitis.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	<p>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. UV (initial): Prescribed by or in consultation with a rheumatologist or an ophthalmologist.</p>
<b>Coverage Duration</b>	<p>UC: (Initial) 12 wks. Other uses (initial): 6 months. All uses (reauth): plan year.</p>

<b>Other Criteria</b>	<p>Ulcerative Colitis (UC) (Initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-MP, azathioprine, corticosteroid (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine). Hidradenitis suppurativa (HS) (Initial): Dx of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA, PsA, AS, PsO, CD, HS, UV (Reauth): Patient demonstrates positive clinical response to therapy. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Patient has clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Patient demonstrates positive clinical response to therapy.</p>
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# IBRANCE

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## 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.

# ICATIBANT

## Products Affected

- Icatibant Acetate

- Sajazir

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. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. 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 or an allergist
Coverage Duration	Plan year
Other Criteria	N/A

# 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) Both of the following: Disease is in the chronic phase AND 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, or c) Both of the following: Disease is in the accelerated or blast phase AND no other kinase inhibitors are indicated. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL). One of the following: a) No other kinase inhibitors are indicated, b) Confirmed documentation of T315I mutation, c) Disease is relapsed or refractory, d) Used as a component of HyperCVAD regimen (hyper-fractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone, alternating with high-dose methotrexate and cytarabine) induction or consolidation.
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.

# 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 60 years of age or older AND one of the following: 1) Patient is not a candidate for or patient declines intensive induction therapy or 2) Used for post induction therapy following response to low intensity induction therapy.
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.

# 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 5q32 translocations or 2) Disease is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements or 3) disease is associated with a t(5:12) translocation associated with the ETV6-PDGFRbeta fusion gene. Aggressive systemic mastocytosis (ASM): Diagnosis of ASM. Patient is without the D816V c-Kit mutation or c-Kit mutational status unknown or eosinophilia is present with FIP1L1-PDGFRalpha fusion gene. 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# IMBRUVICA

## Products Affected

- Imbruvica CAPS
- Imbruvica SUSP
- Imbruvica TABS 140MG, 280MG, 420MG

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. Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Chronic Graft Versus Host Disease (cGVHD): Diagnosis of cGVHD AND trial and failure of at least one other systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate, etc.).
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.

# 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	N/A
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	One of the following: 1) Both of the following: a) Diagnosis of myelodysplastic syndrome (MDS) and b) Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS), OR 2) Diagnosis of 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	N/A
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: Patient demonstrates 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 an endocrinologist
Coverage Duration	Initial, reauth: plan year
Other Criteria	N/A

# IRESSA

## Products Affected

- Gefitinib

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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# ISOTRETINOIN

## Products Affected

- Accutane
- Amnesteem
- Claravis
- Isotretinoin CAPS
- Zenatane

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 (at least 6 weeks) 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Reauth: Retreatment - 6 months
Other Criteria	N/A

# ISTURISA

## Products Affected

- Isturisa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cushing's disease (initial): Diagnosis of Cushing's disease. One of the following: a) Patient is not a candidate for pituitary surgery, OR b) Pituitary surgery has not been curative for the patient.
Age Restrictions	N/A
Prescriber Restrictions	Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Cushing's disease (initial, reauth): Plan Year
Other Criteria	Cushing's disease (reauth): Patient demonstrates positive clinical response to therapy.

# 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: Diagnosis of fingernail or toenail onychomycosis confirmed by one of the following: KOH test, fungal culture, or nail biopsy.
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

# IVERMECTIN TABLETS

## Products Affected

- Ivermectin TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Any medically accepted indication [e.g., Onchocerciasis due to nematode parasite, Pediculosis, Strongyloidiasis, Ascariasis, Scabies (including crusted scabies), Cutaneous larva migrans (hook worm disease), Enterobiasis, Filariasis, Trichuriasis, or Gnathostomiasis].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A

## IVIG (NON - PREFERRED)

### Products Affected

- Panzyga

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<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>
Age Restrictions	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>All (except reauth): TF/C/I to one of the following: Bivigam, Flebogamma, Gammagard, Gammagard SD, Gammaked, Gammaplex, Gamunex-C, Octagam, Privigen, OR allow for continuation of therapy if within the past 365 days. Subject to Part B vs. Part D review. Pt does not meet criteria for Part B or patient is in a long-term care facility. 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 sxs 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 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: teriflunomide, interferon beta-1b, interferon beta-1a, glatiramer acetate, natalizumab, dimethyl fumarate, 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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## IVIG (PREFERRED)

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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
- 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.

Other Criteria	<p>Subject to Part B vs. Part D review. Pt does not meet criteria for Part B or patient is in a long-term care facility. 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.</p> <p>Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) initial: dx of CIDP confirmed by: 1) progressive sxs 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 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: teriflunomide, interferon beta-1b, interferon beta-1a, glatiramer acetate, natalizumab, dimethyl fumarate, 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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# 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.). Graft versus host disease (GVHD): Diagnosis of GVHD. Disease is steroid-refractory.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# JAYPIRCA

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## Products Affected

- Jaypirca

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). Disease is one of the following: a) relapsed, or b) refractory. Patient has received at least two prior systemic therapies [e.g., chemotherapy] for MCL, one of which is a Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Calquence (acalabrutinib), Brukinsa (zanubrutinib)].
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.

# KALYDECO

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## Products Affected

- Kalydeco PACK 13.4MG, 25MG, 50MG, 75MG
- Kalydeco TABS

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 at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation.
Age Restrictions	CF (initial): Patient is 1 month of age or older.
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	CF (reauth): Patient demonstrates positive clinical response to therapy.

## KERENDIA (SGLT2)

### Products Affected

- Kerendia

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>	Initial: Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D). Urine albumin-to-creatinine ratio (UACR) greater than or equal to 30 mg/g. Estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min/1.73 m <sup>2</sup> . Serum potassium level less than or equal to 5.0 mEq/L prior to initiating treatment. One of the following: 1) Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with one of the following: a) generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril), or b) generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan), OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs. Trial and failure, contraindication or intolerance to one sodium-glucose cotransporter 2 (SGLT2) inhibitor [e.g., Farxiga (dapagliflozin), Jardiance (empagliflozin)].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial, Reauth: Plan year
<b>Other Criteria</b>	Reauth: Patient demonstrates positive clinical response to therapy. One of the following: 1) Patient continues to be on a maximally tolerated dose of ACE inhibitor or ARB, OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs.

