

## **ACTEMRA SC**

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### **MEDICATION(S)**

ACTEMRA, ACTEMRA ACTPEN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Patient has had T/F, CI to Enbrel (etanercept) AND Humira (adalimumab), OR for continuation of prior Actemra therapy. Patient is not receiving Actemra in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Actemra in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

RA (Initial): Prescribed by or in consultation with a rheumatologist.

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

RA (Reauth): Documentation of positive clinical response to Actemra therapy. Patient is not receiving Actemra in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Actemra in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

## **ACTIMMUNE**

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### **MEDICATION(S)**

ACTIMMUNE

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **ADAGEN**

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### **MEDICATION(S)**

ADAGEN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Excluded if patient has severe thrombocytopenia

### **REQUIRED MEDICAL INFORMATION**

Adenosine deaminase (ADA) deficiency: Diagnosis of ADA deficiency in a patient with severe combined immunodeficiency disease (SCID) AND patient is not a suitable candidate for, or who has failed, bone marrow transplantation, hematopoietic stem cell transplant, or gene therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **ADAKVEO**

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### **MEDICATION(S)**

ADAKVEO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

To reduce the frequency of vasoocclusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease (SCD). Patient has the diagnosis of sickle cell disease, identified by any genotype (e.g. HbSS, HbSC, HbS/beta0-thalassemia, or HbS/beta pos/neg minus thalassemia). Patient has had an insufficient response to a minimum 3-month trial of hydroxyurea (unless contraindicated or intolerant) AND patient has experienced one or more vaso-occlusive crises (VOC) within the past 12 months.

### **AGE RESTRICTION**

Patient must be 16 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **ADAPALENE**

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### **MEDICATION(S)**

ADAPALENE 0.1% CREAM, ADAPALENE 0.1% GEL, ADAPALENE 0.1% SOLUTION, ADAPALENE 0.3% GEL, ADAPALENE 0.3% GEL PUMP

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of acne.

### **AGE RESTRICTION**

PA applies to members 26 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **ADCIRCA**

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### **MEDICATION(S)**

ALYQ, TADALAFIL 20MG (GENERIC ADCIRCA)

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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.

## **ADDERALL XR**

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### **MEDICATION(S)**

DEXTROAMPHETAMINE-AMPHET ER

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

### **AGE RESTRICTION**

PA applies to members 19 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **ADEMPAS**

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### **MEDICATION(S)**

ADEMPAS

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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**

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### **MEDICATION(S)**

AFINITOR 10 MG TABLET, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET

### **PA INDICATION INDICATOR**

3 - 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 but patient is not a candidate for curative surgical resection. Renal cell carcinoma: Diagnosis of advanced or metastatic 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 AND Patient does not require immediate surgery. Breast Cancer: Patient is a postmenopausal woman AND Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole) AND AFINITOR (EVEROLIMUS) will be used in combination with AROMASIN (exemestane). 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All Indications: Prescribed by or in consultation with an oncologist and or a neurologist.

### **COVERAGE DURATION**

All Indications: 12 months

**OTHER CRITERIA**

All Indications: Approve for continuation of prior therapy

## **AFINITOR DISPERZ**

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### **MEDICATION(S)**

AFINITOR DISPERZ

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Subependymal Giant Cell Astrocytoma (SEGA): Diagnosis of SEGA associated with tuberous sclerosis complex (TSC) that requires therapeutic intervention but patient is not a candidate for curative surgical resection.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist OR a neurologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **AJOVY**

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### **MEDICATION(S)**

AJOVY AUTOINJECTOR, AJOVY SYRINGE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For migraine PROPHYLAXIS to be approved if: Patient has had at least 4 migraine days per month or one or more severe migraines lasting for greater than 12 hours AND there is documentation of T/F, CI to at least one agent in any two of the following classes below : (a)antidepressants: amitriptyline, venlafaxine or (b) beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol or (c) calcium channel blocker: verapamil or (d) antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin or (e) Botox (for chronic migraine) AND to either EMGALITY or AIMOVIG.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist, headache specialist or pain specialist.

