PRIOR AUTHORIZATION PROTOCOLS

How do I request an exception to the Ultimate Health Plans' Formulary?

You can ask Ultimate Health Plans to make an exception to our coverage rules. There are several types of exceptions that you can ask us to make.

- You can ask us to cover your drug even if it is not on our formulary. If approved, this drug will be covered at a pre-determined cost-sharing level, and you would not be able to ask us to provide the drug at a lower cost-sharing level.
- You can ask us to cover a formulary drug at a lower cost-sharing level if this drug is not on the specialty tier. If approved this would lower the amount you must pay for your drug.
- You can ask us to waive coverage restrictions or limits on your drug. For example, for certain drugs, Ultimate Health Plans limits the amount of the drug that we will cover. If your drug has a quantity limit, you can ask us to waive the limit and cover a greater amount.

Generally, Ultimate Health Plans will only approve your request for an exception if the alternative drugs included on the plan's formulary, the lower cost-sharing drug or additional utilization restrictions would not be as effective in treating your condition and/or would cause you to have adverse medical effects.

You should contact us to ask us for an initial coverage decision for a formulary, or utilization restriction exception. When you request a formulary or utilization restriction exception you should submit a statement from your prescriber or physician supporting your request. Generally, we must make our decision within 72 hours of getting your prescriber's supporting statement. You can request an expedited (fast) exception if you or your doctor believe that your health could be seriously harmed by waiting up to 72 hours for a decision. If your request to expedite is granted, we must give you a decision no later than 24 hours after we get a supporting statement from your doctor or other prescriber.

Your prescriber must submit a statement supporting your coverage determination or exception request. In order to help us make a decision more quickly, you should include supporting medical information from your prescriber when you submit your exception request.

What if I have additional questions?

You can call us at: 1-800-311-7517 (seven days a week, 24 hours a day) if you have any additional questions. If you have a hearing or speech impairment, please call us at TTY 1-866-706-4757.

ACTIMMUNE (S)

Products Affected

• Actimmune

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of one of the following: 1) Chronic granulomatous disease (CGD), or 2) severe malignant osteopetrosis (SMO).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

ADCIRCA (S)

Products Affected

• Tadalafil TABS 20MG

• Alyq

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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

ADEMPAS (S)

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) (Initial): 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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH, CTEPH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH, CTEPH (Reauth): Documentation of positive clinical response to therapy.

AFINITOR (S)

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	Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. Renal cell carcinoma: Diagnosis of advanced renal cell carcinoma AND trial and failure, contraindication, or intolerance to SUTENT (sunitinib) or NEXAVAR (sorafenib). Neuroendocrine tumors of pancreatic origin (pNET): Diagnosis of progressive pNET that are unresectable, locally advanced, or metastatic. Renal angiomyolipoma: Diagnosis of renal angiomyolipoma and TSC. Breast Cancer: Diagnosis of advanced hormone receptor-positive, HER2- negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole). Neuroendocrine tumors of gastrointestinal (GI) or lung origin: Diagnosis of progressive, well-differentiated, non-functional NET of GI or lung origin AND patient has unresectable, locally advanced or metastatic disease.
Age Restrictions	SEGA associated with TSC: Patient is 1 year of age or older.
Prescriber Restrictions	N/A
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

AFINITOR DISPERZ (S)

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	Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. TSC-associated partial-onset seizures: Diagnosis of TSC-associated partial-onset seizures.
Age Restrictions	SEGA associated with TSC: Patient is 1 year of age or older. TSC- associated partial-onset seizures: Patient is 2 years of age or older.
Prescriber Restrictions	TSC-associated partial-onset seizures: Prescribed by or in consultation with a neurologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

ALECENSA (S)

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 NSCLC.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

ALPHA-1 PROTEINASE INHIBITOR, NON-PREFERRED (S)

Products Affected

• Aralast Np INJ 1000MG

- Prolastin-c INJ 1000MG
- Zemaira

• Glassia

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. Continued conventional treatment for emphysema (e.g., bronchodilators). One of the following: 1) PiZZ, PiZ(null), or Pi(null)(null) protein phenotypes (homozygous) OR 2) other rare AAT disease genotypes associated with pre-treatment serum AAT level less than 11 μ M/L [e.g., Pi(Malton, Malton), Pi(SZ)]. One of the following: Circulating pre-treatment serum AAT level less than 11 μ M/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 the patient has a concomitant diagnosis of necrotizing panniculitis. Trial and failure, or intolerance to Prolastin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	AAT deficiency (initial, reauth): 12 months
Other Criteria	AAT deficiency (reauth): Documentation of positive clinical response to therapy. Continued conventional treatment for emphysema (e.g., bronchodilators).

ALUNBRIG (S)

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 NSCLC.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

AMPYRA (S)

Products Affected

• Dalfampridine Er

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS) (initial): Diagnosis of MS. Physician confirmation that patient has difficulty walking (eg, timed 25 foot walk test). One of the following: expanded disability status scale (EDSS) score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).
Age Restrictions	N/A
Prescriber Restrictions	MS (initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	MS (Initial): 6 months. (Reauth): 12 months.
Other Criteria	MS (Reauth): Physician confirmation that the patient's walking improved with therapy. One of the following: EDSS score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).

APOKYN (S)

Products Affected

• Apomorphine Hydrochloride INJ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	PD (Initial): Not used with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron)
Required Medical Information	Parkinson's disease (PD) (Initial): Diagnosis of PD. Patient is experiencing acute intermittent hypomobility (defined as "off" episodes characterized by muscle stiffness, slow movements, or difficulty starting movements). Used in combination with other medications for the treatment of PD (e.g., carbidopa/levodopa, pramipexole, ropinirole, etc.).
Age Restrictions	N/A
Prescriber Restrictions	PD (Initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	PD (Initial, reauth): 12 months
Other Criteria	PD (Reauth): Documentation of positive clinical response to therapy.

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 with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, 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. Anemia with chemo (Initial): Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is receiving chemo. CKD (init, reauth), Chemo (init), MDS (init): Verify iron evaluation for adequate iron stores. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CKD (Init): 6 mo. CKD (reauth): 12 mo. Chemo(init, reauth): 3 mo. MDS: (init) 3 mo,(reauth) 12 mo.

Other Criteria	Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) 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, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or 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. Chemo (Reauth): Anemia by lab values (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. MDS (Reauth): Most recent or avg Hct over 3 months is 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. Off-label uses (except MDS, HCV): Will not be approved if patient hes Hab grapter than 10 g/dL or Hat grapter than 20%.
	if patient has Hgb greater than 10 g/dL or Hct greater than 30%.

ARCALYST (S)

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 Periodic Syndromes (CAPS) (Initial): Diagnosis of CAPS, including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS). The medication will not be used in combination with another biologic. 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	CAPS (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist, or specialist with expertise in the management of CAPS. Recurrent Pericarditis (initial): Prescribed by or in consultation with a cardiologist.
Coverage Duration	CAPS, Recurrent Pericarditis (initial, reauth): 12 months. DIRA: 12 months.

Other Criteria	CAPS (Reauth): Patient has experienced disease stability or improvement in clinical symptoms while on therapy as evidence by one of the
	following: A) improvement in rash, fever, joint pain, headache,
	conjunctivitis, B) decreased number of disease flare days, C)
	normalization of inflammatory markers (CRP, ESR, SAA), D)
	corticosteroid dose reduction, OR E) improvement in MD global score or
	active joint count. Recurrent Pericarditis (Reauth): Documentation of
	positive clinical response to therapy.

AUBAGIO (S)

Products Affected

• Aubagio

PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Multiple Sclerosis (MS) (initial, reauth): Not used in combination with Exclusion another disease-modifying therapy for MS. Criteria Required MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated Medical syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). Information N/A **Age Restrictions** Prescriber MS (initial, reauth): Prescribed by or in consultation with a neurologist Restrictions Coverage MS (initial, reauth): 12 months **Duration** Other Criteria MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

Teriflunomide

•

AUSTEDO (S)

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	Initial: 3 months. Reauth: 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to therapy.

AYVAKIT (S)

Products Affected

• Ayvakit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. Disease is one of the following: unresectable or metastatic. Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Advanced Systemic Mastocytosis (AdvSM): Diagnosis of AdvSM. Patient has one of the following: a) aggressive systemic mastocytosis (ASM), b) systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or c) mast cell leukemia (MCL). Ayvakit 25 mg - Indolent Systemic Mastocytosis (ISM): Diagnosis of ISM. Platelet count is greater than 50 x 10^9/L.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

BALVERSA (S)

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 AND Patient has fibroblast growth factor receptor (FGFR) 3 or FGFR2 genetic alterations as detected by an U.S. Food and Drug Administration (FDA)-approved test (therascreen FGFR RGQ RT-PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). One of the following: 1) Patient has progressed during or following at least one line of prior platinum-containing chemotherapy (e.g., gemcitabine with cisplatin or carboplatin, dose dense methotrexate vinblastine doxorubicin cisplatin [DDMVAC] with growth factor support, 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	12 months
Other Criteria	Approve for continuation of prior therapy.

BENLYSTA (S)

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) (init): 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 (init): 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).
Age Restrictions	N/A
Prescriber Restrictions	SLE (init): Prescribed by or in consultation with a rheumatologist. Lupus Nephritis (init): Prescribed by or in consultation with a nephrologist or rheumatologist.
Coverage Duration	SLE, Lupus Nephritis (init, reauth): 6 months
Other Criteria	SLE, Lupus Nephritis (reauth): Documentation of positive clinical response to therapy.

BESREMI (S)

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	12 months
Other Criteria	Approve for continuation of prior therapy.

BOSULIF (S)

Products Affected

• Bosulif

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 Philadelphia chromosome-positive (Ph+) CML.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

BRAFTOVI (S)

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. Cancer is BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 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. Cancer is BRAF V600E mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Erbitux (cetuximab).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

BRIVIACT (S)

Products Affected

• Briviact TABS

• Briviact SOLN

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	Patient is 1 month of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

BRUKINSA (S)

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 relapsed or refractory MCL. Trial and failure, contraindication, or intolerance to at least ONE combination treatment of rituximab and chemotherapy (e.g., BR, R- CHOP, R-CVP, R-FCM). 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 prior anti-CD20- based regimen for MZL (e.g., rituximab, obinutuzumab). Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of ONE of the following: CLL or SLL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months.
Other Criteria	Approve for continuation of prior therapy.

CABOMETYX (S)

Products Affected

• Cabometyx

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: a) Trial and failure, 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 (local disease or local disease with minimal extrahepatic disease only), or e) Disease is unresectable. Differentiated Thyroid Cancer (DTC): Diagnosis of DTC. Disease has progressed following prior VEGFR- targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib]). Disease or patient is refractory to radioactive iodine treatment or ineligible.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

CALQUENCE (S)

Products Affected

• Calquence

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Mantle Cell Lymphoma: Diagnosis of mantle cell lymphoma (MCL) AND patient has received at least one prior therapy for MCL. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

CAPLYTA (S)

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 generic formulary atypical antipsychotic agents: asenapine, aripiprazole, olanzapine, paliperidone, quetiapine (IR or ER), risperidone, 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. Trial and failure, contraindication, or intolerance to quetiapine (IR or ER) or olanzapine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

CAPRELSA (S)

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 medullary thyroid cancer (MTC).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

CARISOPRODOL (S)

Products Affected

• Carisoprodol TABS 350MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication. If the patient is 65 years of age or older, the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

CAYSTON (S)

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) (Initial, Reauth): Diagnosis of CF AND Patient has evidence of Pseudomonas aeruginosa in the lungs.
Age Restrictions	CF (Initial): 7 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	CF (Initial, reauth): 12 months
Other Criteria	CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).

CERDELGA (S)

Products Affected

• Cerdelga

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 Gaucher disease type 1. Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test.
Age Restrictions	Gaucher disease: Patient is 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Gaucher disease: 12 months
Other Criteria	N/A

CHENODAL (S)

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	Initial, Reauth: Prescribed by or in consultation with a gastroenterologist or provider who has specialized expertise in the management of gallstones
Coverage Duration	Initial, reauth: 12 months.
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 (S)

Products Affected

• Cholbam

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect based on one of the following: a) an abnormal urinary bile acid analysis by mass spectrometry OR b) molecular genetic testing consistent with the diagnosis. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of a peroxisomal disorder based on one of the following: a) an abnormal urinary bile acid analysis by mass spectrometry OR b) molecular genetic testing consistent with the diagnosis, 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.
Age Restrictions	N/A
Prescriber Restrictions	All uses (initial): Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.
Coverage Duration	All uses: 4 months (initial), 12 months (reauth).
Other Criteria	All uses (reauth): documentation of positive clinical response to therapy as evidenced by improvement in liver function (e.g., aspartate aminotransferase [AST], alanine aminotransferase [ALT]).