# 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) 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	N/A
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	N/A
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 therapy or patient has stable glucose tolerance while on therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
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, bladder/bowel dysfunction).
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.

# KRAZATI

## Products Affected

- Krazati

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. Presence of KRAS G12C mutation. Disease is recurrent, advanced, or metastatic. Patient has received at least one prior systemic therapy (e.g., chemotherapy).
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

# LAPATINIB

## Products Affected

- Lapatinib Ditosylate

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), Arimedes (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	N/A
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.

# LEUPROLIDE ACETATE

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## Products Affected

- Leuprolide Acetate INJ 1MG/0.2ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Treatment of advanced prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prostate Cancer: 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 (e.g., bevacizumab). 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	N/A
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
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. One of the following: A) Disease is advanced, metastatic, or recurrent and anaplastic lymphoma kinase (ALK)-positive 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).
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.

# LUMAKRAS

## Products Affected

- Lumakras

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 one of the following: a) recurrent, b) advanced or c) metastatic. Tumor is KRAS G12C-mutated. Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy).
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.

# 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): Treatment of advanced prostate cancer. Endometriosis (3.75 mg, 11.25 mg) (initial): Diagnosis of endometriosis. One of the following: a) Patient has had surgical ablation to prevent recurrence, or b) trial and failure, contraindication, or intolerance to one NSAID (e.g., diclofenac, ibuprofen, meloxicam, naproxen) and one oral contraceptive (e.g., norethindrone-ethinyl estradiol, estradiol and norethindrone). Endometriosis (3.75 mg, 11.25 mg) (reauthorization): Symptoms recur after one course. Used in combination with one of the following: norethindrone 5 mg daily, other "add -back" sex hormones (e.g., estrogen, medroxyprogesterone), or other bone-sparing agents (e.g., bisphosphonates). 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.

# LUPRON DEPOT PED

## Products Affected

- Lupron Depot-ped INJ 45MG
- Lupron Depot-ped (1-month) INJ 7.5MG

- Lupron Depot-ped (3-month) INJ 11.25MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Central Precocious Puberty (CPP) (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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CPP (ini, reauth): plan yr.
Other Criteria	CPP (Reauthorization): Documentation of bone age monitoring (eg, radiographic imaging).

# LYNPARZA (TABLETS)

## Products Affected

- Lynparza TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>High risk early breast cancer: Diagnosis of high risk early breast cancer. 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) Both of the following: i) Disease is HR-positive AND ii) Patient is continuing concurrent treatment with endocrine therapy. Patient has been previously treated with neoadjuvant or adjuvant chemotherapy (e.g., anthracycline, taxane). Metastatic or recurrent 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.).</p>
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year

<b>Other Criteria</b>	<p>Ovarian cancer (Maintenance Therapy): Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Disease is one of the following: advanced or recurrent. One of the following: 1) Patient has had a complete or partial response to platinum-based chemotherapy (e.g., carboplatin, cisplatin), or 2) Both of the following: a) patient has had a complete or partial response to first-line platinum-based chemotherapy (e.g., carboplatin, cisplatin) AND b) one of the following: i) presence of deleterious or suspected deleterious germline or somatic BRCA-mutations OR ii) both of the following: cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation or genomic instability AND used in combination with bevacizumab (e.g., Avastin, Myasi). Will be used as maintenance therapy.</p> <p>Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer. One of the following: 1) Both of the following: a) Presence of deleterious or suspected deleterious homologous recombination repair (HRR) gene mutations and b) Disease has progressed following prior treatment with one of the following: i) enzalutamide (Xtandi), or ii) abiraterone (e.g., Zytiga, Yonsa), OR 2) All of the following: a) Presence of deleterious or suspected deleterious BRCA-mutation, b) Used in combination with abiraterone (e.g., Zytiga, Yonsa), and c) Used in combination with prednisone or prednisolone. 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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# LYTGOBI

## Products Affected

- Lytgobi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of intrahepatic cholangiocarcinoma. Disease is one of the following: a) unresectable locally advanced, or b) metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangements. Patient has been previously treated.
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.

# 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 not used 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. 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). Solid tumors: Presence of solid tumor. Disease is unresectable or metastatic. Patient has progressed on or following prior systemic treatment (e.g., carboplatin, 5-fluorouracil, paclitaxel). Cancer is BRAF V600E mutant type. Medication is used in combination with Tafenlar (dabrafenib).
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.

# 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	N/A
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 2MG/ML
- 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

# METHOTREXATE INJECTION PREFERRED

## 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

# 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	Obstructive sleep apnea (OSA) (Initial): Diagnosis (dx) of OSA 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 disorder (SWD) (Initial): Dx of SWD 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). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. 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.
Age Restrictions	N/A

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

# 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): Patient demonstrates positive clinical response to 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



# NAYZILAM

## Products Affected

- Nayzilam

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Epilepsy: Diagnosis of epilepsy. Frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern.
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.

# 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 based therapy (e.g., Herceptin, Kanjinti, etc.). 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	N/A
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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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
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.

# NUBEQA

## 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 (NM-CRPC): 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 (e.g., Zoladex [goserelin], Vantas [histrelin], Lupron [leuprolide], Trelstar [triptorelin]) OR 2) Patient received bilateral orchiectomy. Metastatic hormone-sensitive prostate cancer (mHSPC): Diagnosis of mHSPC. Used in combination with docetaxel. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g., Zoladex [goserelin], Vantas [histrelin], Lupron [leuprolide], Trelstar [triptorelin]) OR 2) Patient received bilateral orchiectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	NM-CRPC, mHSPC: Plan year
Other Criteria	NM-CRPC, mHSPC: 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	<p>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 two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months 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) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and additional asthma controller medication [e.g., leukotriene receptor antagonist (e.g., montelukast), long-acting beta-2 agonist (LABA) (e.g., salmeterol), tiotropium], OR one maximally-dosed combination ICS/LABA product (eg, Advair [fluticasone propionate/ salmeterol], Symbicort [budesonide/ formoterol], Breo Ellipta [fluticasone/vilanterol]), unless there is a contraindication or intolerance to these medications.</p> <p>Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (init): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone). Used in combination with another agent for CRSwNP. 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.</p>
Age Restrictions	Severe asthma initial: Age greater than or equal to 6 years