### **COVERAGE DURATION**

Initial: 6 mths Reauth: 12 mths if patient has had positive response to tx

### **OTHER CRITERIA**

N/A

## **ALDURAZYME**

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### **MEDICATION(S)**

ALDURAZYME

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Mucopolysaccharidosis I: confirmed diagnosis of Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I), OR confirmed diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I) who have moderate to severe symptoms.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **ALECENSA**

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### **MEDICATION(S)**

ALECENSA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Confirmed diagnosis of anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **ALPHA-1 PROTEINASE INHIBITOR, NON-PREFERRED**

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### **MEDICATION(S)**

ARALAST NP, GLASSIA, ZEMAIRA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Alpha1-proteinase inhibitor deficiency for the long-term augmentation and maintenance therapy in adults with severe hereditary??deficiency of alpha1-antitrypsin??(AAT) with clinically evident??emphysema AND Patient has had trial and failure or intolerance to Prolastin-C.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **ALPHA-1 PROTEINASE INHIBITOR, PROLASTIN**

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### **MEDICATION(S)**

PROLASTIN C

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Alpha1-proteinase inhibitor deficiency for the long-term augmentation and maintenance therapy in adults with severe hereditary deficiency of alpha1-antitrypsin (AAT) with clinically evident emphysema.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A



## **ALUNBRIG**

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### **MEDICATION(S)**

ALUNBRIG

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **AMPYRA**

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### **MEDICATION(S)**

DALFAMPRIDINE ER

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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 DALFAMPRIDINE ER 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).

## **ANADROL-50**

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### **MEDICATION(S)**

ANADROL-50

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Anemia (initial): Diagnosis of anemia caused by deficient red cell production AND trial and failure or intolerance to standard therapies for anemia that include any 2 drugs from any of the 2 following classes: erythropoiesis-stimulating agents and immunosuppressants (eg., Aranesp, Procrit, Retacrit, cyclosporine, ATGAM) AND Treatment will not replace other supportive measures (e.g., transfusion, correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, antibacterial therapy, corticosteroids).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial and reauth: 12 months

### **OTHER CRITERIA**

Anemia (reauth): patient has experienced an objective improvement in anemia (e.g., increased hemoglobin, increased reticulocyte count, reduction/elimination for need of blood transfusions)

## **APOKYN**

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### **MEDICATION(S)**

APOKYN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

PD (Initial, reauth): Patient is using Apokyn with any 5-HT3 antagonist (eg, ondansetron, granisetron, dolasetron, palonosetron, alosetron)

### **REQUIRED MEDICAL INFORMATION**

Parkinson's disease (PD) (Initial): Diagnosis of advanced PD. Patient is experiencing acute intermittent hypomobility (defined as off episodes characterized by muscle stiffness, slow movements, or difficulty starting movements). Patient is receiving Apokyn in combination with other medications for the treatment of PD (e.g., carbidopa/levodopa, pramipexole, ropinirole, benztropine, etc.).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

PD (Initial, reauth): 12 months

### **OTHER CRITERIA**

PD (Reauth): Patient is benefiting from therapy (eg, patient had an improvement in motor function).

## **ARANESP**

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### **MEDICATION(S)**

ARANESP 10 MCG/0.4 ML SYRINGE, ARANESP 100 MCG/0.5 ML SYRINGE, ARANESP 100 MCG/ML VIAL, ARANESP 150 MCG/0.3 ML SYRINGE, ARANESP 200 MCG/0.4 ML SYRINGE, ARANESP 200 MCG/ML VIAL, ARANESP 25 MCG/0.42 ML SYRING, ARANESP 25 MCG/ML VIAL, ARANESP 300 MCG/0.6 ML SYRINGE, ARANESP 300 MCG/ML VIAL, ARANESP 40 MCG/0.4 ML SYRINGE, ARANESP 40 MCG/ML VIAL, ARANESP 500 MCG/1 ML SYRINGE, ARANESP 60 MCG/0.3 ML SYRINGE, ARANESP 60 MCG/ML VIAL

### **PA INDICATION INDICATOR**

3 - 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 concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS. CKD (init, reauth), Chemo (init), MDS (init): Verify iron evaluation for adequate iron stores.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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. Most recent or average (avg) Hct over 3 mo is 33% or less OR most recent or avg Hgb over 3 months is 11 g/dL or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more 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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. 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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Off-label uses (except MDS): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.

## **ARCALYST**

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### **MEDICATION(S)**

ARCALYST

### **PA INDICATION INDICATOR**

3 - 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.

### **AGE RESTRICTION**

CAPS (Initial): 12 years of age or older

### **PRESCRIBER RESTRICTION**

CAPS (Initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist.

### **COVERAGE DURATION**

CAPS (initial, reauth): 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.

## **ARIKAYCE**

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### **MEDICATION(S)**

ARIKAYCE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patients with non-refractory MAC lung disease.