CIALIS (S)

Products Affected

• Tadalafil TABS 2.5MG, 5MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Concurrent use of nitrates.
Required Medical Information	Diagnosis of benign prostatic hyperplasia (BPH). Trial and failure, contraindication, or intolerance to an alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) or a 5-alpha reductase inhibitor (e.g., dutasteride, finasteride).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

CICLOPIROX (S)

Products Affected

• Ciclopirox Nail Lacquer

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	All of the following: 1) Patient does not have lunula (matrix) involvement, 2) one of the following: a) Diagnosis of onychomycosis of the toenails, OR b) Diagnosis of onychomycosis of the fingernails, 3) Diagnosis of onychomycosis has been confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, 4) If toenail onychomycosis, patient has mild to moderate disease involving at least 1 target toenail, AND 5) Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	48 weeks.
Other Criteria	N/A

CINRYZE (S)

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	HAE (prophylaxis): Patient is 6 years of age or older
Prescriber Restrictions	HAE (prophylaxis): Prescribed by or in consultation with an immunologist or an allergist
Coverage Duration	12 months
Other Criteria	N/A

COMETRIQ (S)

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 MTC.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses: 12 months
Other Criteria	Approve for continuation of prior therapy.

COPIKTRA (S)

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], Rituxan [rituximab], etc.).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

CORLANOR (S)

Products Affected

• Corlanor

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic heart failure (CHF) (initial): Diagnosis of CHF. Patient has NYHA Class II, III, or IV symptoms. Patient has a left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm. Patient has a resting heart rate of greater than or equal to 70 beats per minute. 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).
Age Restrictions	N/A
Prescriber Restrictions	CHF, DCM (initial): Prescribed by or in consultation with a cardiologist
Coverage Duration	CHF, DCM (initial, reauth): 12 months

Other Criteria	CHF, DCM (reauth): Documentation of positive clinical response to therapy.
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CORTROPHIN (S)

Products Affected

• Cortrophin

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Infantile Spasms (IS) (West Syndrome) [off-label]: Diagnosis of IS (West Syndrome). Multiple Sclerosis (MS): Diagnosis of acute exacerbation of MS. One of the following: 1) Both of the following: a) Patient is new to therapy with corticotropin AND b) Trial and failure, contraindication, or intolerance (TF/C/I) to treatment with two high dose corticosteroid treatments (e.g., prednisone, IV methylprednisolone) OR 2) All of the following: a) Patient's MS exacerbations have been treated in the past with corticotropin AND b) Patient has benefitted from treatment with corticotropin for acute exacerbations of MS AND c) Medication is being used to treat a new exacerbation of MS. Other FDA-Approved Indications: Diagnosis of one of the following: 1) Rheumatic disorders: As adjunctive therapy for short-term administration in: psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis, or acute gouty arthritis, OR 2) Collagen diseases: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus or systemic dermatomyositis (polymyositis), OR 3) Dermatologic diseases: Severe erythema multiforme, Stevens-Johnson syndrome, or severe psoriasis, OR 4) Allergic states: Serum sickness or atopic dermatitis, OR 5) Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as one of the following: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation, or allergic conjunctivitis, OR 6) Respiratory diseases: Symptomatic sarcoidosis, OR 7) Edematous state: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. TF/C/I to treatment with two corticosteroids (e.g., prednisone, methylprednisolone).
Age Restrictions	IS: less than 2 years old

Prescriber Restrictions	IS, MS: neurologist. Rheumatic disorder, collagen disease: rheumatologist. Dermatologic: dermatologist. Allergic state: allergist, immunologist. Ophthalmic disease: optometrist, ophthalmologist. Respiratory diseases: pulmonologist. Edematous state: nephrologist, rheumatologist.
Coverage Duration	IS: 4 weeks. MS: 3 weeks. Other FDA-Approved Indications: 3 months.
Other Criteria	IS: Dosing for IS (West Syndrome) is in accordance with the United States Food and Drug Administration (FDA) approved labeling: not to exceed 150U/m ² daily. MS: Dosing for MS is in accordance with the United States FDA approved labeling: not to exceed 120 units once daily. Other FDA-Approved Indications: Dosing is in accordance with the United States FDA approved labeling: not to exceed 80 units per day.

COSENTYX (S)

Products Affected

2/N/T

• Cosentyx Unoready

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

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. 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 trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) Enthesitis-Related Arthritis (ERA) (Initial): Diagnosis of active ERA. nr- axSpA, ERA (Initial): 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. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS, nr-axSpA, ERA (initial): Prescribed by or in consultation with a rheumatologist.

Coverage Duration	All uses (initial): 6 months. All uses (reauth): 12 months
Other Criteria	 PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS, nr-axSpA (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. ERA (Reauth): Documentation of a positive clinical response to therapy as evidenced by at least one of the following: Reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, fatigue, inflammation) (eg, pain, stiffness), inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. ERA (Reauth): Documentation of a positive clinical response to therapy as evidenced by at least one of the following: Reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline.

COTELLIC (S)

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. Patient has a BRAF V600E or V600K mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with vemurafenib. Histiocytic Neoplasm: Diagnosis of histiocytic neoplasm. Used as monotherapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

CUPRIMINE (S)

Products Affected

• Penicillamine CAPS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: One of the following: 1) Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration), 2) Diagnosis of cystinuria AND trial and failure, contraindication, or intolerance to Thiola (tiopronin), or 3) Diagnosis of severe active rheumatoid arthritis AND patient has been unresponsive to conventional therapy (e.g., traditional DMARDs [e.g., methotrexate, sulfasalazine], TNF inhibitor [e.g., Humira (adalimumab), Enbrel (etanercept)], Non-TNF biologic [e.g., Rinvoq (upadacitinib), Xeljanz (tofacitinib)]).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Reauth: Documentation of a positive clinical response to therapy

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	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 TF/C/I 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. PsO (Initial): Diagnosis 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. Ankylosing Spondylitis (AS) (Initial): Diagnosis 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): Diagnosis 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. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.
Age Restrictions	N/A

Prescriber Restrictions	RA, AS, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.
Coverage Duration	UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo.

Other Criteria	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, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, OR reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline. OR improvement in symptoms (eg, puritus, inflammation) from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline. AS (Reauth): Documentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentatio
	positive clinical response to therapy as evidenced by at least one of the

DALIRESP (S)

Products Affected

• Daliresp

PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A **Exclusion** N/A Criteria Required Chronic Obstructive Pulmonary Disease (COPD) (initial): Diagnosis of Medical COPD. History of COPD exacerbations which required the use of Information 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 N/A Restrictions Coverage COPD (init, reauth): 12 months **Duration Other Criteria** COPD (reauth): Documentation of positive clinical response to therapy.

• Roflumilast

DARAPRIM(S)

Products Affected

• Pyrimethamine TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Toxoplasmosis: 1) Patient is using pyrimethamine for the treatment of toxoplasmic encephalitis, secondary prophylaxis of toxoplasmic encephalitis, or treatment of congenital toxoplasmosis OR 2) Patient is using pyrimethamine for the primary prophylaxis of toxoplasmic encephalitis, patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX), and one of the following: patient has been re-challenged with TMP-SMX using a desensitization protocol and is still unable to tolerate, or evidence of life-threatening reaction to TMP-SMX in the past (eg, toxic epidermal necrolysis, Stevens-Johnson syndrome). Malaria: Patient is using pyrimethamine for the treatment of acute malaria or chemoprophylaxis of malaria. Patient does not have megaloblastic anemia due to folate deficiency. The provider acknowledges that pyrimethamine is not recommended by the Centers for Disease Control and Prevention (CDC) for the treatment and/or prophylaxis of malaria.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	12 months
Other Criteria	Toxoplasmosis only: Approve for continuation of prior therapy.

DAURISMO (S)

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 Used 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 comorbidities that preclude the use of intensive induction chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

DEFERASIROX (S)

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 due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Myelodysplastic Syndrome (MDS) (Initial): Diagnosis of MDS. Patient has Low or Intermediate-1 disease or is a potential transplant patient. Patient has received more than 20 red blood cell transfusions. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) (Initial): Diagnosis of chronic iron overload due to NTDT. Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher. Serum ferritin level greater than 300 mcg/L.
Age Restrictions	Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Iron Overload Due to Blood Transfusions, MDS (initial, reauth):12 mo. NTDT (initial, reauth): 6mo.
Other Criteria	Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin level or LIC.

DIACOMIT (S)

Products Affected

• Diacomit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with clobazam. Patient weighs 7kg or more.
Age Restrictions	Patient is 6 months of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

DOXEPIN TOPICAL (S)

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

DUPIXENT (S)

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) (init): Diagnosis (dx) of mod 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) (init): Dx of mod to 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/microliter. One of the following: 1) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (eg, prednisone) within the past 12 mo, 2) Prior asthma-related hospitalization within the past 12 mo. Corticosteroid Dependent Asthma (CDA) (init): Dx of mod to severe asthma. Patient is currently dependent on oral corticosteroids for the treatment of asthma. EA, CDA (init): 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: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist (eg, montelukast), long-acting beta-2 agonist (LABA) (eg, salmeterol), tiotropium], OR b) One max-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)].
Age Restrictions	Asthma (initial): Patient is 6 years of age or older. AD (initial): Patient is 6 months or age or older. CRSwNP, PN: no age restriction. EoE (initial): Patient is at least 12 years of age.

Prescriber Restrictions	AD, Prurigo Nodularis (PN) (Initial): Prescribed by or in consultation with one of the following: dermatologist, allergist/immunologist. Asthma (initial, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (initial, reauth): Prescribed by or in consultation with an otolaryngologist, allergist/immunologist, or pulmonologist. EoE (initial): Prescribed by or in consultation with a gastroenterologist or allergist/immunologist.
Coverage Duration	CRSwNP, EoE (Init/Reauth): 12 months. Asthma, AD, PN (Init): 6 mo. Asthma, AD, PN (reauth): 12 mo.

Other Criteria	Chronic rhinosinusitis with nasal polyposis (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. Eosinophilic esophagitis (EoE) (initial): Dx of EoE. Patient has symptoms of esophageal dysfunction (eg, dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain). Patient has at least 15 intraepithelial eosinophils per high power field (HPF). Other causes of esophageal eosinophils per high power field (HPF). Other causes of esophageal eosinophilis have been excluded. Patient weighs at least 40 kg. Trial and failure, contraindication, or intolerance to at least an 8-week trial of one of the following: proton pump inhibitors (eg, pantoprazole, omeprazole) or topical (esophageal) corticosteroids (eg, budesonide, fluticasone). PN (init): Diagnosis of PN. TF/C/I to one medium or higher potency topical corticosteroid. AD (reauth): Documentation of a positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. EA (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications). CDA (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, reduction in oral corticosteroid dose). 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
	measures (eg, esophageal intraepithelial eosinophil count), or endoscopic measures (eg, edema, furrows, exudates, rings, strictures). PN (reauth): Documentation of a positive clinical response to therapy.

EMGALITY (S)

Products Affected

• Emgality

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Episodic Migraines (EM) (120 mg/mL strength only) (initial): Diagnosis of EM. Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month. Chronic Migraines (CM) (120 mg strength/mL only) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months. Episodic Cluster Headache (ECH) (100 mg/mL strength only) (initial): Diagnosis of episodic cluster headache. 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. EM, CM (120 mg/mL strength only) (initial): Two of the following: a) History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine), OR patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine), b) History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate), OR patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate), c) History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, OR patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, or d) History of failure (after at least a two month trial) or intolerance to Atacand (candesartan), OR patient has a contraindication to Atacand (candesartan). Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.
Age Restrictions	EM, CM, ECH (initial): 18 years of age or older.

Prescriber Restrictions	N/A
Coverage Duration	EM, CM (initial): 6 months. ECH (initial): 3 months. EM, CM, ECH (reauth): 12 months.
Other Criteria	EM, CM (120 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (120 mg/mL strength only) (reauth): Patient continues to be monitored for medication overuse headache. ECH (100 mg/mL strength only) (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.

ENBREL (S)

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	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance 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. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti- inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses.
Age Restrictions	N/A
Prescriber Restrictions	RA (initial), PJIA (initial), 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.
Coverage Duration	All uses (initial): 6 months. All uses (reauth): 12 months

EPCLUSA PREFERRED (S)

Products Affected

• 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. Not used 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 will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	N/A

EPIDIOLEX (S)

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	LGS, DS, TSC: Patient is 1 year of age or older.
Prescriber Restrictions	LGS, DS, TSC: Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

EPOETIN ALFA (S)

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 with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, 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. Anemia with chemo (Initial):Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is receiving chemo. 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. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon/peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 36% or Hgb less than 12 g/dL) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa. Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage	CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo.
Duration	MDS:(init) 3mo,(reauth)12mo. Preop:1mo.
Other Criteria	Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or 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. 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. Chemo (Reauth): Anemia by lab values (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. HCV (Reauth): Most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 36% or less. Documentation of a positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 12 g/dl or less. Documentation of a positive clinical response to therapy from pre-treatment level. Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores.