<b>Prescriber Restrictions</b>	Severe asthma (initial): Prescribed by or in consultation with a pulmonologist or allergy/immunology specialist. CRSwNP (init): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist. EGPA (init): Prescribed by or in consultation with a pulmonologist, rheumatologist or allergist/immunologist. HES (init): Prescribed by or in consultation with an allergist/immunologist or hematologist.
<b>Coverage Duration</b>	Asthma (init): 6 mo, Asthma (reauth): plan year. CRSwNP, EGPA, HES (Initial, reauth): plan year
<b>Other Criteria</b>	Hypereosinophilic Syndrome (HES) (init): Diagnosis of HES. Patient has been diagnosed for at least 6 months. Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy). Patient is FIP1L1-PDGFR $\alpha$ -negative. Patient has uncontrolled HES defined as both of the following: a) History of 2 or more flares within the past 12 months AND b) Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter. Trial and failure, contraindication, or intolerance to corticosteroid therapy (e.g., prednisone) or cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib). Severe asthma (reauth): Patient demonstrates positive clinical response to therapy. Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium), unless there is a contraindication or intolerance to these medications. CRSwNP (reauth): Patient demonstrates positive clinical response to therapy. Used in combination with another agent for CRSwNP. EGPA, HES (reauth): Patient demonstrates positive clinical response to therapy.

# 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	<p>Pseudobulbar affect (PBA) (initial): Diagnosis of PBA, confirmed by one of the following: 1) Physician attestation that a baseline Center for Neurologic Studies Lability Scale (CNS-LS) score has been assessed OR 2) Patient attestation that patient has experienced involuntary, sudden, or frequent episodes of laughing and/or crying. Patient has a brain injury or neurologic disease from one of the following: amyotrophic lateral sclerosis, multiple sclerosis, Parkinson's disease, stroke, or traumatic brain injury. Patient does not have any of the following contraindications: a) Concomitant use with other drugs containing quinidine, quinine, or mefloquine, b) History of Nuedexta, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression, or lupus-like syndrome, c) Known hypersensitivity to dextromethorphan (e.g., rash, hives), d) Taking monoamine oxidase inhibitors (MAOIs) (e.g., phenelzine, selegiline, tranylcypromine) or have taken MAOIs within the preceding 14 days, e) Has prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, or has heart failure, f) Receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), g) Has complete atrioventricular (AV) block without implanted pacemakers, or at high risk of complete AV block.</p>
Age Restrictions	N/A
Prescriber Restrictions	PBA (initial/reauth): Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist.
Coverage Duration	PBA (initial/reauth): plan year

<b>Other Criteria</b>	<p>PBA (reauth): One of the following: 1) Physician attestation that the patient's CNS-LS score has improved since baseline OR 2) Physician attestation that frequency of laughing and/or crying episodes has decreased since baseline. Diagnosis of PBA. Patient has a brain injury or neurologic disease from one of the following: amyotrophic lateral sclerosis, multiple sclerosis, Parkinson's disease, stroke, or traumatic brain injury. Patient does not have any of the following contraindications: a) Concomitant use with other drugs containing quinidine, quinine, or mefloquine, b) History of Nuedexta, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression, or lupus-like syndrome, c) Known hypersensitivity to dextromethorphan (e.g., rash, hives), d) Taking monoamine oxidase inhibitors (MAOIs) (e.g., phenelzine, selegiline, tranylcypromine) or have taken MAOIs within the preceding 14 days, e) Has prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, or has heart failure, f) Receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), g) Has complete atrioventricular (AV) block without implanted pacemakers, or at high risk of complete AV block.</p>
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# 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.

# NURTEC

## Products Affected

- Nurtec

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute Treatment of Migraine (initial): Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Patient has fewer than 15 headache days per month. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. Medication will not be used in combination with another oral CGRP inhibitor. Preventive Treatment of Episodic Migraine (EM) (initial): Diagnosis of EM with both of the following: 1) Less than or equal to 18 headache days per month and 2) Patient has 4 to 18 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), f) Candesartan (Atacand). Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.
Age Restrictions	N/A
Prescriber Restrictions	Acute Treatment of Migraine (initial): Prescribed by or in consultation with one of the following specialists with expertise in the treatment of migraine: neurologist, pain specialist, headache specialist. Preventive Treatment of EM (initial): Prescribed by or in consultation with one of the following specialists with expertise in the treatment of episodic migraine: neurologist, pain specialist, headache specialist.
Coverage Duration	All Indications (initial, reauth): Plan year

<b>Other Criteria</b>	<p>Acute Treatment of Migraine (reauth): Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). Medication will not be used in combination with another oral CGRP inhibitor. Preventive Treatment of EM (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.</p>
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# OCTREOTIDE

## Products Affected

- Octreotide Acetate INJ 1000MCG/ML, 100MCG/ML, 200MCG/ML, 500MCG/ML, 50MCG/ML

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 requiring symptomatic treatment of severe diarrhea or flushing episodes. Vasoactive Intestinal Peptide Tumors, symptomatic treatment of diarrhea (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea. 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): Patient demonstrates positive clinical response to therapy.</p>
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All Indications: Plan Year

<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	N/A
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.</p> <p>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.</p> <p>IPF, SSc-ILD, Chronic Fibrosing ILDs with a progressive phenotype (reauth): Patient demonstrates 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>	N/A
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# ONUREG

## Products Affected

- Onureg

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). Patient has received previous treatment with an intensive induction chemotherapy regimen (e.g., cytarabine + daunorubicin, cytarabine + idarubicin). Patient has achieved one of the following: a) first complete remission (CR) or b) complete remission with incomplete blood count recovery (CRi). Patient is not a candidate for intensive curative therapy.
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.

# 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

## 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	<p>Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate (MTX), leflunomide, sulfasalazine. TF/C/I to one of the following: Enbrel (etanercept), Formulary adalimumab product, Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinib), OR for continuation of prior therapy if within the past 120 days. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. One of the following: TF/C/I to Enbrel (etanercept), Formulary adalimumab product, Xeljanz (tofacitinib), OR for continuation of prior therapy if within the past 120 days. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. TF/C/I to one of the following: Enbrel (etanercept), Formulary adalimumab product, Cosentyx (secukinumab), Stelara (ustekinumab), Skyrizi (risankizumab-rzaa), Xeljanz/Xeljanz XR (tofacitinib), Rinvoq (upadacitinib), or Otezla (apremilast), OR for continuation of prior therapy if within the past 120 days.</p>
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): 6 months, (Reauth): plan year

<b>Other Criteria</b>	All indications (Reauth): Patient demonstrates positive clinical response to therapy.
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# ORENITRAM

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## Products Affected

- Orenitram
- Orenitram Titration Kit Month 1
- Orenitram Titration Kit Month 2
- Orenitram Titration Kit Month 3

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

# ORGOVYX

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## Products Affected

- Orgovyx

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.