### **REQUIRED MEDICAL INFORMATION**

Treatment of Mycobacterium avium complex (MAC) lung disease in adults who have not achieved negative sputum cultures after treatment with a multidrug regimen that includes: 1) azithromycin or clarithromycin and 2) ethambutol and 3) rifampin or rifabutin.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Subject to Part B vs. Part D review



## **ARZERRA**

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### **MEDICATION(S)**

ARZERRA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of one of the following: 1. chronic lymphocytic leukemia (CLL) (previously untreated) AND in combination with chlorambucil when fludarabine-based therapy is considered inappropriate. 2. relapsed CLL AND in combination with fludarabine and cyclophosphamide. 3. CLL refractory to fludarabine and alemtuzumab 4. recurrent or progressive CLL for extended treatment when the patient has had complete or partial response after at least 2 lines of therapy.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist oncologist

### **COVERAGE DURATION**

Initial and Reauth: 6 mths

### **OTHER CRITERIA**

N/A

## **AUBAGIO**

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### **MEDICATION(S)**

AUBAGIO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Multiple Sclerosis (MS): Diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease with evidence of new brain lesions.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **AURYXIA**

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### **MEDICATION(S)**

AURYXIA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Treatment of iron deficiency anemia in patients with CKD not on dialysis

### **REQUIRED MEDICAL INFORMATION**

Patient must have a diagnosis of Hyperphosphatemia: For the control of serum phosphorus levels in patients with chronic kidney disease (CKD) receiving dialysis. This drug is excluded from Medical Part D Coverage when used for the treatment of iron deficiency anemia.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a Nephrologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **AUSTEDO**

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### **MEDICATION(S)**

AUSTEDO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For the treatment of chorea associated with Huntington disease AND the patient has tried and failed tetrabenazine. For the treatment of tardive dyskinesia (TD) AND If TD is related to drug use, and if appropriate for this patient, the causative drug must be discontinued or tried at a lower dose AND Baseline evaluation of TD using one of the following: Abnormal Involuntary Movement Scale (AIMS) greater than or equal to 10 or Clinical Global Impression of Severity (CGI-S) score greater than or equal to 4.

### **AGE RESTRICTION**

Must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

Initial: 3 mths. Reauth: 6 months

### **OTHER CRITERIA**

Reauth Criteria: Patients therapy has been re-evaluated within the last 3mths AND patient is tolerating treatment AND patient has disease stabilization or improvement in disease.

# AVASTIN

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## MEDICATION(S)

AVASTIN, ZIRABEV

## PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 months

## OTHER CRITERIA

Avastin may be approved for Diabetic macular edema, Established neovascular wet AMD, Macular edema from branch retinal vein occlusion, Macular edema from central retinal vein occlusion, Neovascular glaucoma, Pseudoxanthoma elasticum, radiation retinopathy, Retinopathy of prematurity, diabetic retinopathy with or w/o diabetic macular edema, or Other rare causes of choroidal neovascularization for one or more of the following conditions: angioid streaks or choroiditis (including, but not limited to histoplasmosis induced choroiditis) or degenerative myopia, idiopathic or retinal dystrophies or trauma. For metastatic Colon, Rectal, or small bowel adenocarcinoma, Bevacizumab is used in combination with 5FU based chemotherapy irinotecan or oxaliplatin and has not progressed on more than 2 lines of bevacizumab containing regimen. For NSCLC, Bevacizumab is being used in combination with both platinum based therapies with a taxane or pemetrexed with ECOG status of 0-1 with no hx of hemoptysis for the first-line treatment of patients with unresectable, locally advanced,

recurrent or metastatic nonsquamous NSCLC. Maintenance therapy for NSCLC is approved when Bevacizumab was prev used as a first-line combination regimen AND used as a single agent AND can be used until disease progression. For Metastatic Breast Carcinoma, HER2 negative disease, Bevacizumab is being used as first-line therapy in combination with paclitaxel or paclitaxel protein bound. For Metastatic Clear Cell Renal Carcinoma, Bevacizumab is being used as first-line therapy in combination with interferon or as a single agent for relapsed or medically unresectable stage IV disease with predominant clear cell histology in individuals who have progressed on prior cytokine therapy. For primary central nervous system tumors who have failed radiation therapy, bevacizumab will be used in a single line of therapy AND tumor to be treated is a WHO Grade III/IV glioma (includes but is not limited to): Anaplastic astrocytoma, Progressive or recurrent ependymoma that has failed radiation therapy, Anaplastic glioma, High-grade glioma, Recurrent, Glioblastoma, OR Glioblastoma multiforme. For recurrent, metastatic epithelial ovarian cancer, fallopian tube cancer, or recurrent primary peritoneal cancer, bevacizumab will be used in a single line of therapy AND used for relapsed or refractory disease and used as a single agent or in combination with other chemotherapy. For malignant mesothelioma, in combination with cisplatin or carboplatin and pemetrexed and ECOG status of 0-2 with no history of bleeding or thrombosis. For maintenance therapy, Bevacizumab was previously administered as an agent in a first-line combination chemotherapy regimen and used as a single agent until disease progression. For all uses except for ophthalmic use (e.g. diabetic macular edema, established neovascular wet AMD), patient must have tried and failed biosimilar ZIRABEV (Bevacizumab-bvzr).