ERIVEDGE (S)

Products Affected

• Erivedge

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Basal cell carcinoma: One of the following: A) Diagnosis of metastatic basal cell carcinoma OR B) Both of the following: 1) Diagnosis of locally advanced basal cell carcinoma AND 2) One of the following: a) Disease recurred following surgery or b) Patient is not a candidate for surgery and radiation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

ERLEADA (S)

Products Affected

• Erleada

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Castration-resistant or castration-recurrent prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or recurrent prostate cancer. Castration-sensitive prostate cancer (CSPC): Diagnosis of castration-sensitive prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

ESBRIET (S)

Products Affected

• Esbriet CAPS

• 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 as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity), AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF.
Age Restrictions	N/A
Prescriber Restrictions	IPF (initial): Prescribed by or in consultation with a pulmonologist
Coverage Duration	initial, reauth: 12 months
Other Criteria	IPF (reauth): Documentation of positive clinical response to therapy.

EVRYSDI (S)

Products Affected

• Evrysdi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Spinal muscular atrophy (SMA) (initial): Diagnosis of spinal muscular atrophy (SMA) type I, II, or III. Both of the following: a) The mutation or deletion of genes in chromosome 5q resulting in one of the following: 1) Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13) or 2) Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]) AND b) Patient has at least 2 copies of SMN2. Patient is not dependent on both of the following: 1) Invasive ventilation or tracheostomy and 2) Use of non-invasive ventilation beyond use for naps and nighttime sleep. At least one of the following exams (based on patient age and motor ability) has been conducted to establish baseline motor ability: Hammersmith Infant Neurological Exam Part 2 (HINE-2) (infant to early childhood), Hammersmith Functional Motor Scale Expanded (HFMSE), Revised Upper Limb Module (RULM) Test (Non ambulatory), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Motor Function Measure 32 (MFM-32) Scale, or Item 22 of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III). Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).
Age Restrictions	N/A
Prescriber Restrictions	SMA (Initial, Reauth): Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA

Coverage Duration	Initial, Reauth: 12 months
Other Criteria	SMA (Reauth): Documentation of positive clinical response to therapy. Patient (Pt) continues to not be dependent on both of the following: 1) Invasive ventilation or tracheostomy AND 2) use of non-invasive ventilation beyond use for naps and nighttime sleep. Pt is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) pt has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) pt has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).

EXKIVITY (S)

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 as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has progressed on or following prior treatment with a platinum-containing regimen (e.g., carboplatin, cisplatin).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

FASENRA (S)

Products Affected

• Fasenra Pen

• Fasenra

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Asthma (initial): Diagnosis of 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: 1) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months, OR 2) 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: i) High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and ii) 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	Asthma (Initial): Patient is 12 years of age or older
Prescriber Restrictions	Asthma (Initial/Reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist
Coverage Duration	Asthma (init): 6 months. Asthma (reauth): 12 months

Other Criteria	Asthma (Reauth): Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory
	volume in 1 second [FEV1], decreased use of rescue medications). 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 (S)

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	For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have 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 μ g/hr, Oxycodone at a dose of greater than or equal to 8 mg/day, Oral hydromorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.
Coverage Duration	12 months
Other Criteria	N/A

FERRIPROX (S)

Products Affected

• Deferiprone

PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Transfusional iron overload (Initial): Diagnosis of transfusional iron Medical overload due to one of the following: thalassemia syndromes, sickle cell Information disease, or other transfusion-dependent anemias. Patient has Absolute Neutrophil Count (ANC) greater than 1.5 x 10⁹/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 N/A Restrictions Coverage 12 months Duration **Other Criteria** All uses (reauth): Documentation of positive clinical response to therapy. ANC greater than $1.5 \ge 10^9/L$.

Ferriprox Twice-a-day

•

FINTEPLA (S)

Products Affected

• Fintepla

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Dravet Syndrome: Diagnosis of seizures associated with Dravet syndrome. Lennox-Gastaut Syndrome: Diagnosis of seizures associated with Lennox-Gastaut syndrome.
Age Restrictions	Lennox-Gastaut Syndrome: Patient is 2 years of age or older.
Prescriber Restrictions	All Indications: Prescribed by or in consultation with a neurologist.
Coverage Duration	All Indications: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

Products Affected

• Icatibant Acetate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. 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	Patient is 18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an immunologist or an allergist
Coverage Duration	12 months
Other Criteria	N/A

• Sajazir

FIRMAGON (S)

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	Diagnosis of advanced or metastatic prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

FOTIVDA (S)

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	12 months
Other Criteria	Approve for continuation of prior therapy.

FULPHILA (S)

Products Affected

• Fulphila

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose- limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of FN (off-label): Patient has received or is receiving myelosuppressive anticancer drugs associated complications. Acute radiation syndrome (ARS) (off-label): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.
Other Criteria	All Indications: Trial and failure or intolerance to both of the following: Neulasta/Neulasta Onpro AND Udenyca.

GATTEX (S)

Products Affected

• Gattex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Short Bowel Syndrome (SBS) (Initial): Diagnosis of SBS. Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 months.
Age Restrictions	SBS (initial): Patient is 1 year of age or older.
Prescriber Restrictions	SBS (Init, reauth): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	SBS (Init): 6 months. SBS (Reauth): 12 months.
Other Criteria	SBS (Reauth): Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on therapy.

GAVRETO (S)

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. Presence of metastatic rearranged during transfection (RET) gene fusion-positive tumor(s). Thyroid Cancer: Diagnosis of thyroid cancer. Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s). 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	12 months
Other Criteria	Approve for continuation of prior therapy

GILENYA (S)

Products Affected

• Fingolimod

• Gilenya CAPS 0.5MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.
Required Medical Information	MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	N/A
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

GILOTRIF (S)

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): A) Diagnosis of advanced or metastatic (stage IIIB or IV) NSCLC AND B) One of the following: 1) Both of the following: a) Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND b) GILOTRIF will be used as first-line treatment, OR 2) All of the following: a) disease progressed after platinum-based chemotherapy (e.g., cisplatin, carboplatin) and b) squamous NSCLC.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

GLATIRAMER ACETATE (S)

Products Affected

• Glatiramer Acetate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.
Required Medical Information	MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	N/A
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

• Glatopa

GLEEVEC (S)

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	One of the following: A) Diagnosis of Philadelphia chromosome positive (Ph+)/BCR ABL-positive chronic myelogenous leukemia (CML) OR B) Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL) OR C) Gastrointestinal stromal tumor (GIST) OR D) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic OR E) Hypereosinophilic syndrome or chronic eosinophilic leukemia OR F) Myelodysplastic syndrome (MDS) or myeloproliferative disease OR G) Aggressive systemic mastocytosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses: 12 months
Other Criteria	All uses: Approve for continuation of prior therapy.

GROWTH HORMONE, PREFERRED (S)

Products Affected

• Genotropin Miniquick

• Genotropin

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

Age Restrictions	N/A
Prescriber Restrictions	PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by or in consultation with an endocrinologist. GFCRI: prescribed by or in consultation with an endocrinologist or nephrologist
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	AGHD(initial):dx of AGHD with clin records supporting dx of childhood onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT],glucagon,macimorelin) to confirm adult GHD w/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. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial): attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structura 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/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 aft

H.P. ACTHAR GEL (S)

Products Affected

• Acthar

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Infantile Spasms (IS) (West Syndrome): Diagnosis of IS (West Syndrome). Multiple Sclerosis (MS): Diagnosis of acute exacerbation of MS. One of the following: 1) Both of the following: a) Patient is new to therapy with corticotropin AND b) Trial and failure, contraindication, or intolerance (TF/C/I) to treatment with two high dose corticosteroid treatments (e.g., prednisone, IV methylprednisolone) OR 2) All of the following: a) Patient's MS exacerbations have been treated in the past with corticotropin AND b) Patient has benefitted from treatment with corticotropin for acute exacerbations of MS AND c) Medication is being used to treat a new exacerbation of MS. Other FDA-Approved Indications: Diagnosis of one of the following: 1) Rheumatic disorders: As adjunctive therapy for short-term administration in: psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis, or acute gouty arthritis, OR 2) Collagen diseases: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, or systemic dermatomyositis (polymyositis), OR 3) Dermatologic diseases: Severe erythema multiforme, Stevens-Johnson syndrome, or severe psoriasis, OR 4) Allergic states: Serum sickness or atopic dermatitis, OR 5) Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as one of the following: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation, or allergic conjunctivitis, OR 6) Respiratory diseases: Symptomatic sarcoidosis, OR 7) Edematous state: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. TF/C/I to treatment with two corticosteroids (e.g., prednisone, methylprednisolone).
Age Restrictions	Infantile spasms: less than 2 years old

Prescriber Restrictions	Infantile Spasm, MS: neurologist. Rheumatic disorder, collagen disease: rheumatologist. Dermatologic: dermatologist. Allergic state: allergist, immunologist. Ophthalmic disease: optometrist, ophthalmologist. Respiratory diseases: pulmonologist. Edematous state: nephrologist, rheumatologist.
Coverage Duration	Infantile Spasms: 4 weeks. MS: 3 weeks. All other FDA-approved uses: 3 months.
Other Criteria	IS: Dosing for IS (West Syndrome) is in accordance with the United States Food and Drug Administration (FDA) approved labeling: not to exceed 150U/m^2 daily. MS: Dosing for MS is in accordance with the United States FDA approved labeling: not to exceed 120 units once daily. Other FDA-Approved Indications: Dosing is in accordance with the United States FDA approved labeling: not to exceed 80 units per day.

HARVONI (S)

Products Affected

• Ledipasvir/sofosbuvir

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 (including patients with genotype 5 or 6 infection AND decompensated cirrhosis): A) Diagnosis of chronic hepatitis C, B) Patient is not receiving ledipasvir/sofosbuvir in combination with another HCV direct acting antiviral agent [eg, Sovaldi (sofosbuvir)]. ONE of the following: Trial and failure, intolerance, or contraindication (eg, safety concerns, not indicated for patient's age/weight) to a) Mavyret (except patients with decompensated cirrhosis, and b) sofosbuvir/velpatasvir, OR for continuation of prior ledipasvir/sofosbuvir therapy.
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

HETLIOZ (S)

Products Affected

• Hetlioz

PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Non-24-Hour Sleep-Wake Disorder (Non-24) (initial): Both of the Medical following: 1) Diagnosis of non-24-hour sleep-wake disorder (also known Information as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome), AND 2) patient is totally blind (has no light perception). Smith-Magenis Syndrome (SMS) (initial): 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 (initial): 16 years of age or older Prescriber Non-24 (initial): Prescribed by or in consultation with a specialist in sleep Restrictions disorders or neurologist. SMS (initial): Prescribed by or in consultation with a specialist in sleep disorders or neurologist. Coverage Non-24, SMS (initial): 6 mo. (reauth): 12 mo Duration **Other Criteria** Non-24 (reauth): Documentation of positive clinical response to therapy. SMS (reauth): Documentation of positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality)

Tasimelteon

•

HRM - MEGESTROL SUSPENSION

Products Affected

• Megestrol Acetate SUSP 40MG/ML, 625MG/5ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

HRM - MEGESTROL TABLET

Products Affected

• Megestrol Acetate TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Applies to New Starts only.

HUMIRA (S)

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
Required Medical Information	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 TF/C/I 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. PsO (Initial): Diagnosis 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. Ankylosing Spondylitis (AS) (Initial): Diagnosis 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): Diagnosis 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. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.
Age Restrictions	N/A

Prescriber Restrictions	RA, AS, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.
Coverage Duration	UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo.

Other Criteria	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, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline. OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by inprovement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Document
	following: improvement in intestinal inflammation (eg, mucosal healing,

IBRANCE (S)

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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

ICLUSIG (S)

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 leukemia: Diagnosis of chronic myelogenous leukemia. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses: 12 months
Other Criteria	All uses: Approve for continuation of prior therapy.

IDHIFA (S)

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. Disease is relapsed or refractory. Patient has an isocitrate dehydrogenase-2 (IDH2) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH2 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

IMBRUVICA (S)

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): Diagnosis of CLL. Waldenstrom's macroglobulinemia: Diagnosis of Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma. Small lymphocytic lymphoma (SLL): Diagnosis of SLL. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD AND trial and failure of one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All Uses: 12 months
Other Criteria	All Uses: Approve for continuation of prior therapy.