# 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.
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	CF (reauth): Patient demonstrates positive clinical response to therapy.

# 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 1 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): Patient demonstrates positive clinical response to therapy. One of the following: A) Patient is 1 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.



# ORSERDU

## Products Affected

- Orserdu

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of breast cancer. Disease is advanced or metastatic. One of the following: a) Patient is male, or b) Patient is a postmenopausal woman. Disease is estrogen receptor (ER)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Presence of estrogen receptor (ESR1) mutation(s). Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant)].
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.

# 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

## Products Affected

- Otezla

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Psoriatic arthritis (PsA, initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Diagnosis of plaque psoriasis. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Oral ulcers associated with Behcet's Disease (initial): Diagnosis of Behcet's Disease. Patient has active oral ulcers.
Age Restrictions	N/A
Prescriber Restrictions	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.
Coverage Duration	All uses (initial): 6 months. All uses (reauth): plan year.
Other Criteria	All indications (Reauth): Patient demonstrates positive clinical response to therapy.

# PANRETIN

## Products Affected

- Panretin

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Kaposi's sarcoma lesions: Diagnosis of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma (KS). Not used when systemic anti-KS therapy is required (e.g., more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement).
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.

## PEGFILGRASTIM PREFERRED

### Products Affected

- Neulasta
- Udenyca

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Neutropenia Associated with Dose Dense Chemotherapy (NDDC): Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, or a dose-dense chemotherapy regimen for which the incidence of febrile neutropenia is unknown. Chemotherapy-Induced Febrile Neutropenia (CFN): Patient is receiving a chemotherapy regimen associated with greater 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). Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	ARS: 1 mo. CFN, NDDC, FN (prophylaxis): 3 mo or duration of tx.
Other Criteria	N/A

## PEGINTERFERON ALFA - 2A

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### Products Affected

- Pegasys

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	Cholangiocarcinoma: 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. Myeloid/Lymphoid neoplasms: Diagnosis of myeloid/lymphoid neoplasm (MLNs). Disease is relapsed or refractory. Disease has presence of a fibroblast growth factor receptor 1 (FGFR1) rearrangement.
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.

# 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# PIRFENIDONE

## Products Affected

- Pirfenidone

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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): Patient demonstrates positive clinical response to therapy.
Age Restrictions	N/A
Prescriber Restrictions	(initial): Prescribed by or in consultation with a pulmonologist.
Coverage Duration	(initial, reauth): plan year
Other Criteria	N/A

# 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. Used in combination with dexamethasone. 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) [e.g., Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide), Dovato (dolutegravir/lamivudine), Triumeq (dolutegravir/abacavir/lamivudine)], OR 2) Both of the following: a) Diagnosis of KS and b) Patient is HIV-negative.
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.

# POSACONAZOLE

## Products Affected

- Posaconazole Dr

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of 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. Treatment of IFI: Used as treatment of invasive fungal infections caused by Aspergillus.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prophylaxis of IFI: plan year. Treatment of IFI: 3 months.
Other Criteria	N/A

# 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	<p>HeFH/ASCVD/Primary HLD(init): 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 (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-C values while on maximally tolerated lipid lowering 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. HoFH (init): Pt is receiving other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD (reauth): Pt continues to receive statin at the maximally tolerated dose (unless pt has documented inability to take statins). HoFH (reauth): Pt continues to receive other lipid-lowering tx (eg statin, ezetimibe).</p> <p>HeFH/ASCVD/Primary HLD/HoFH (reauth): Patient has experienced LDL-C reduction while on Praluent therapy. HeFH/ASCVD/Primary HLD/HoFH (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. HoFH (Init, reauth): Not used in combo w/ Juxtapid.</p>
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# PREVYMIS ORAL

## Products Affected

- Prevymis TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cytomegalovirus (CMV) Prophylaxis in Hematopoietic Stem Cell Transplant (HSCT): Used for prophylaxis of CMV infection and disease AND patient is a CMV-seropositive recipient [R+] of an allogeneic HSCT. CMV Prophylaxis in Kidney Transplant: Used for prophylaxis CMV infection and disease. Patient is a CMV-seronegative recipient [R-]. Patient is receiving a kidney transplant from a CMV-seropositive donor [D+].
Age Restrictions	N/A
Prescriber Restrictions	CMV Prophylaxis in HSCT: Prescribed by or in consultation with an oncologist, hematologist, physician experienced in the management of transplant patients, or infectious disease specialist. CMV Prophylaxis in Kidney Transplant: Prescribed by or in consultation with a nephrologist, physician experienced in the management of transplant patients, or infectious disease specialist.
Coverage Duration	CMV Prophylaxis in HSCT: 4 months. CMV Prophylaxis in Kidney Transplant: 7 months.
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	Idiopathic thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: persistent ITP, 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): Patient demonstrates positive clinical response to 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): Patient demonstrates positive clinical response to therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1stline SAA:6mo.HepC (init):3mo.RefractSAA(init):16wk.ITP,HepC(reauth),RefractSAA(reauth):plan yr

<b>Other Criteria</b>	<p>ITP (initial): Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Chronic Hepatitis C-associated thrombocytopenia (Reauthorization): One of the following criteria: For patients that started treatment with eltrombopag prior to initiation of treatment with interferon, eltrombopag 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 eltrombopag treatment by week 9. OR for patients that started treatment with eltrombopag while on concomitant treatment with interferon, eltrombopag 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).</p>
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# PURIXAN

## 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.

# PYRUKYND

## Products Affected

- Pyrukynd

- Pyrukynd Taper Pack

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count). Diagnosis of pyruvate kinase deficiency confirmed by molecular testing of ALL the following mutations on the PKLR gene: a) Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant AND b) Patients is not homozygous for the c.1436G to A (p.R479H) variant AND c) Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene. Hemoglobin is less than or equal to 10g/dL. Patient has symptomatic anemia or is transfusion dependent. Exclusion of other causes of hemolytic anemias (e.g., infections, toxins, drugs).
Age Restrictions	N/A
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with a hematologist.
Coverage Duration	Initial: 6 months. Reauth: Plan Year.
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.

# 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	N/A
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	N/A
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.