## **AYVAKIT**

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### **MEDICATION(S)**

AYVAKIT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of one of the following: 1. unresectable or metastatic gastrointestinal stromal tumor harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. 2. advanced systemic mastocytosis (AdvSM), including aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, and mast cell leukemia.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist, allergist or immunologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **BELEODAQ**

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### **MEDICATION(S)**

BELEODAQ

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Peripheral T-cell lymphoma (PTCL): Diagnosis of PTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (e.g., conventional chemotherapy).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist/oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.



## **BENLYSTA**

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### **MEDICATION(S)**

BENLYSTA

### **PA INDICATION INDICATOR**

3 - 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), CellCept (mycophenolate mofetil)]).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

SLE (init): Prescribed by or in consultation with a rheumatologist

### **COVERAGE DURATION**

SLE (init, reauth): 6 months

### **OTHER CRITERIA**

SLE (reauth): Documentation of positive clinical response to Benlysta therapy

## **BEOVU**

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### **MEDICATION(S)**

BEOVU

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patient must not have an active ocular or periocular infection.

### **REQUIRED MEDICAL INFORMATION**

Patient must have a Diagnosis of Neovascular (wet) age-related macular degeneration and has tried and failed or had an intolerance to Avastin.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an Ophthalmologist.

### **COVERAGE DURATION**

N/A

### **OTHER CRITERIA**

12 months

## **BERINERT**

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### **MEDICATION(S)**

BERINERT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Firazyr, Kalbitor, or Ruconest).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

HAE: Prescribed by an immunologist, allergist, or rheumatologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **BLNREP**

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### **MEDICATION(S)**

BLNREP

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Dx of relapsed or refractory multiple myeloma (MM). Patient has received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist/oncologist.

### **COVERAGE DURATION**

Initial and Reauth: 6 months.

### **OTHER CRITERIA**

N/A

## **BOSULIF**

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### **MEDICATION(S)**

BOSULIF

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Confirmed diagnosis of newly-diagnosed chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) or treatment of chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy with one of the following tyrosine kinase inhibitors (TKI): Gleevec [imatinib], Tasigna [nilotinib], Sprycel [dasatinib] AND Patient has received mutation testing AND does not have the T315I or V299L mutation OR B) Ph+ CML with intolerance to prior therapy with one of the following tyrosine kinase inhibitors (TKI): Gleevec [imatinib], Tasigna [nilotinib], Sprycel [dasatinib]

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist or hematologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

# **BOTOX**

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## **MEDICATION(S)**

BOTOX

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Neuromuscular Disorders (init): Strabismus, blepharospasm associated with dystonia (eg, benign essential blepharospasm), treatment of upper or lower limb spasticity, VII cranial nerve disorders (hemifacial spasms), cervical dystonia Hyperhidrosis(HH): (Init) Dx of primary axillary HH. Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) or skin maceration with secondary infection. Trial and failure, contraindication, or intolerance (TF/C/I) to topical prescription strength drying agents [eg, Drysol, Hypercare, Xerac AC (aluminum chloride hexahydrate)]. Migraine:(Init) Dx of chronic migraines (greater than or equal to 15 migraine headache days per month with headache lasting 4 hours a day or longer). TF/C/I to prophylactic therapy with at least two of the following agents, each given for a trial of at least two months: antidepressants [ie, Effexor (venlafaxine)], antiepileptics [ie, Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [eg, atenolol, Inderal (propranolol), nadolol, timolol, Toprol XL (metoprolol)] Achalasia:(Init) High risk of complication from or failure to pneumatic dilation or myotomy, or prior dilation caused esophageal perforation, or patient has an epiphrenic diverticulum or hiatal hernia. Anal Fissure (AF)(Init): Dx of chronic AF. At least 2 months of either nocturnal pain and bleeding or postdefecation pain. Chronic Back Pain (CBP):(Init) Dx of low back pain lasting greater than or equal to six months. Urinary incontinence (UI):(init) Neurogenic detrusor overactivity associated with a neurologic condition (eg, spinal cord injury [SCI], multiple sclerosis) or detrusor sphincter dyssynergia with SCI. Overactive bladder (OAB): (init) Dx of OAB. One of the following symptoms: urge urinary incontinence, urgency, frequency.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Migraine (Initial): Prescribed by a neurologist or pain specialist. CBP (Initial): Prescribed by a neurologist, neurosurgeon, orthopedist, or pain specialist. UI, OAB (initial): Prescribed by a neurologist, neurosurgeon, or urologist.