INCRELEX (S)

Products Affected

• Increlex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Insulin-like Growth Factor-1 (IGF-1) deficiency (initial): 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 (initial): Diagnosis of GH gene deletion in patients who have developed neutralizing antibodies to GH.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	(Reauth): Documentation of positive clinical response to therapy.

INLYTA (S)

Products Affected

• Inlyta

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. One of the following: (1) used as first-line treatment in combination with avelumab or pembrolizumab or (2) used after failure of one prior systemic therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

INQOVI (S)

Products Affected

• Inqovi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

INREBIC (S)

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	12 months
Other Criteria	Approve for continuation of prior therapy.

Products Affected

• Gefitinib

• Iressa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

IVERMECTIN (S)

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	Strongyloidiasis: Diagnosis of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis. Onchocerciasis: Diagnosis of onchocerciasis due to the nematode parasite Onchocerca volvulus.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Strongyloidiasis: 3 weeks. Onchocerciasis: 6 months.
Other Criteria	N/A

Products Affected

• Octagam INJ 1GM/20ML, 2GM/20ML

• Gamunex-c INJ 1GM/10ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Octagam only: Allergy to corn.
Required Medical Information	Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG – Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. Continued in Other Criteria Section.
Age Restrictions	HIV (initial): patient is less than or equal to 12 years of age.

Prescriber Restrictions	All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist).
Coverage Duration	4 months: Solid organ transplant. 12 months: all other diagnoses.
Other Criteria	[D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-Barr¿ syndrome. 3) Inflammatory myopathies (dermatomyositis or polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplan and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient _x s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus

JAKAFI (S)

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: Diagnosis of primary myelofibrosis, OR post- polycythemia vera myelofibrosis, OR post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera, AND trial and failure, contraindication, or intolerance to hydroxyurea. Acute graft versus host disease (aGVHD): Diagnosis of aGVHD. Disease is steroid-refractory. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD. Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months.
Other Criteria	Approve for continuation of prior therapy.

JAYPIRCA (S)

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 therapies for MCL, one of which is a Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Imbruvica (ibrutinib), Calquence (acalabrutinib), Brukinsa (zanubrutinib)].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

JUXTAPID (S)

Products Affected

Juxtapid CAPS 10MG, 20MG, 30MG, 5MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Homozygous familial hypercholesterolemia (HoFH) (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated/pre-treatment LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. One of the following: a) patient is receiving other lipid-lowering therapy, or b) patient has an inability to take other lipid-lowering therapy. Trial and failure, contraindication, or intolerance to Repatha therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.
Age Restrictions	N/A
Prescriber Restrictions	HoFH (initial, reauth): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	HoFH (initial): 6 months. (reauth): 12 months
Other Criteria	HoFH (reauthorization): One of the following: a) patient continues to receive other lipid-lowering therapy, or b) patient has an inability to take other lipid-lowering therapy. Submission of medical records (eg, chart notes, laboratory values) documenting LDL-C reduction from baseline while on therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.

KALYDECO (S)

Products Affected

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

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 cystic fibrosis. Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	CF (initial): Patient is 1 month of age or older.
Prescriber Restrictions	CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	CF (Reauth): Documentation of positive clinical response (i.e. improvement in lung function [percent predicted forced expiratory volume in one second (PPFEV1)], decreased number of pulmonary exacerbations) while on therapy.

KERENDIA (S)

Products Affected

• Kerendia

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 m2. 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauth: Documentation of 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.

KEVEYIS (S)

Products Affected

• Keveyis

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Periodic paralysis (Initial): Diagnosis of one of the following: Primary hyperkalemic periodic paralysis, Primary hypokalemic periodic paralysis, or Paramyotonia Congenita with periodic paralysis.
Age Restrictions	N/A
Prescriber Restrictions	All uses (initial): Prescribed by or in consultation with a neurologist
Coverage Duration	All uses (Initial): 3 months. (Reauth): 12 months
Other Criteria	All uses (Reauth): Documentation of positive clinical response to therapy.

KISQALI (S)

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 breast cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

KISQALI-FEMARA PACK (S)

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 breast cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

KORLYM (S)

Products Affected

• Korlym

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cushing's syndrome (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.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial, reauth: 6 months
Other Criteria	Reauth: Documentation of one of the following: patient has improved glucose tolerance while on therapy or patient has stable glucose tolerance while on therapy.

KOSELUGO (S)

Products Affected

• Koselugo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Neurofibromatosis Type 1 (NF1): Diagnosis of NF1. Patient has plexiform neurofibromas that are both of the following: inoperable and causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment). Patient is able to swallow a capsule whole.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

KRAZATI (S)

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. Disease is one of the following: locally advanced or metastatic. Disease is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

KUVAN (S)

Products Affected

• Sapropterin Dihydrochloride

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient will have blood Phe levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PKU (Init): 2 months (Reauth): 12 months
Other Criteria	PKU (reauth): Documentation of a positive clinical response to therapy. Patient will continue to have blood Phe levels measured periodically during therapy.

LENVIMA (S)

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 (RCC): Diagnosis of RCC. One of the following: 1) Both of the following: a) Used as first-line treatment and b) Used in combination with Keytruda (pembrolizumab), or 2) Both of the following: a) Treatment follows one prior anti-angiogenic therapy and b) Used in combination with everolimus. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Endometrial Carcinoma (EC): Diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR). Patient has disease progression following systemic therapy. Used in combination with Keytruda (pembrolizumab) therapy. Patient is not a candidate for curative surgery or radiation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

LETAIRIS (S)

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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH (Initial): 6 months. PAH (Reauth): 12 months
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

LEUPROLIDE BRAND (S)

Products Affected

• Leuprolide Acetate INJ 22.5MG

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 or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to any brand Lupron formulation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

LIDOCAINE TOPICAL (S)

Products Affected

• Lidocaine OINT 5%

- Lidocaine Hcl SOLN 4%
- Lidocaine/prilocaine CREA

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	3 months
Other Criteria	N/A

LIDODERM (S)

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	12 months
Other Criteria	N/A

LONSURF (S)

Products Affected

• Lonsurf

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Colorectal Cancer: Diagnosis of metastatic colorectal cancer AND One of the following: Used as a single agent or Used in combination with bevacizumab AND trial and failure, contraindication, or intolerance to at least one component in the following: fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI) AND trial and failure, contraindication, or intolerance to at least one anti- VEGF therapy (e.g., bevacizumab)) AND One of the following: A) patient has RAS wild-type tumors and trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux) OR B) Patient has RAS mutant tumors. 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: fluropyrimidine-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	12 months
Other Criteria	Approve for continuation of prior therapy.

LORBRENA (S)

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 metastatic NSCLC.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

LOTRONEX (S)

Products Affected

• Alosetron Hydrochloride

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women (initial): All of the following: 1) diagnosis of severe diarrhea-predominant IBS, 2) symptoms for at least 6 months, 3) female patient, AND 4) trial and failure, contraindication, or intolerance to an antidiarrheal agent [eg, loperamide].
Age Restrictions	Initial: 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	IBS (initial): 12 weeks. IBS (reauth): 6 mo.
Other Criteria	IBS (reauth): Symptoms of IBS continue to persist. Documentation of positive clinical response to therapy (e.g., relief of IBS abdominal pain and discomfort, improvement in stool consistency and frequency, improvement as measured by the Global Improvement Scale).

LUMAKRAS (S)

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) locally advanced or b) metastatic. Tumor is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

LUPRON (S)

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: Diagnosis of advanced or metastatic prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prostate CA: 12 months
Other Criteria	Approve for continuation of prior therapy.

LUPRON DEPOT (S)

Products Affected

- Lupron Depot (1-month) INJ 3.75MG
- 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): Diagnosis of advanced or metastatic prostate cancer. Endometriosis (3.75 mg, 11.25 mg): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID (e.g., diclofenac, ibuprofen, meloxicam, naproxen) and one oral contraceptive (e.g., norethindrone-ethinyl estradiol, estradiol and norethindrone). Uterine Leiomyomata (UL) (3.75 mg, 11.25 mg): a) For use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) OR b) all of the following: treatment of anemia, anemia is caused by uterine leiomyomata (fibroids), and for use prior to surgery.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prostate CA: 12 mo. Endomet:6mo. UL (anemia):3 mo (fibroids):4 mo
Other Criteria	Approve for continuation of prior therapy.

LUPRON DEPOT PED (S)

Products Affected

- Lupron Depot-ped (1-month) INJ 7.5MG
- Lupron Depot-ped (3-month) INJ 11.25MG
- Lupron Depot-ped (6-month)

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 CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range.
Age Restrictions	N/A
Prescriber Restrictions	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
Coverage Duration	CPP (initial, reauth): 12 months
Other Criteria	CPP (reauth): Patient demonstrates positive clinical response to therapy.

Lynparza Tablet (s)

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	Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Breast cancer: Diagnosis of breast cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Pancreatic adenocarcinoma: Diagnosis of pancreatic adenocarcinoma. Prostate cancer: Diagnosis of castration-resistant prostate cancer. BRCA- mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC): Diagnosis of metastatic castration-resistant prostate cancer (mCRPC). Presence of a deleterious or suspected deleterious BRCA- mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with abiraterone and one of the following: a) prednisone or b) prednisolone. All indications: Approve for continuation of prior therapy.

LYTGOBI (S)

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, b) locally advanced, or c) metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangements. Patient has been previously treated (e.g., chemotherapy).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

MARINOL (S)

Products Affected

• Dronabinol

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

MAVYRET (S)

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 will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	N/A

MAYZENT (S)

Products Affected

• Mayzent

PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Multiple Sclerosis (MS) (initial, reauth): Not used in combination with Exclusion another disease-modifying therapy for MS. Criteria Required MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated Medical syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). Information N/A **Age Restrictions** Prescriber MS (initial, reauth): Prescribed by or in consultation with a neurologist Restrictions Coverage MS (initial, reauth): 12 months Duration Other Criteria MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

Mayzent Starter Pack

•

MEKINIST (S)

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 V600E or V600K mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Tafinlar (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 as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Tafinlar (dabrafenib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic ATC. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID- BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Tafinlar (dabrafenib).
Age Restrictions	Solid tumors, Low-grade glioma: Patient is 1 year of age or older.
Prescriber Restrictions	N/A
Coverage Duration	12 months

solid tumors. Disease is unresectable or metastatic. Patient has progresse on or following prior treatment and have no satisfactory alternative treatment options. Cancer is BRAF V600E mutant type as detected by a FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Tafinlar (dabrafenib). Low-grade glioma: Diagnosis of low-grade glioma. Patient requires systemic therap Cancer is BRAF V600E mutant type as detected by an FDA-approved test		treatment options. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Tafinlar (dabrafenib). Low-grade glioma: Diagnosis of low-grade glioma. Patient requires systemic therapy. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
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Mektovi (s)

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. Cancer is BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Braftovi (encorafenib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

METHYLTESTOSTERONE (S)

Products Affected

• Methyltestosterone CAPS

• Methitest

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth.
Age Restrictions	HG (init): Patient is 18 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC: 12 mo. DP: 6 mo.

Other CriteriaHG (Reauth): 1) Follow-up total serum T level within or below the normal limits of the reporting lab, or 2) Follow-up total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Follow-up calculated free or bioavailable T level within or below the normal limits of the reporting lab, or follow-up calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.	hin
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MIGRANAL (S)

Products Affected

• Dihydroergotamine Mesylate 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, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
Coverage Duration	Initial: 3 months. Reauth: 12 months.
Other Criteria	Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea).

MS INTERFERONS (NON-PREFERRED) (S)

Products Affected

- Rebif
- Rebif Rebidose

- Rebif Rebidose Titration Pack
- Rebif Titration Pack

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.
Required Medical Information	MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following: Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Extavia (interferon beta-1b), Plegridy (peginterferon beta-1a), or 2) for continuation of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

MS INTERFERONS (PREFERRED) (S)

Products Affected

• Avonex INJ 30MCG/0.5ML

- Betaseron
- Plegridy

• Avonex Pen

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.
Required Medical Information	MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	N/A
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

MYALEPT (S)

Products Affected

• Myalept

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lipodystrophy (initial): Diagnosis of congenital or acquired generalized lipodystrophy AND one of the following: 1) Diabetes mellitus or insulin resistance despite insulin therapy at maximum tolerated doses OR 2) Hypertriglyceridemia.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Lipodystrophy (reauth): Documentation of positive clinical response to therapy.