# REGRANEX

## 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)]. OIC (pain caused by active cancer, non-cancer pain, pain related to prior cancer or its treatment): TF/C/I to Movantik (naloxegol).

## 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 Movantik (naloxegol).

# REPATHA

## Products Affected

- Repatha
- Repatha Pushtronex System
- Repatha Sureclick

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
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 lipid lowering 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).</p> <p>HeFH/ASCVD/Primary HLD/HoFH (reauth): Pt has experienced LDL reduction while on Repatha tx. HeFH/ASCVD/Primary HLD/HoFH (Init, reauth): 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	Non-Small Cell 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 rearrangement 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. Solid Tumors: Presence of RET gene fusion-positive solid tumor. Disease is recurrent, advanced, or metastatic.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Non-Small Cell Lung Cancer, MTC, Thyroid Cancer, Solid Tumors: Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# REVCovi

## Products Affected

- Rencovi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Plan year
Other Criteria	N/A

# REVLIMID

## Products Affected

- Lenalidomide

- 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. 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# REZLIDHIA

## Products Affected

- Rezlidhia

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). Disease is relapsed or refractory. Presence of a susceptible isocitrate dehydrogenase-1(IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay).
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.

# RINVOQ

## Products Affected

- Rinvoq

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) (init - 15 mg): Diagnosis (Dx) of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Psoriatic arthritis (PsA) (init - 15 mg): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement.</p> <p>Ankylosing spondylitis (AS) (init - 15 mg): Dx of active AS. Non-radiographic axial spondyloarthritis (NRAS) (init - 15mg): Dx of active NRAS. Patient has signs of inflammation. Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Cimzia). AS, NRAS (init - 15mg): Minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Atopic dermatitis (AD) (init - 15 mg and 30 mg): Dx of moderate to severe AD. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa ointment. One of the following: 1) Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of AD (examples include, but are not limited to, Adbry, Dupixent, etc.), OR 2) Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved AD therapies: Adbry and Dupixent. Not used in combination with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine).</p>
Age Restrictions	AD (initial): Patient is 12 years of age or older.

<b>Prescriber Restrictions</b>	RA, AS, NRAS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. AD (initial): Prescribed by or in consultation with a dermatologist or allergist/immunologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	RA, PsA, AS, NRAS, AD, CD, UC (initial): 6 months, (reauth): Plan year.
<b>Other Criteria</b>	RA, PsA, AS (init - 15 mg): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). RA, PsA, AS, NRAS (init, reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). Crohn's disease (CD) (init): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). CD/UC (init): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Humira). Not used in combination with other JAK inhibitors, biological therapies for CD/UC, or potent immunosuppressants (eg, azathioprine, cyclosporine). All indications (reauth): Patient demonstrates positive clinical response to therapy. AD (reauth): Not used in combination with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine). CD/UC (reauth): Not used in combination with other JAK inhibitors, biological therapies for CD/UC, or potent immunosuppressants (eg, azathioprine, cyclosporine).

# ROFLUMILAST

## Products Affected

- Roflumilast

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 (e.g., Combivent, Spiriva).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, reauth: plan year
Other Criteria	COPD (reauth): Patient demonstrates positive clinical response to therapy.



# 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	N/A
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. Both of the following: 1) Disease is recurrent, and 2) Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Presence of deleterious BRCA-mutation (germline and/or somatic). 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days

# 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days

# SCSEMBLIX

## Products Affected

- Scemblix

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). Disease is Philadelphia chromosome-positive (Ph+). Disease is in chronic phase. One of the following: 1) Patient has been previously treated with two or more alternative tyrosine kinase inhibitors (TKI) [e.g., Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib), Iclusig (ponatinib)] and prescribed medication dose will not exceed 80 mg per day, OR 2) Disease is T315I mutation positive and prescribed medication dose will not exceed 400 mg per day.
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.

# SHINGRIX

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## 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). One of the following: A) Age greater than or equal to 50 years OR B) Both of the following: 1) Age 18 to 49 years and 2) Patient is or will be at increased risk of herpes zoster due to immunodeficiency or immunosuppression caused by known disease or therapy.
Age Restrictions	N/A
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	N/A
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

## Products Affected

- Simponi

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 of moderately to severely active rheumatoid arthritis. Used in combination with methotrexate. One of the following: Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinib), OR for continuation of prior therapy if within the past 120 days. Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. One of the following: TF/C/I to two agents from the following different mechanisms of action: TNF [ie, Enbrel (etanercept) or Humira (adalimumab)], IL-17 [ie, Cosentyx (secukinumab)], IL-23 [ie, Stelara (ustekinumab) or Skyrizi (risankizumab-rzaa)], JAK [ie, Xeljanz/Xeljanz XR (tofacitinib) or Rinvoq (upadacitinib)], PDE4 [ie, Otezla (apremilast)], 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 two agents from the following different mechanisms of action: TNF [ie, Enbrel (etanercept) or Humira (adalimumab)], IL-17 [ie, Cosentyx (secukinumab)], JAK [ie, Rinvoq or Xeljanz/Xeljanz XR (tofacitinib)], OR for continuation of prior therapy if within the past 120 days. Ulcerative Colitis (UC) (initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. One of the following: TF/C/I to two of the following: Humira (adalimumab), Stelara (ustekinumab), Rinvoq (upadacitinib), or Xeljanz/Xeljanz XR (tofacitinib), OR for continuation of prior therapy if within the past 120 days.</p>
Age Restrictions	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 (Reauth): plan year. RA, AS, PsA (initial): 6 months, (reauth): plan year
<b>Other Criteria</b>	All indications (Reauth): Patient demonstrates positive clinical response to 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

# SKYCLARYS

## Products Affected

- Skyclarys

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of Friedreich's ataxia confirmed via genetic testing demonstrating mutation in the FXN gene. Patient has a Modified Friedreich's Ataxia Rating Scale (mFARS) score of greater than or equal to 20 and less than or equal to 80. Patient has a B-type natriuretic peptide value less than or equal to 200 pg/mL.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with one of the following: Neurologist, Neurogeneticist, or Physiatrist (Physical Medicine and Rehabilitation Specialist).
Coverage Duration	Initial, Reauth: Plan Year.
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.

# SKYRIZI

## Products Affected

- Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML
- Skyrizi 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>	Plaque Psoriasis (initial): Diagnosis of chronic moderate to severe plaque psoriasis. One of the following: at least 3% body surface area involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Psoriatic arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active CD. Will be used as a maintenance dose following the intravenous induction doses.
<b>Age Restrictions</b>	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 (Initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	All uses (initial): 6 months. All uses (reauth): plan year.
<b>Other Criteria</b>	All indications (Reauth): Patient demonstrates positive clinical response to therapy.