NATPARA (S)

Products Affected

• Natpara

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hypocalcemia (Initial): Diagnosis of hypocalcemia due to chronic hypoparathyroidism. Not used in the setting of acute post-surgical hypoparathyroidism. Patient does not have a known calcium-sensing receptor mutation. Patient has a documented parathyroid hormone concentration that is inappropriately low for the level of calcium, recorded on at least two occasions within the previous 12 months. Patient has normal thyroid-stimulating hormone concentrations if not on thyroid hormone replacement therapy (or if on therapy, the dose had to have been stable for greater than or equal to 3 months). Patient has normal magnesium and serum 25-hydroxyvitamin D concentrations. Will be used as an adjunct treatment.
Age Restrictions	N/A
Prescriber Restrictions	Hypocalcemia (initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial: 6 months. Reauth: 12 months
Other Criteria	Hypocalcemia (Reauth): Documentation of positive clinical response to therapy.

NERLYNX (S)

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. Advanced or Metastatic Breast Cancer: Dx of advanced or metastatic breast cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

NEULASTA (S)

Products Affected

• Neulasta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) 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). Treatment of FN: Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications.
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.
Other Criteria	N/A

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NEXAVAR (S)

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. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC (ie, follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma). One of the following: locally recurrent disease, metastatic disease, or unresectable 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. One of the following: 1) Disease is progressive or 2) Disease is symptomatic with distant metastases. Trial and failure, contraindication, or intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

NINLARO (S)

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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

NORTHERA (S)

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) (init): 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. Trial and failure, contraindication, or intolerance to one of the following agents: fludrocortisone acetate, midodrine.
Age Restrictions	N/A
Prescriber Restrictions	NOH (init): Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist
Coverage Duration	NOH (init): 1 month (reauth): 12 months
Other Criteria	NOH (reauth): Documentation of positive clinical response to therapy.

NOXAFIL SUSPENSION (S)

Products Affected

• Posaconazole SUSP

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of systemic fungal infections (SFI): 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 OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Oropharyngeal Candidiasis (OPC): Diagnosis of OPC. One of the following: 1) Trial and failure, contraindication, or intolerance to fluconazole OR 2) Susceptibility results demonstrate resistance to fluconazole.
Age Restrictions	Prophylaxis of SFI, OPC: Patient is 13 years or older.
Prescriber Restrictions	N/A
Coverage Duration	Prophylaxis of SFI: 6 months. OPC: 1 month.
Other Criteria	N/A

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NUBEQA (S)

Products Affected

• Nubeqa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Castration-resistant or castration-recurrent prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or castration- recurrent prostate cancer. Hormone-sensitive prostate cancer (HSPC): Diagnosis of HSPC.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CRPC, HSPC: 12 months
Other Criteria	Approve for continuation of prior therapy.

NUEDEXTA (S)

Products Affected

• Nuedexta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pseudobulbar affect (PBA) (initial): Diagnosis of PBA. 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. PBA (reauth): Documentation of clinical benefit from ongoing therapy as demonstrated by a decrease in inappropriate laughing or crying episodes.
Age Restrictions	N/A
Prescriber Restrictions	PBA (initial): Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist.
Coverage Duration	PBA (initial/reauth): 12 months
Other Criteria	N/A

Products Affected

• Nuplazid TABS 10MG

• Nuplazid CAPS

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	12 months
Other Criteria	Approve for continuation of prior therapy.

NUVIGIL (S)

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 sleep study (unless prescriber provides justification confirmed by sleep study is not feasible).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	OSA, SWD: Initial, Reauth: 6 mo. Narcolepsy: Initial, Reauth: 12 mo

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Other Criteria	OSA, Narcolepsy (Reauth): Documentation of positive clinical response to armodafinil therapy. SWD (Reauth): Documentation of positive clinical
	response to armodafinil therapy.

OCALIVA (S)

Products Affected

• Ocaliva

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Primary Biliary Cholangitis (PBC) (initial): Diagnosis of PBC (aka primary biliary cirrhosis). One of the following: a) patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) AND used in combination with UDCA, OR b) contraindication or intolerance to UDCA. Patient does not have evidence of advanced cirrhosis (i.e., cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy). Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).
Age Restrictions	N/A
Prescriber Restrictions	PBC (initial): Prescribed by or in consultation with a hepatologist or gastroenterologist.
Coverage Duration	PBC (initial): 6 months, (reauth): 12 months
Other Criteria	PBC (reauthorization): Submission of medical records (eg, laboratory values) documenting a reduction in ALP level from pre-treatment baseline (ie, prior obeticholic acid therapy) while on therapy. Patient does not have evidence of advanced cirrhosis (i.e., cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy). Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).

ODOMZO(S)

Products Affected

• Odomzo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma AND One of the following: 1) Cancer has recurred following surgery or radiation therapy or 2) Patient is not a candidate for surgery or radiation therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

OFEV (S)

Products Affected

• Ofev

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 as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (initial): Diagnosis of SSc-ILD as documented by all of the following: a) exclusion of other known causes of ILD (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) 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 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, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD, OR ii) in patients subjected to computed tomography (HRCT) showing at least 10% of lung volume with fibrotic features, AND 3) 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.
Age Restrictions	N/A
Prescriber Restrictions	IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (initial): Prescribed by or in consultation with a pulmonologist

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Coverage Duration	Initial, reauth: 12 months
Other Criteria	IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (reauth): Documentation of positive clinical response to therapy.

OJJAARA (S)

Products Affected

• Ojjaara

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of ONE of the following: a) Primary myelofibrosis, b) Post- polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Patient has anemia.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

ONUREG (S)

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, etc.). 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 able to complete intensive curative therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

OPSUMIT (S)

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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

ORENITRAM (S)

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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

ORGOVYX (S)

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. Disease is one of the following: 1) Evidence of biochemical or clinical relapse following local primary intervention with curative intent or 2) Newly diagnosed androgen-sensitive metastatic disease or 3) Advanced localized disease unlikely to be cured by local primary intervention with curative intent.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

ORKAMBI (S)

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 (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)- cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	CF (Initial): Patient is 6 years of age or older
Prescriber Restrictions	CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).

ORSERDU (S)

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. Disease is estrogen receptor (ER)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Presence of estrogen receptor (ESR1) mutation(s) as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

OXBRYTA (S)

Products Affected

• Oxbryta TBSO

• Oxbryta TABS 300MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of Sickle Cell Disease. Documentation of hemoglobin level that does not exceed 10.5 g/dL prior to therapy initiation. Trial and failure or inadequate response, contraindication, or intolerance to hydroxyurea.
Age Restrictions	Initial: Patient is 4 years of age or older.
Prescriber Restrictions	Initial: Prescribed by or in consultation with one of the following: 1) Hematologist/Oncologist or 2) Specialist w/ expertise in the diagnosis and management of sickle cell disease.
Coverage Duration	Initial, Reauth: 12 months.
Other Criteria	Reauth: Documentation of positive clinical response to therapy (e.g., an increase in hemoglobin level of 1 g/dL or greater from baseline, decreased annualized incidence rate of vaso-occlusive crises [VOCs]). Documentation of hemoglobin level that does not exceed 10.5 g/dL.

PEGASYS (S)

Products Affected

• Pegasys

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Criteria will be applied consistent with current AASLD-IDSA guidance.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HepB: 48 wks. HepC: Initial: 28 wks. Reauth: 20 wks.
Other Criteria	N/A

PEMAZYRE (S)

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 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has been previously treated. Myeloid/lymphoid neoplasms: Diagnosis of myeloid/lymphoid neoplasms (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	12 months
Other Criteria	Approve for continuation of prior therapy.

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Products Affected

• Diclofenac Sodium EXTERNAL SOLN 1.5%

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Osteoarthritis of the knees (initial): Diagnosis of osteoarthritis of the knees. Patient meets one of the following: 1) Treatment failure with at least two prescription strength topical or oral non-steroidal anti- inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) OR 2) History of peptic ulcer disease/gastrointestinal bleed OR 3) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Osteoarthritis of the knees (reauth): Documentation of positive clinical response to therapy (e.g., improvement in pain symptoms of osteoarthritis).

PIQRAY (S)

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) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 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	12 months
Other Criteria	Approve for continuation of prior therapy.

POMALYST (S)

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 (MM): Diagnosis of MM. Kaposi sarcoma (KS): One of the following: 1) Diagnosis of AIDS-related KS, 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	12 months
Other Criteria	Approve for continuation of prior therapy.

POSACONAZOLE (S)

Products Affected

• Noxafil SUSP

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of systemic fungal infections (SFI): 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 OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Treatment (Tx) of SFI: Used as treatment of systemic fungal infections caused by Aspergillus. Oropharyngeal Candidiasis (OPC): Diagnosis of OPC. One of the following: 1) Candidiasis is refractory or resistant to treatment with fluconazole OR 2) Trial and failure, contraindication, or intolerance to fluconazole.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prophylaxis of SFI: 6 months. Tx of SFI: 3 months. OPC: 1 month.
Other Criteria	N/A

POSACONAZOLE TABLET (S)

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 systemic fungal infections (SFI): 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 OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Treatment (Tx) of SFI: Used as treatment of systemic fungal infections caused by Aspergillus.
Age Restrictions	Prophylaxis of SFI: Patient is 2 years of age or older. Tx of SFI: Patient is 13 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	Prophylaxis of SFI: 6 months. Tx of SFI: 3 months.
Other Criteria	N/A

PRALUENT (S)

Products Affected

• Praluent

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, iii)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, 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 (init): 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. HeFH/ASCVD/Primary HLD (init): One of the following: set A)Both of the following: 1) One of the following: a) One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: i)LDL greater than or equal to 100 mg/dL w/ASCVD or ii)LDL greater than or equal to 130 mg/dL w/o ASCVD, OR b) Both of the following: i) Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy and ii) LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy has shown a reduction from baseline, AND Continued in Other Criteria

Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Reauth: 12 months

Other Criteria	Set A (cont, initial): 2)One of the following: a)Pt has been receiving at least 12 wks of one high-intensity (HI) statin therapy (tx) and will continue to receive a HI statin [ie, atorvastatin 40-80 mg, rosuvastatin 20- 40 mg] at max tolerated dose, OR b) Both of the following: i) Pt unable to tolerate HI statin 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) AND ii) One of the following: (1) Pt has been receiving at least 12 wks of one moderate-intensity (MI) or low-intensity (LI) statin tx and will continue to receive a MI or LI statin [ie, atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at max tolerated dose, OR (2) Pt is unable to tolerate MI or LI statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN), OR c) Pt has a labeled contraindication to all statins, OR d) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin treatment w/ CK elevations greater than 10 times ULN on one statin tx. OR set B) Both of the following: 1) One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: a) LDL b/t 55 and 99 mg/dL w/ASCVD or b) LDL b/t 100 and 129 mg/dL w/o ASCVD, AND 2) Both of the following: a) 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/ 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 rhabdomyoly
	receive other lipid-lowering tx (eg statins, ezetimibe) at max tolerated dose (unless pt has documented inability to take these medications).

PROMACTA (S)

Products Affected

• Promacta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: relapsed/refractory ITP, persistent ITP, or chronic ITP. Baseline platelet count is less than 30,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. Trial and failure, intolerance, contraindication to corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C-associated thrombocytpenia. One of the following: 1) Planning to initiate and maintain interferon-based treatment, or 2) 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). Used in combination with standard immunosuppressive therapy (e.g., horse antithymocyte globulin, 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 severe aplastic anemia. Patient has a platelet count less than 30,000/mcL. Insufficient response to immunosuppressive therapy (e.g., horse antithymocyte globulin, cyclosporine).
Age Restrictions	N/A
Prescriber Restrictions	ITP and SAA: Prescribed by or in consultation with a hematologist/oncologist. Chronic hepatitis C associated thrombocytopenia: Prescribed by or in consultation with a hematologist/oncologist, gastroenterologist, hepatologist, infectious disease specialist, or HIV specialist certified through the American Academy of HIV Medicine.

Coverage	ITP(init,reauth):12mo.HepC:3mo(init),12mo(reauth).1stline
Duration	SAA:6mo.RefractSAA:16wk-init,12mo-reauth
Other Criteria	ITP (reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding. Hepatitis C (reauth): One of the following: 1) 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: a) Currently on antiviral interferon therapy for treatment of chronic hepatitis C and b) Documentation that the patient reached a threshold platelet count that allows initiation of antiviral interferon therapy with eltrombopag treatment by week 9, OR 2) For patients that started treatment with eltrombopag while on concomitant treatment with interferon, eltrombopag will be approved based on the following: Currently on antiviral interferon therapy for treatment of chronic hepatitis C. Refractory SAA (reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count.