# SOMAVERT

## Products Affected

- Somavert

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 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): Patient demonstrates positive clinical response to therapy.</p>
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Acromegaly (Initial, Reauth): plan year
Other Criteria	N/A

# SORAFENIB

## Products Affected

- Sorafenib Tosylate TABS

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: 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# 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

## 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). Plaque psoriasis (Initial regardless of dose): One of the following: at least 3% body surface area involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. 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. PsA (Initial regardless of dose): One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (initial): Diagnosis of moderately to severely active Crohn's disease. Will be used as a maintenance dose following the intravenous induction dose.</p>
Age Restrictions	N/A
Prescriber Restrictions	<p>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.</p>
Coverage Duration	All indications (initial): 6 months. All indications (reauth): plan year.



<b>Other Criteria</b>	Ulcerative colitis (UC) (initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction dose. All indications (Reauth): Patient demonstrates positive clinical response to therapy.
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# STIVARGA

## Products Affected

- Stivarga

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Colorectal Cancer (CRC): Diagnosis of advanced or metastatic colorectal cancer. Trial and failure, contraindication, or intolerance to treatment with all the following: oxaliplatin-based chemotherapy, irinotecan-based chemotherapy, fluoropyrimidine-based chemotherapy, and anti-VEGF therapy-based chemotherapy. One of the following: 1) Tumor is RAS mutant-type OR 2) Tumor is RAS wild-type and trial and failure, contraindication, or intolerance to anti-EGFR therapy. Gastrointestinal stromal tumor (GIST): Diagnosis of progressive, locally advanced, unresectable or metastatic GIST. Trial and failure, contraindication, or intolerance to imatinib mesylate or sunitinib malate. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Trial and failure or intolerance to Nexavar (sorafenib tosylate).
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.

# SUNITINIB

## Products Affected

- Sunitinib Malate

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): Both of the following: (1) Diagnosis of islet cell tumors/progressive pNET (2) Disease is one of the following: unresectable, locally advanced or metastatic.
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.

# 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	N/A
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). One of the following: a) Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors or b) High level MET amplification in lung 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.

## 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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist
Coverage Duration	ATTR-CM (initial, reauth): Plan year
Other Criteria	ATTR-CM (reauth): Patient demonstrates 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). Solid tumors: Presence of solid tumor. Disease is unresectable or metastatic. Patient has progressed on or following prior systemic treatment (e.g., carboplatin, 5-fluorouracil, paclitaxel). Cancer is BRAF V600E mutant type. Medication is used in combination with Mekinist (trametinib).
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.

# TAGRISO

## 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): One of the following: A) All of the following: Diagnosis of NSCLC. Disease is one of the following: 1) advanced, 2) recurrent, or 3)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)]. OR B) All of the following: Diagnosis of NSCLC. One of the following: 1) Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions, OR 2) Tumors are positive for EGFR exon 21 L858R mutations. Both of the following: 1) Patient is receiving as adjuvant therapy, AND 2) Patient has had a complete surgical resection of the primary NSCLC tumor.
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.

# 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# TASIGNA

## 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.

# TASIMELTEON CAPSULE

## Products Affected

- Tasimelteon

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 hypernychthemeral syndrome). Smith-Magenis Syndrome (SMS): Diagnosis of Smith-Magenis Syndrome (SMS). Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking).
Age Restrictions	SMS: 16 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Non-24, SMS: 6 months
Other Criteria	Non-24: Patient is totally blind (has no light perception).

# TAZAROTENE

## Products Affected

- Tazarotene CREA

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. Subsequent therapy for one of the following: a) EZH2 mutation positive relapsed/refractory disease after two prior therapies, OR b) EZH2 wild-type or unknown relapsed/refractory disease and no satisfactory alternative treatment options.
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.



# TEPMETKO

## Products Affected

- Tepmetko

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 one of the following: recurrent, advanced, or metastatic. Tumor is MET exon 14 skipping mutation positive.
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.

# TERIPARATIDE

## Products Affected

- Forteo INJ 600MCG/2.4ML

- 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 (initial): 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. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All indications (initial, reauth): plan year.

<b>Other Criteria</b>	<p>Glucocorticoid-Induced Osteoporosis (initial): 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). All uses (initial, reauth): One of the following: 1) Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime, or 2) Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]).</p>
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# TETRABENAZINE

## Products Affected

- Tetrabenazine

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	Tardive dyskinesia: Age greater than or equal to 18 years.
Prescriber Restrictions	Huntington's: Prescribed by a neurologist. Tardive dyskinesia, Tourette's: Prescribed by a neurologist or psychiatrist.
Coverage Duration	Plan year.
Other Criteria	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	N/A
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 60 years old OR 2) Patient has comorbidities that preclude the use of intensive induction chemotherapy. Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is locally advanced, unresectable, or metastatic. Cholangiocarcinoma is IDH1 mutation-positive. Disease has progressed on or after systemic treatment.
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.

# TOBI PODHALER

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## Products Affected

- Tobii 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

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## Products Affected

- Tretinoin CREA
- Tretinoin GEL 0.01%, 0.025%
- Tretinoin Microsphere GEL 0.04%, 0.1%

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



# 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: 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

## Products Affected

- Trientine Hydrochloride CAPS 250MG

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. Colorectal cancer: Diagnosis of colorectal cancer (HER2-amplified and RAS and BRAF wild-type). Disease is HER2-positive. Disease is one of the following: a) advanced, b) unresectable, c) metastatic. One of the following: a) patient has previously been treated with one of the following regimens: i) fluoropyrimidine-based chemotherapy, ii) oxaliplatin-based chemotherapy, iii) irinotecan-based chemotherapy or b) patient is not appropriate for intensive therapy. Used in combination with trastuzumab.
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.

# TURALIO

## Products Affected

- Turalio CAPS 125MG

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	N/A
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	One of the following diagnoses: 1) Postmenopausal osteoporosis or osteopenia, OR 2) 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 (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., 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

# VALCHLOR

## 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-type cutaneous T-cell lymphoma (MF-CTCL): Both of the following: 1) diagnosis of Stage IA MF-CTCL OR diagnosis of Stage IB MF-CTCL AND 2) patient has received at least one prior skin-directed therapy (e.g., topical corticosteroids, bexarotene topical gel [Targretin topical gel], etc.).
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.