PROVIGIL (S)

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. 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. Idiopathic Hypersomnia (Initial): Diagnosis of idiopathic hypersomnia 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	Narcolepsy: Init, Reauth: 12 mo. All other indications: Init, Reauth: 6 mo.
Other Criteria	OSA, Narcolepsy, Idiopathic Hypersomnia (Reauth): Documentation of positive clinical response to modafinil therapy. SWD (Reauth): Documentation of positive clinical response to modafinil therapy. MS Fatigue (reauth): Patient is experiencing relief of fatigue with modafinil therapy. Depression (reauth): Documentation of positive clinical response to modafinil therapy. Used as adjunctive therapy.

PULMOZYME (S)

Products Affected

• Pulmozyme SOLN 2.5MG/2.5ML

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, Reauth): Diagnosis of CF.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	Part B vs D determination applies. CF (reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).

PYRUKYND (S)

Products Affected

• Pyrukynd

PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Initial: Diagnosis of hemolytic anemia confirmed by the presence of Medical chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated Information 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 Initial, Reauth: Prescribed by or in consultation with a hematologist. Restrictions Coverage Initial: 6 months. Reauth: 12 months. **Duration Other Criteria** Reauth: Documentation of positive clinical response to therapy.

• Pyrukynd Taper Pack

QINLOCK (S)

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 advanced. Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

QUALAQUIN (S)

Products Affected

• Quinine Sulfate CAPS 324MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Excluded if used solely for the treatment or prevention of nocturnal leg cramps.
Required Medical Information	Malaria: Diagnosis of uncomplicated malaria. One of the following: 1) Treatment in areas of chloroquine-sensitive malaria, and trial and failure, contraindication, or intolerance to chloroquine or hydroxychloroquine, OR 2) Treatment in areas of chloroquine-resistant malaria.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	N/A

RAVICTI (S)

Products Affected

• Ravicti

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Urea cycle disorders (UCDs) (Initial): Both of the following: 1) Diagnosis of UCD AND 2) One of the following deficiencies: a) carbamylphosphate synthetase (CPS), b) ornithine transcarbamylase (OTC), or c) argininosuccinic acid synthetase (AS). Molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene. Inadequate response to one of the following: 1) Dietary protein restriction or 2) Amino acid supplementation.
Age Restrictions	N/A
Prescriber Restrictions	UCDs (initial): Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders.
Coverage Duration	UCDs (Initial, reauth): 12 months
Other Criteria	UCDs (reauth): Documentation of positive clinical response to therapy (e.g., plasma ammonia or amino acid levels within normal limits).

REGRANEX (S)

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	5 months
Other Criteria	N/A

REPATHA (S)

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, iii)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, 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 (init): 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. HeFH/ASCVD/Primary HLD (init): One of the following: set A)Both of the following: 1) One of the following: a) One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: i)LDL greater than or equal to 100 mg/dL w/ASCVD or ii)LDL greater than or equal to 130 mg/dL w/o ASCVD, OR b) Both of the following: i) Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy and ii) LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy has shown a reduction from baseline, AND Continued in Other Criteria

Age Restrictions	(Initial) HeFH/HoFH: 10 years or older.
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Reauth: 12 months

Other Criteria	Set A (cont, initial): 2) One of the following: a) Pt has been receiving at least 12 wks of one high-intensity (HI) statin therapy (tx) and will continue to receive a HI statin [ie, atorvastatin 40-80 mg, rosuvastatin 20- 40 mg] at max tolerated dose, OR b) Both of the following: i) Pt unable to tolerate HI statin 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) AND ii) One of the following: (1) Pt has been receiving at least 12 wks of one moderate-intensity (MI) or low-intensity (LI) statin tx and will continue to receive a MI or LI statin [ie, atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at max tolerated dose, OR (2) Pt is unable to tolerate MI or LI statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN), OR c) Pt has a labeled contraindication to all statins, OR d) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin treatment w/ CK elevations greater than 10 times ULN on one statin tx. OR set B) Both of the following: 1) One of the following LDL values while on max tolerated lipid lowering tx w/in the last 120 days: a) LDL b/t 55 and 99 mg/dL w/ ASCVD or b) LDL b/t 100 and 129 mg/dL w/o ASCVD, AND 2) Both of the following: a) 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/ 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 rhabdomyolysi
	dose (unless pt has documented inability to take these medications).

RETACRIT (S)

Products Affected

• Retacrit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, 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. Anemia with chemo (Initial):Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is receiving chemo. 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. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon/peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 36% or Hgb less than 12 g/dL) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa. Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.
Age Restrictions	N/A
Prescriber Restrictions	N/A

Coverage	CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo.
Duration	MDS:(init) 3mo,(reauth)12mo. Preop:1mo.
Other Criteria	Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or 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. 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. Chemo (Reauth): Anemia by lab values (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. HCV (Reauth): Most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 36% or less. Documentation of a positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hct over 3 months is 12 g/dl or less. Documentation of a positive clinical response to therapy from pre-treatment level. Other Offlabel uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores.

RETEVMO (S)

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 locally advanced or metastatic. Disease has presence of RET gene fusion-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 tumor(s). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. Patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate. Solid Tumors: Diagnosis of solid tumors. Disease is locally advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s). ONE of the following: a) Disease has progressed on or following prior systemic treatment (e.g., chemotherapy), OR b) There are no satisfactory alternative treatment options.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Non-Small Cell Lung Cancer, MTC, Thyroid Cancer, Solid Tumors: 12 months
Other Criteria	Approve for continuation of prior therapy.

REVATIO (S)

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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

REVATIO SUSPENSION (S)

Products Affected

• Sildenafil Citrate SUSR

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) (Initial): 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. One of the following: A) Intolerance to generic Revatio tablets, OR B) Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following: age, oral- motor difficulties, or dysphagia.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

REVCOVI (S)

Products Affected

• Revcovi

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	12 months
Other Criteria	N/A

REVLIMID (S)

Products Affected

• Lenalidomide

PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A **Exclusion** N/A Criteria Required Multiple myeloma (MM): Diagnosis of MM. Myelodysplastic syndromes Medical (MDS): Diagnosis of transfusion-dependent anemia due to low- or Information intermediate-1-risk MDS associated with a deletion 5q. Mantle cell lymphoma (MCL): Diagnosis of MCL. Follicular Lymphoma (FL): Diagnosis of FL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. **Age Restrictions** N/A Prescriber N/A Restrictions Coverage 12 months **Duration Other Criteria** Approve for continuation of prior therapy.

• Revlimid

REYVOW (S)

Products Affected

• Reyvow

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 with or without aura. Will be used for the acute treatment of migraine. Patient has less 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. Prescriber attests that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 8 hours after taking each dose of Reyvow.
Age Restrictions	Initial: 18 years of age or older.
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.
Coverage Duration	Initial: 3 months. Reauth: 12 months.
Other Criteria	Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). Will not be used for preventive treatment of migraine.

REZLIDHIA (S)

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) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

RILUTEK (S)

Products Affected

• Riluzole

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Amyotrophic lateral sclerosis (ALS): Diagnosis of amyotrophic lateral sclerosis (ALS).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ALS: 12 months
Other Criteria	N/A

RINVOQ(S)

Products Affected

• Rinvoq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA) (init): Diagnosis (Dx) of moderately to severely active RA. Minimum (min) duration of a 3-mo 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): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing spondylitis (AS) (init): Dx of active AS. Non-radiographic axial spondyloarthritis (NRAS, init): Dx of active NRAS. Pt has signs of inflammation. Pt has had an inadequate response or intolerance to one or more TNF inhibitors (eg, certolizumab pegol). AS, NRAS (init): Min duration of a one-mo TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. RA, PsA, AS (init): Pt has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept). RA, PsA, AS, NRAS (init, reauth): Not used in combination with other JAK inhibitors (JAK-I), biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). Atopic dermatitis (AD) (init): Dx of moderate to severe AD. One of the following: Involvement of at least 10% body surface area (BSA), or SCORing Atopic Dermatitis (SCORAD) index value of at least 25. TF of a min 30- day supply (14-day supply for topical corticosteroids), C/I to at least one of the following: Medium or higher potency topical corticosteroid, Pimecrolimus cream, Tacrolimus oint, or Eucrisa oint. One of the following: 1) TF of a min 12-week supply of at least one systemic drug product for the treatment of AD (ex include, but are not limited to, Adbry, Dupixent, etc.), OR 2) Pt has a C/I, or treatment is inadvisable with both of the following FDA-approved AD therapies: Adbry and Dupixent. Not used in combination with other JAK-I, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine).
Age Restrictions	AD (initial): Patient is 12 years of age or older

Prescriber Restrictions	RA, AS, NRAS (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. AD (init): Prescribed by or in consultation with a dermatologist or allergist/immunologist. CD, UC (init): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	RA, PsA, AS, NRAS, CD, UC, AD (init): 6 months, (reauth): 12 months.

Other Criteria	Crohn's disease (CD) (init): Dy of moderately to severally estive CD. One
Other Criteria	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. Not used in combination with other JAK-I, biological therapies for CD, or potent immunosuppressants (e.g., azathioprine, cyclosporine). Ulcerative colitis (UC) (init): Dx of moderately to severely active UC. One of the following: greater than 6 stools/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). Not used in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine). CD, UC (init): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab). RA (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (ESR, CRP level), function, axial status (eg, lumba
	(swollen and tender) joint count. AD (reauth): Documentation of a positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. Not used in combination with other JAK inhibitors, biologic immunomodulators, or
	other immunosuppressants (eg, azathioprine, cyclosporine). CD, UC (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, ESR, CRP level]) from baseline OR reversal of high fecal output state. Not used in combination with other JAK inhibitors, biological therapies for CD/UC, or potent immunosuppressants (eg, azathioprine, cyclosporine).

ROZLYTREK (S)

Products Affected

• Rozlytrek CAPS

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	12 months
Other Criteria	Approve for continuation of prior therapy.

RUBRACA (S)

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 epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Prostate cancer: Diagnosis of castration-resistant prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

RUCONEST (S)

Products Affected

• Ruconest

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. 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	12 months
Other Criteria	N/A

RYDAPT (S)

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): Newly diagnosed acute myeloid leukemia (AML), FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. 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	12 months
Other Criteria	Approve for continuation of prior therapy.

SABRIL (S)

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. Failure, contraindication, or intolerance to two formulary anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)]. Infantile Spasms (IS): Diagnosis of infantile spasms.
Age Restrictions	IS: 1 month to 2 years of age. CPS: 2 years or older.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

SAMSCA (S)

Products Affected

• Tolvaptan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of significant hyponatremia (euvolemic or hypervolemic). Treatment has been initiated or re-initiated in a hospital setting prior to discharge within the past 30 days.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	30 days
Other Criteria	N/A

SANDOSTATIN (S)

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	Acromegaly (initial): Diagnosis of acromegaly. One of the following: A) Inadequate response to surgical resection and/or pituitary irradiation OR B) Patient is not a candidate for surgical resection or pituitary irradiation. Trial and failure, contraindication or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	Acromegaly (reauth): Documentation of positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): Patient has improvement in number of diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (reauth): Patient has improvement in number of diarrhea episodes.

SCEMBLIX (S)

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)], OR 2) Disease is T315I mutation positive.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

SIGNIFOR (S)

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 (initial): Diagnosis of Cushing's disease. One of the following: a) Pituitary surgery has not been curative for the patient or b) Patient is not a candidate for pituitary surgery.
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): 12 months
Other Criteria	Cushing's disease (reauth): Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease).

SKYCLARYS (S)

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	Initial: Patient is 16 years of age or older.
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: 12 months.
Other Criteria	Reauth: Documentation of positive clinical response to therapy.

SKYRIZI (S)

Products Affected

- Skyrizi Pen
- Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML

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. 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.
Age Restrictions	N/A
Prescriber Restrictions	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.
Coverage Duration	All uses (initial): 6 months, (reauth): 12 months

Other Criteria	Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. CD (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal
	output state.

SOMAVERT (S)

Products Affected

• Somavert

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acromegaly (initial): Diagnosis of acromegaly AND Failure to surgery and/or radiation therapy and/or other medical therapies (such as dopamine agonists [e.g., bromocriptine, cabergoline]) unless patient is not a candidate for these treatment options AND trial and failure or intolerance to generic octreotide (a somatostatin analogue)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial and reauth: 12 months
Other Criteria	Acromegaly (reauth): Patient has experienced a positive clinical response to therapy (biochemical control, decrease or normalization of IGF-1 levels).

Products Affected

• Itraconazole SOLN

• Itraconazole CAPS

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) patient has a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), OR 2) all of the following: a) patient has a diagnosis of onychomycosis confirmed by one of the following (CAPSULE ONLY): i) positive potassium hydroxide (KOH) preparation, OR ii) fungal culture, OR iii) nail biopsy, AND b) patient has had a trial and failure, contraindication, or intolerance to oral terbinafine, OR 3) both of the following (ORAL SOLUTION ONLY): a) patient has a diagnosis of candidiasis (esophageal or oropharyngeal), AND b) one of the following: i) candidiasis is refractory or resistant to treatment with fluconazole OR ii) trial and failure, contraindication, or intolerance to fluconazole.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Systemic fungal infxn:6mo.Candidiasis:1mo.Fingernail onycho:5wks.Toenail onycho, other:3mo.
Other Criteria	N/A

SPRYCEL (S)

Products Affected

• Sprycel

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Philadelphia chromosome positive (Ph+)/BCR ABL chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML. Ph+/BCR ABL acute lymphoblastic leukemia (ALL): Diagnosis of Ph+/BCR ABL ALL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All Uses: 12 months
Other Criteria	All Uses: Approve for continuation of prior therapy.

STELARA (S)

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	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): One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. 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): 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.
Age Restrictions	N/A
Prescriber Restrictions	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.
Coverage Duration	All uses (Initial): 6 months. All uses (reauth): 12 months

Other Criteria	Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction dose. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD (Reauth), UC (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate. C-reactive protein levell) from
	counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.

STIVARGA (S)

Products Affected

• Stivarga

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. Gastrointestinal stromal tumor (GIST): Diagnosis of locally advanced, unresectable or metastatic GIST. Hepatocellular Carcinoma (HCC): Diagnosis of HCC.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

SUTENT (S)

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	Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma. Gastrointestinal stromal tumor (GIST): Diagnosis of GIST after disease progression on, or contraindication or intolerance to Gleevec (imatinib). Pancreatic neuroendocrine tumors: Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumor that is unresectable locally advanced or metastatic disease. Adjuvant treatment of renal cell carcinoma: Diagnosis of renal cell carcinoma (RCC). Used as adjuvant therapy. Patient is at high risk of recurrent RCC following nephrectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

Formulary ID: 23540, Version: 20, Effective Date: 12/01/2023 Last Updated: November 2023

SYMLIN (S)

Products Affected

• Symlinpen 120

• Symlinpen 60

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: One of the following diagnoses: A) Type 1 diabetes OR B) Type 2 diabetes. Patient has failed to achieve desired glucose control despite optimal insulin therapy. Patient is taking concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Reauth: Patient has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline. Patient is receiving concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog).

Formulary ID: 23540, Version: 20, Effective Date: 12/01/2023 Last Updated: November 2023

SYNRIBO (S)

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 myelogenous leukemia (CML): Diagnosis of CML in the chronic or accelerated phase.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

SYPRINE (S)

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	Initial: 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	12 months
Other Criteria	Reauth: Documentation of a positive clinical response to therapy

TABRECTA (S)

Products Affected

• Tabrecta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of non-small cell lung cancer (NSCLC). Disease is metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

TADLIQ (S)

Products Affected

• Tadliq

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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

TAFAMIDIS (S)

Products Affected

• Vyndamax

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): 12 months
Other Criteria	ATTR-CM (reauth): Documentation of positive clinical response to therapy. Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure.

TAFINLAR (S)

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 or metastatic melanoma AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR both of the following: cancer is BRAF V600E or V600K mutant type as detected by an FDA- approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and medication is used in combination with Mekinist (trametinib). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 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): Diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA- approved test (THxID-BRAF Kit) or a test performed at a facility approved test (THxID-BRAF Kit) or a test performed at a facility approved test (THxID-BRAF Kit) or a test performed at a facility approved test (THxID-BRAF Kit) or a test performed at a facility approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Mekinist (trametinib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic anaplastic thyroid cancer. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Mekinist (trametinib) .
Age Restrictions	Solid tumors, Low-grade glioma: Patient is 1 year of age or older.
Prescriber Restrictions	N/A

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Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Mekinist (trametinib). Low-grade Glioma: Diagnosis of low-grade glioma. Patient requires systemic therapy. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved test (THxID-BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Mekinist (trametinib).

TAGRISSO (S)

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 metastatic NSCLC. One of the following: 1) Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), OR 2) Both of the following: a) Patient has known active EGFR T790M mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved test or a test performed at a facility approved test or a test performed at a facility approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and b) Patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib), or Vizimpro (dacomitinib). OR B) All of the following: Diagnosis of NSCLC. Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 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	12 months
Other Criteria	Approve for continuation of prior therapy.

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TALZENNA (S)

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. Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer (mCRPC). Disease is homologous recombination repair (HRR) gene-mutated. Taken in combination with Xtandi (enzalutamide).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

TARCEVA (S)

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): Diagnosis of locally advanced or metastatic (Stage III or IV) NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Pancreatic Cancer: Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer AND erlotinib will be used in combination with gemcitabine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

TARGRETIN (S)

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 CTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [eg, corticosteroids {ie, clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}] or systemic therapies [eg, interferons]).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

TASIGNA (S)

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 myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

TAZVERIK (S)

Products Affected

• Tazverik

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Epithelioid sarcoma: Diagnosis of epithelioid sarcoma. Disease is one of the following: metastatic or locally advanced. Patient is not eligible for complete resection. Follicular lymphoma: Diagnosis of follicular lymphoma. Disease is one of the following: relapsed or refractory.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

TECFIDERA (S)

Products Affected

• Dimethyl Fumarate CPDR

• Dimethyl Fumarate Starterpack CDPK 0

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.
Required Medical Information	MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	N/A
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

TEGSEDI (S)

Products Affected

• Tegsedi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) (initial): Diagnosis of hATTR amyloidosis with polyneuropathy. Patient has a transthyretin (TTR) mutation (e.g., V30M). One of the following: 1) Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb, 2) Patient has baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2, OR 3) Patient has a baseline neuropathy impairment score (NIS) between 10 and 130. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy).
Age Restrictions	N/A
Prescriber Restrictions	hATTR amyloidosis (initial): Prescribed by or in consultation with a neurologist
Coverage Duration	hATTR amyloidosis (initial, reauth): 12 months
Other Criteria	hATTR amyloidosis (reauth): Patient has demonstrated a benefit from therapy (e.g., improved neurologic impairment, slowing of disease progression, quality of life assessment). One of the following: 1) Patient continues to have a PND score less than or equal to IIIb, 2) Patient continues to have a FAP stage of 1 or 2, OR 3) Patient continues to have a NIS between 10 and 130.

ТЕРМЕТКО (S)

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 metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

TERIPARATIDE (S)

Products Affected

• Forteo INJ 600MCG/2.4ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Postmenopausal osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia (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 uses (initial): 24 months. All uses (reauth): 12 months.

Other Criteria	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, 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, or 4) either glucocorticoid dosing of at least 30 mg per day or cumulative glucocorticoid dosing of at least 5 grams per year. 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)].

TESTOSTERONE (S)

Products Affected

- Testosterone GEL 20.25MG/1.25GM, 40.5MG/2.5GM
- PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at Required Medical birth AND one of the following: 1) Two pre-treatment serum total Information testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Gender Dysphoria (GD)/Gender Incongruence (off-label): Dx of GD/Gender Incongruence. **Age Restrictions** HG (init): Patient is 18 years of age or older. Prescriber N/A **Restrictions** HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reauth): Coverage Duration 12 mo. GD: 12 mo.

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• Testosterone Pump GEL 1.62%

normal lim outside of r adjusted, C thyroid dis of the follo or below th free or bioa	h): 1) Follow-up total serum T level within or below the its of the reporting lab, or 2) Follow-up total serum T level upper limits of normal for the reporting lab and the dose is OR 3) Has a condition that may cause altered SHBG (eg, order, HIV disease, liver disorder, diabetes, obesity), and one wing: Follow-up calculated free or bioavailable T level within ne normal limits of the reporting lab, or follow-up calculated available T level outside of upper limits of normal for the ab and the dose is adjusted.
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THALOMID (S)

Products Affected

• Thalomid

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 MM. Used in combination with dexamethasone, unless the patient has an intolerance to steroids. Erythema nodosum leprosum (ENL): Diagnosis of moderate to severe ENL with cutaneous manifestations. Thalomid is not used as monotherapy if moderate to severe neuritis is present.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

TIBSOVO (S)

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. Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. One of the following: 1) patient is greater than or equal to 75 years old OR 2) patient has comorbidities that preclude use of intensive induction chemotherapy. Locally Advanced or Metastatic Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is locally advanced or metastatic. Patient has been previously treated. All indications: Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)- approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

TOPICAL RETINOID (S)

Products Affected

- Tretinoin CREA
- Tretinoin GEL

• Tretinoin Microsphere GEL 0.04%, 0.1%

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne).
Age Restrictions	PA applies to members 26 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

TRIKAFTA (S)

Products Affected

• Trikafta

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 at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility: F508del mutation OR a mutation in the CFTR gene that is responsive based on in vitro data.
Age Restrictions	CF (initial): For granule packets: patient is at least 2 to less than 6 years of age. For tablets: patient is 6 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, reauth): 12 months
Other Criteria	CF (reauth): Documentation of positive clinical response to therapy (e.g., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations).

TUKYSA (S)

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 received one or more prior anti- HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine). Colorectal cancer: Diagnosis of colorectal cancer. Disease is one of the following: a) unresectable or b) metastatic. Disease is HER2- positive. Patient has RAS wild-type tumors. Used in combination with trastuzumab. Patient has progressed following treatment with one of the following: a) fluoropyrimidine-based chemotherapy, b) oxaliplatin-based chemotherapy, c) irinotecan-based chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

TURALIO (S)

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	12 months
Other Criteria	Approve for continuation of prior therapy.

TYKERB (S)

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: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic or recurrent breast cancer. Used in combination with one of the following: Trastuzumab, Xeloda (capecitabine), or aromatase inhibitors [eg, Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

UBRELVY (S)

Products Affected

• Ubrelvy

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 with or without aura. Will be used for the acute treatment of migraine. 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.
Age Restrictions	Initial: 18 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Reauth: 12 months.
Other Criteria	Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). Will not be used for preventive treatment of migraine. Medication will not be used in combination with another oral CGRP inhibitor.

UDENYCA (S)

Products Affected

• Udenyca

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose- limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of FN (off-label): Patient has received or is receiving myelosuppressive anticancer drugs associated complications. Acute radiation syndrome (ARS) (off-label): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.
Other Criteria	N/A

UPTRAVI (S)

Products Affected

• Uptravi TABS

PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Pulmonary arterial hypertension (PAH) (initial): Diagnosis of PAH. PAH Medical is symptomatic. One of the following: A) Diagnosis of PAH was Information confirmed by right heart catheterization OR B) Patient is currently on any therapy for the diagnosis of PAH. One of the following: A) Trial and failure, contraindication, or intolerance to a PDE5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)] or Adempas (riociguat), and trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g., Letairis (ambrisentan), Opsumit (macitentan), or Tracleer (bosentan)] OR B) For continuation of prior therapy. Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]. N/A **Age Restrictions** Prescriber PAH (initial): Prescribed by or in consultation with a pulmonologist or Restrictions cardiologist. Initial: 6 months. Reauth: 12 months Coverage Duration **Other Criteria** PAH (Reauth): Documentation of positive clinical response to therapy. Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)].

• Uptravi Titration Pack

VALCHLOR (S)

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) (initial): All 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	12 months
Other Criteria	Approve for continuation of prior therapy.

VANFLYTA (S)

Products Affected

• Vanflyta

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. Patient has a FMS- like tyrosine kinase 3 (FLT3) internal tandem duplication (FLT3-ITD) mutation as detected by a U.S. Food and Drug Administration (FDA)- approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Both of the following: a) Used in combination with standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin) induction and cytarabine consolidation, and b) Used as maintenance monotherapy following consolidation chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

VENCLEXTA (S)

Products Affected

• Venclexta

PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A **Exclusion** N/A Criteria Required Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma Medical (SLL): Diagnosis of CLL or SLL. Acute Myeloid Leukemia (AML): Information Diagnosis of newly diagnosed AML. Used in combination with azacitidine, or decitabine, or low-dose cytarabine. One of the following: 1) age 75 years or older OR 2) comorbidities that preclude use of intensive induction chemotherapy. **Age Restrictions** N/A Prescriber N/A **Restrictions** Coverage 12 months Duration **Other Criteria** Approve for continuation of prior therapy.

•

Venclexta Starting Pack

VENTAVIS (S)

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) (Initial): 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 (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH (Initial): 6 months. (Reauth): 12 months
Other Criteria	Subject to Part B vs D review. PAH (Reauth): Documentation of positive clinical response to therapy.