# VALTOCO

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## Products Affected

- Valtoco 10 Mg Dose
- Valtoco 15 Mg Dose
- Valtoco 20 Mg Dose
- Valtoco 5 Mg Dose

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Epilepsy: Diagnosis of epilepsy. Frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern.
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.

# VANDETANIB

## 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
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. 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.)
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.

# 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.

# VERQUVO

## Products Affected

- Verquvo

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 an ejection fraction less than 45 percent. Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms. One of the following: A) Patient was hospitalized for heart failure within the last 6 months, or B) Patient used outpatient intravenous diuretics (e.g., bumetanide, furosemide) for heart failure within the last 3 months. Trial and failure, contraindication, or intolerance to two of the following at a maximally tolerated dose: A) One of the following: 1) Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), 2) Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan), or 3) Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)], B) One of the following: 1) bisoprolol, 2) carvedilol, or 3) metoprolol succinate extended release, C) Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)], or D) Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone].
Age Restrictions	N/A
Prescriber Restrictions	CHF (initial): Prescribed by or in consultation with a cardiologist.
Coverage Duration	CHF (initial, reauth): plan year
Other Criteria	CHF (reauth): Patient demonstrates positive clinical response to therapy.

# 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	Advanced, Recurrent, or Metastatic 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. Early Breast Cancer: Diagnosis of early breast cancer at high risk of recurrence. Disease is hormone receptor (HR)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Used in combination with one of the following endocrine therapies: 1) tamoxifen or 2) aromatase inhibitor (e.g., anastrozole, letrozole, exemestane).
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.

# 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, G623R, G696A, F617L]. 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	N/A
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 advanced or 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# VONJO

## Products Affected

- Vonjo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Patient has been diagnosed with one of the following: a) Primary myelofibrosis, b) Post-polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Patient has a platelet count below $50 \times 10^9/L$ .
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.



# VORICONAZOLE INJECTION

## Products Affected

- Voriconazole INJ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Invasive aspergillosis: Diagnosis of invasive aspergillosis (IA). Candidemia: Diagnosis of candidemia. One of the following: (1) patient is non-neutropenic or (2) infection is located in skin, abdomen, kidney, bladder wall, or wounds. Esophageal Candidiasis: Diagnosis of esophageal candidiasis. Mycosis: Diagnosis of fungal infection caused by <i>Scedosporium apiospermum</i> (asexual form of <i>Pseudallescheria boydii</i> ) or <i>Fusarium</i> spp. including <i>Fusarium solani</i> . For fusariosis: Patient is intolerant of, or refractory to, other therapy (e.g., liposomal amphotericin B, amphotericin B lipid complex).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 weeks
Other Criteria	N/A

# VOSEVI

## Products Affected

- Vosevi

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 Vosevi 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	12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	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.

# VOWST

## Products Affected

- Vowst

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>	Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following: 1) Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for two consecutive days, and 2) A positive stool test for C.difficile toxin or toxigenic C.difficile. Patient has a history of two or more recurrent episodes of CDI within 12 months. All of the following: 1) Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst: oral vancomycin or Difcid (fidaxomicin), 2) Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst, and 3) Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist or infectious disease specialist.
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	N/A

# VRAYLAR

## Products Affected

- Vraylar

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Schizophrenia: Diagnosis of schizophrenia. Trial and failure, contraindication, or intolerance to two of the following atypical antipsychotics: aripiprazole, lurasidone, olanzapine, paliperidone, quetiapine (IR or ER), risperidone, or ziprasidone. Manic/Mixed Episodes: Diagnosis of bipolar I disorder. Prescribed medication is being used for the acute treatment of manic or mixed episodes. Trial and failure, contraindication, or intolerance to two of the following atypical antipsychotics: aripiprazole, olanzapine, or ziprasidone. Depressive Episodes: Diagnosis of bipolar I disorder. Prescribed medication is being used for the treatment of depressive episodes. Trial and failure, contraindication, or intolerance to both of the following atypical antipsychotics: lurasidone and quetiapine ER. Major Depressive Disorder: Diagnosis of major depressive disorder (MDD). Prescribed medication is being used as adjunctive therapy to antidepressants for the treatment of MDD. Trial and failure, contraindication, or intolerance to both of the following atypical antipsychotics: aripiprazole and quetiapine ER.
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.

# WELIREG

## Products Affected

- Welireg

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of von Hippel-Lindau (VHL) disease. Patient requires therapy for one of the following: a) renal cell carcinoma (RCC), b) central nervous system (CNS) hemangioblastoma, or c) pancreatic neuroendocrine tumor (pNET). Patient does not require immediate surgery.
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. Anaplastic Large Cell Lymphoma (ALCL): Diagnosis of systemic ALCL. Disease is relapsed or refractory. Tumor is anaplastic lymphoma kinase (ALK)-positive. Inflammatory Myofibroblastic Tumor (IMT): Diagnosis of IMT. Disease is one of the following: a) unresectable, b) recurrent, or c) refractory. Tumor is anaplastic lymphoma kinase (ALK)-positive.
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 one nonsteroidal anti-inflammatory drug (NSAID) (e.g., diclofenac, ibuprofen, meloxicam, naproxen).
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): Patient demonstrates positive clinical response to 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

## Products Affected

- Xeljanz

- Xeljanz Xr

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Xeljanz tab/Xeljanz XR tab: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Xeljanz tab/Xeljanz XR tab: Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Xeljanz tab/Xeljanz XR tab: Ankylosing spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. RA, PsA, AS (Initial): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). Xeljanz tab/Xeljanz XR tab: Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Humira). Not used in combination with other Janus kinase (JAK) inhibitors, biological therapies for UC, or potent immunosuppressants (eg, azathioprine, cyclosporine).</p>
Age Restrictions	N/A
Prescriber Restrictions	RA, PJIA, AS (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/PJIA/PsA/AS (init): 6 mo. UC (init): 4 mo. RA/PJIA/PsA/AS/UC (reauth): plan year.
<b>Other Criteria</b>	<p>Xeljanz: Polyarticular course juvenile idiopathic arthritis (PJIA) (Initial): Diagnosis of active polyarticular course juvenile idiopathic arthritis. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). RA, PsA, AS, PJIA (Initial, Reauth): Not used in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (eg, azathioprine, cyclosporine). All indications (Reauth): Patient demonstrates positive clinical response to therapy. UC (Reauth): Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine).</p>