VERZENIO (S)

Products Affected

• Verzenio

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer: Diagnosis of breast cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

VITRAKVI (S)

Products Affected

• Vitrakvi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Presence of solid tumors (e.g., salivary gland, soft tissue sarcoma, infantile fibrosarcoma, thyroid cancer, lung, melanoma, colon, etc.). Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.). Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]. Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy) OR Disease has no satisfactory alternative treatments.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

VIZIMPRO (S)

Products Affected

• Vizimpro

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Disease is positive for one of the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletion or exon 21 L858R substitution.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

VONJO (S)

Products Affected

• Vonjo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of ONE of the following: a) Primary myelofibrosis, b) Post- polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Pre-treatment platelet count below 50 x 10^9/L.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

VORICONAZOLE INJECTION (S)

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 Scedosporium apiospermum (asexual form of Pseudallescheria boydii) or Fusarium spp. including Fusarium solani. 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

VOTRIENT (S)

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 advanced/metastatic RCC. Soft tissue sarcoma: Diagnosis of advanced soft tissue sarcoma.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

VUMERITY (S)

Products Affected

• Vumerity

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.
Required Medical Information	MS (initial): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).

WELIREG (S)

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	12 months
Other Criteria	Approve for continuation of prior therapy.

XALKORI (S)

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 advanced or metastatic NSCLC AND One of the following: A) Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) or B) Patient has MET amplification- or ROS1 rearrangement-positive tumor as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Anaplastic Large Cell Lymphoma (ALCL): Diagnosis of systemic ALCL. Disease is relapsed or refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Inflammatory Myofibroblastic Tumor (IMT): Diagnosis of IMT. Disease is one of the following: a) unresectable, b) recurrent, or c) refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Inflammatory Myofibroblastic Tumor (IMT): Diagnosis of JMT. Disease is one of the following: a) unresectable, b) recurrent, or c) refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	IMT: Patient is 1 year of age or older.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

XCOPRI (S)

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	12 months
Other Criteria	Approve for continuation of prior therapy.

Products Affected

• Xeljanz Xr

• Xeljanz

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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. 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 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, adalimumab, etanercept). 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, adalimumab). Not used in combination with other Janus kinase (JAK) inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine).
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.

Coverage Duration	RA/PJIA/PsA/AS (initial): 6 mo, (reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo.
Other Criteria	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, adalimumab, etanercept). RA, PsA, AS, PJIA (Initial): Not used in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (eg, azathioprine, cyclosporine). RA, PJIA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. RA, PsA, AS, PJIA (reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). UC (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level])

XENAZINE (S)

Products Affected

• Tetrabenazine

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 (HD) (Initial): Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia (Initial): 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 (Initial) Patient has tics associated with Tourette's syndrome. Trial and failure, contraindication, or intolerance to Haldol (haloperidol).
Age Restrictions	N/A
Prescriber Restrictions	HD (Initial): Prescribed by or in consultation with a neurologist. Tardive dyskinesia, Tourette's syndrome (Initial): Prescribed by or in consultation with neurologist or psychiatrist.
Coverage Duration	All uses: (initial) 3 months. (Reauth) 12 months.
Other Criteria	All indications (Reauth): Documentation of clinical response and benefit from therapy.

XERMELO (S)

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 [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) 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: 12 months
Other Criteria	Carcinoid syndrome diarrhea (Reauthorization): Documentation of a positive clinical response to therapy AND drug will continue to be used in combination with SSA therapy.

XGEVA (S)

Products Affected

• Xgeva

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Myeloma (MM)/Bone metastasis from solid tumors (BMST): One of the following: 1) Both of the following: a) Diagnosis of multiple myeloma and b) Trial and failure, contraindication (e.g., renal insufficiency), or intolerance to one bisphosphonate therapy, OR 2) Both of the following: a) Diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) and b) Documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Both of the following: 1) Diagnosis of giant cell tumor of bone AND 2) One of the following: a) tumor is unresectable, OR b) surgical resection is likely to result in severe morbidity. Hypercalcemia of malignancy (HCM): Both of the following: 1) Diagnosis of hypercalcemia of malignancy, AND 2) Trial and failure, contraindication, or intolerance to one bisphosphonate therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	MM/BMST, GCTB: 12 mo. HCM: 2 mo.
Other Criteria	GCTB: Approve for continuation of prior therapy.

XIFAXAN (S)

Products Affected

• Xifaxan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Travelers' diarrhea (TD) (200 mg strength only): Diagnosis of travelers' diarrhea, AND one of the following: a) Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR b) resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin). Prophylaxis of hepatic encephalopathy (HE) recurrence (550mg strength only): Used for the prophylaxis of hepatic encephalopathy recurrence, AND trial and failure, contraindication or intolerance to lactulose. Treatment of HE: Used for the treatment of HE. Trial and failure, contraindication, or intolerance to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (550mg strength only) (initial): Diagnosis of IBS-D, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	TD: 14 days. HE (prophylaxis, treatment): 12 months. IBS-D (initial, reauth): 2 weeks.
Other Criteria	IBS-D (reauth): Patient experiences IBS-D symptom recurrence.

XOLAIR (S)

Products Affected

• Xolair

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Asthma (init): Diagnosis of moderate to severe persistent allergic asthma. Positive skin test or in vitro reactivity to a perennial aeroallergen. Pretreatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL for patients 12 years of age and older OR 30 to 1300 IU/mL for patients 6 years to less than 12 years of age. 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: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) 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)]. Chronic Spontaneous Urticaria (CSU) (init): Diagnosis of CSU. Persistent symptoms (itching and hives) with a second generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines. Patient has tried and had an inadequate response or intolerance or contraindication to at least one of the following additional therapies: H2 antagonist (e.g., famotidine, cimetidine), leukotriene receptor antagonist (e.g., fautidia, cimetidine), leukotriene receptor antagonist (e.g., fautidia, cimetidine), leukotriene receptor antagonist (e.g., fautidia, cimetidine), leukotriene receptor antagonist (e.g., functidine, cimetidine), leukotriene receptor anta
Age Restrictions	N/A

Prescriber Restrictions	Asthma (init/reauth): Prescribed by or in consultation with an allergist/immunologist, or pulmonologist. CSU (init): Prescribed by or in consultation with an allergist/immunologist, or dermatologist. CRSwNP (init/reauth): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist.
Coverage Duration	Asthma, init: 6 mo, reauth: 12 mo. CSU, init: 3 mo, reauth: 6 mo. CRSwNP, init/reauth: 12 mo.
Other Criteria	Asthma (reauth): Documentation of positive clinical response to therapy (e.g., Reduction in asthma exacerbations, improvement in forced expiratory volume in 1 second (FEV1), decreased use of rescue medications). 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 (reauth): Patient's disease status has been re- evaluated since the last authorization to confirm the patient's condition warrants continued treatment. Patient has experienced one or both of the following: Reduction in itching severity from baseline or Reduction in the number of hives from baseline. CRSwNP (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS: 0-8 scale], improvement in nasal congestion/obstruction score [NCS: 0-3 scale]). Used in combination with another agent for chronic rhinosinusitis with nasal polyps.

XOSPATA (S)

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). Disease is relapsed or refractory. Patient has a FMS-like tyrosine kinase (FLT3) mutation as determined by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

XPOVIO (S)

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), Diffuse large B-cell lymphoma (DLBCL): Diagnosis of one of the following: 1) DLBCL OR 2) Multiple Myeloma.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

XTANDI (S)

Products Affected

• Xtandi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Castration-resistant or castration-recurrent prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or recurrent prostate cancer. Castration-sensitive prostate cancer (CSPC): Diagnosis of castration-sensitive prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

XYREM (S)

Products Affected

• Sodium Oxybate

PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of Medical narcolepsy as confirmed by sleep study (unless the prescriber provides Information 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 one of the following: 1) amphetamine-based stimulant (eg. amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant. N/A **Age Restrictions** Prescriber All uses (initial): Prescribed by or in consultation with one of the Restrictions following: neurologist, psychiatrist, or sleep medicine specialist. Coverage All uses (initial): 6 months. All uses (reauth): 12 months Duration 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.

• Xyrem

Products Affected

• Yuflyma 1-pen Kit

PA Criteria **Criteria Details** Indications All Medically-accepted Indications. **Off-Label Uses** N/A Exclusion N/A Criteria Required Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely Medical active RA. Minimum duration of a 3-month trial and failure, Information 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 TF/C/I 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. PsO (Initial): Diagnosis 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. Ankylosing Spondylitis (AS) (Initial): Diagnosis 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): Diagnosis 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. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. **Age Restrictions** N/A

Yuflyma 2-syringe Kit

Prescriber Restrictions	RA, AS, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.
Coverage Duration	UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo.

Other Criteria	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, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline. OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by inprovement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Document
	following: improvement in intestinal inflammation (eg, mucosal healing,

ZAVESCA (S)

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.
Age Restrictions	Gaucher disease: Patient is 18 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	Gaucher disease: 12 months
Other Criteria	N/A

ZEJULA (S)

Products Affected

• Zejula

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

ZELBORAF (S)

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 melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (eg, cobas 4600 BRAFV600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 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	12 months
Other Criteria	All indications: Approve for continuation of therapy.

ZEPOSIA (S)

Products Affected

• Zeposia

- Zeposia 7-day Starter Pack
- Zeposia Starter Kit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy. Ulcerative Colitis (UC) (init): 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: a) Trial and failure, contraindication, or intolerance to two of the following: Humira (adalimumab)/Cyltezo/or Yuflyma, Stelara (ustekinumab), Rinvoq (upadacitinib), or Xeljanz IR (tofacitinib IR)/Xeljanz XR (tofacitinib XR), OR b) for continuation of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist. UC (init): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	MS (initial, reauth): 12 months. UC (init): 12 weeks, (reauth): 12 months.

Other Criteria	MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). UC (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level])
	from baseline OR reversal of high fecal output state.

ZOKINVY (S)

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 ² and above.
Age Restrictions	Patient is 12 months of age or older.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

ZOLINZA (S)

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. Progressive, persistent or recurrent disease on or contraindication or intolerance to two systemic therapies (e.g., bexarotene, romidepsin, etc.).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

ZORBTIVE (S)

Products Affected

• Zorbtive

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

ZTALMY (S)

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	12 months
Other Criteria	Approve for continuation of prior therapy.

ZYDELIG (S)

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. Used in combination with Rituxan (rituximab). The patient has relapsed on at least one prior therapy (eg, purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab]). Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (eg, coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD]).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

ZYKADIA (S)

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	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC that is metastatic or recurrent. Tumor is anaplastic lymphoma kinase (ALK)- positive as detected by a U.S. Food and Drug Administration (FDA)- approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

ZYTIGA (PREFERRED) (S)

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	Castration-Resistant Prostate Cancer (CRPC): Diagnosis of castration- resistant (chemical or surgical) or recurrent prostate cancer. Castration- Sensitive Prostate Cancer (CSPC): Diagnosis of castration-sensitive prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CRPC, CSPC: 12 months
Other Criteria	Approve for continuation of prior therapy

PART B VERSUS PART D

Products Affected

- Abelcet
- Acetylcysteine SOLN
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Ambisome
- Amphotericin B INJ
- Amphotericin B Liposome
- Aprepitant CAPS
- Arformoterol Tartrate
- Astagraf XL
- Azathioprine TABS
- Budesonide SUSP
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix E 2.75%/dextrose 5% INJ 570MG/100ML; 316MG/100ML; 33MG/100ML; 5GM/100ML; 515MG/100ML; 132MG/100ML; 165MG/100ML; 201MG/100ML; 159MG/100ML; 51MG/100ML; 154MG/100ML; 454MG/100ML; 187MG/100ML; 161MG/100ML; 116MG/100ML; 50MG/100ML; 11MG/100ML; 160MG/100ML
- Clinimix E 4.25%/dextrose 10%
- Clinimix E 4.25%/dextrose 5%
- Clinimix E 5%/dextrose 15%
- Clinimix E 5%/dextrose 20%
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclophosphamide TABS
- Cyclosporine CAPS
- Cyclosporine Modified
- Emend SUSR

- Engerix-b
- Envarsus Xr
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Formoterol Fumarate NEBU
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hydrochloride TABS
- Heplisav-b
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/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
- Pentamidine Isethionate INHALATION
 SOLR
- Plenamine INJ 147.4MEQ/L;
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 1.04GM/100ML; 894MG/100ML;
 592MG/100ML; 749MG/100ML;
 250MG/100ML; 39MG/100ML;
 960MG/100ML
- 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
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- Prosol
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- Recombivax Hb
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- Sirolimus TABS
- Tacrolimus CAPS
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- 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; 34MG/100ML; 152MG/100ML
- Trimethobenzamide Hydrochloride
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Details

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

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