# XERMELO

## Products Affected

- Xermelo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Carcinoid syndrome diarrhea (Initial): Diagnosis of carcinoid syndrome diarrhea AND diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide, lanreotide) for at least 3 months AND used in combination with SSA therapy.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
Coverage Duration	Initial: 6 months, Reauth: plan year
Other Criteria	Carcinoid syndrome diarrhea (Reauthorization): Patient demonstrates positive clinical response to 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): Patient demonstrates positive clinical response to 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	<p>Asthma (Initial): Diagnosis of moderate to severe persistent allergic 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. One of the following: a) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months, OR b) 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: 1) one maximally-dosed combination inhaled corticosteroid/long-acting beta2-agonist [eg, Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)] or 2) Both of the following: a) one high-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and b) one additional asthma controller medication {e.g., leukotriene receptor antagonist, long-acting beta2-agonist [eg, Foradil (formoterol fumarate), Serevent (salmeterol xinafoate)], tiotropium}. Chronic Spontaneous Urticaria (CSU) (Previously Chronic Idiopathic Urticaria) (Initial): Diagnosis of CSU (previously chronic idiopathic urticaria). Persistent symptoms (itching and hives) with a second generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is a history of contraindication or intolerance to H1 antihistamines. Patient has tried and had an inadequate response or intolerance or contraindication to one of the following additional therapies: H1-antihistamine, Hydroxyzine, H2-antagonist (e.g., famotidine, cimetidine), Leukotriene receptor antagonist (e.g., montelukast).</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	Asthma (Init): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CSU (Init): Prescribed by or in consultation with an allergist/immunologist, or dermatologist. CRSwNP (Init): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist.
<b>Coverage Duration</b>	Asthma, Init: 6 mo, Reauth: plan year. CSU, Init: 3 mo, Reauth: 6 mo. CRSwNP, Init/Reauth: plan yr.
<b>Other Criteria</b>	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (Previously Nasal Polyps) (Initial): Diagnosis of CRSwNP (previously nasal polyps). Unless contraindicated, the patient has had an inadequate response to an intranasal corticosteroid (e.g., fluticasone, mometasone). CRSwNP (Reauthorization): Patient demonstrates positive clinical response to therapy. CRSwNP (Initial/Reauth): Used in combination with another agent for chronic rhinosinusitis with nasal polyps. Asthma (Reauthorization): Patient demonstrates positive clinical response to therapy. Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. CSU (Reauthorization): Patient demonstrates positive clinical response to therapy.



# XOSPATA

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## 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# XPOVIO

## Products Affected

- Xpovio
- Xpovio 60 Mg Twice 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 multiple myeloma. Patient has received at least one prior therapy (e.g., lenalidomide, bortezomib, daratumumab, pomalidomide). Used in combination with bortezomib and dexamethasone. Relapsed/Refractory Multiple Myeloma (RRMM): Diagnosis of relapsed or refractory multiple myeloma (RRMM). Patient has received at least four prior therapies (e.g., lenalidomide, bortezomib, daratumumab, pomalidomide). 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 (e.g., CHOP: cyclophosphamide, doxorubicin, vincristine, and prednisone plus rituximab).
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.

# XTANDI

## Products Affected

- Xtandi

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

# XYREM

## Products Affected

- Sodium Oxybate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Reauth: plan year
Other Criteria	Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with 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	Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: 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).
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

# 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	N/A
Coverage Duration	Plan year
Other Criteria	Approve for continuation of prior therapy if within the past 120 days.

# ZOKINVY

## Products Affected

- Zokinvy

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: 1) Diagnosis of Hutchinson-Gilford Progeria Syndrome, OR 2) For treatment of processing-deficient Progeroid Laminopathies with one of the following: i) Heterozygous LMNA mutation with progerin-like protein accumulation OR ii) Homozygous or compound heterozygous ZMPSTE24 mutations. Patient has a body surface area of 0.39 m <sup>2</sup> and above.
Age Restrictions	Patient is 12 months of age or older.
Prescriber Restrictions	N/A
Coverage Duration	Plan Year
Other Criteria	N/A

# ZOLINZA

## 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 (e.g., extracorporeal photopheresis [ECP], systemic retinoids, interferons, etc.).
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.



## ZTALMY

### Products Affected

- Ztalmy

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD). Patient has a mutation in the CDKL5 gene. Trial and failure, contraindication, or intolerance to two formulary anticonvulsants (e.g., valproic acid, levetiracetam, lamotrigine).
Age Restrictions	Patient is 2 years of age or older.
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.

# 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): Diagnosis of CLL. Disease has relapsed or is refractory.
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.

# 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, recurrent, or advanced non-small cell lung cancer (NSCLC), tumor is anaplastic lymphoma kinase (ALK)-positive or ROS1-positive.
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.

## PART B VERSUS PART D

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### Products Affected

- Abelcet
- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Amphotericin B INJ
- Amphotericin B Liposome
- Anzemet TABS 50MG
- Azathioprine TABS 50MG
- Budesonide SUSP
- Calcitriol CAPS
- Calcitriol ORAL SOLN
- Cinacalcet Hydrochloride
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclophosphamide TABS
- 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, 1MG
- Formoterol Fumarate NEBU
- Furosemide INJ
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hydrochloride TABS
- Heparin Sodium INJ 1000UNIT/ML
- Heplisav-b
- 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 Hcl NEBU 0.31MG/3ML, 1.25MG/3ML
- Levalbuterol Hydrochloride NEBU 0.63MG/3ML
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nutrilipid
- Ondansetron Hcl SOLN
- Ondansetron Hydrochloride TABS
- Ondansetron Odt
- Paricalcitol CAPS
- Pentamidine Isethionate INHALATION SOLR
- Perforomist
- Plenamine INJ 147.4MEQ/L; 2.17GM/100ML; 1.47GM/100ML; 434MG/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 749MG/100ML; 1.04GM/100ML; 1.18GM/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 592MG/100ML; 749MG/100ML; 250MG/100ML; 39MG/100ML; 960MG/100ML
- 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%
- Prehevbrio

- 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
- Prograf PACK
- Prosol
- Pulmozyme SOLN 2.5MG/2.5ML
- 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 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

## 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.

Plans are insured through UnitedHealthcare Insurance Company or one of its affiliated companies, a Medicare Advantage organization with a Medicare contract and a Medicare-approved Part D sponsor. Enrollment in the plan depends on the plan's contract renewal with Medicare.

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