## **COVERAGE DURATION**

Achalasia: 6moCBP:1 tx(series of injxs)UI:3mo(1 dose,200units)Other:3mo

## **OTHER CRITERIA**

UI, OAB, CBP, Neuromuscular Disorders:(Reauth) Confirmed improvement in symptoms with initial Botox treatment. At least 3 months have or will have elapsed since the last treatment with Botox  
HH:(Reauth) At least a 2-point improvement in HDSS. Migraine:(Reauth) Reduction in headache frequency or intensity. Confirmation of decreased utilization of pain medications (eg, narcotic analgesics, NSAIDs) or triptans, or a reduction in the number of ER visits. Achalasia:(Reauth) Documentation of improvement or reduction in symptoms of achalasia (ie, dysphagia, regurgitation, chest pain). At least 6 months have or will have elapsed since last series of injections AF: (Reauth) Incomplete healing of fissure or recurrence of fissure. Improved symptoms with prior treatment with Botox.

## **BRAFTOVI**

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### **MEDICATION(S)**

BRAFTOVI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Encorafenib is not indicated for treatment of wild-type BRAF melanoma.

### **REQUIRED MEDICAL INFORMATION**

In combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test OR In combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial 6 months. Reauth 12 months

### **OTHER CRITERIA**

N/A



## **BREYANZI**

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### **MEDICATION(S)**

BREYANZI, BREYANZI CD4 COMPONENT, BREYANZI CD8 COMPONENT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has relapsed or refractory (R/R) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma) high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

### **AGE RESTRICTION**

Patient is 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist oncologist

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

N/A

## **BRONCHITOL**

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### **MEDICATION(S)**

BRONCHITOL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has a diagnosis of Cystic Fibrosis AND will be used as add-on maintenance to improve pulmonary function AND patient has passed the Bronchitol Tolerance Test (BTT).

### **AGE RESTRICTION**

Patient is 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a pulmonologist.

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

N/A

## **BRUKINSA**

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### **MEDICATION(S)**

BRUKINSA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For the treatment of mantle cell lymphoma in adults who have received at least 1 prior therapy AND patient has NOT received any prior treatment with a BTK inhibitor (e.g. ibrutinib (Imbruvica), acalabrutinib (Calquence)) AND zanubrutinib will be used as monotherapy.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial 6 months, Reauth 6 months.

### **OTHER CRITERIA**

For Reauth, patient must continue to meet the above criteria AND must demonstrate disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread.

## **CABLIVI**

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### **MEDICATION(S)**

CABLIVI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Treatment of acquired thrombotic thrombocytopenic purpura (aTTP) in adults, in combination with plasma exchange and immunosuppressive therapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **CABOMETYX**

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### **MEDICATION(S)**

CABOMETYX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1)Renal cell carcinoma (RCC): Diagnosis of RCC. RCC is advanced. Trial and failure, contraindication, or intolerance to at least one prior anti-angiogenic therapy [e.g., Nexavar (sorafenib), Sutent (sunitinib)]. 2)Treatment of hepatocellular carcinoma (HCC) in patients who have previously been treated with Nexavar (sorafenib).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **CAPRELSA**

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### **MEDICATION(S)**

CAPRELSA

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with oncologist or endocrinologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **CAYSTON**

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### **MEDICATION(S)**

CAYSTON

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

CF (Initial): 7 years of age or older

### **PRESCRIBER RESTRICTION**

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**

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### **MEDICATION(S)**

CERDELGA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Gaucher disease (Initial): 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 RESTRICTION**

Gaucher disease (initial): 18 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Gaucher disease (initial, reauth): 12 months

### **OTHER CRITERIA**

Gaucher disease (Reauth): Patient condition has not progressed, as defined by ALL of the following: A) Hemoglobin level decreased greater than 1.5 g/dL from baseline, AND B) Platelet count decreased greater than 25% from baseline, AND C) Spleen volume increased greater than 25% from baseline, AND D) Liver volume increased greater than 20% from baseline.



## **CEREZYME**

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### **MEDICATION(S)**

CEREZYME

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Gaucher disease: Diagnosis of type 1 Gaucher disease. Patient has evidence of symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Gaucher disease: 12 months

### **OTHER CRITERIA**

N/A

## **CGRP RECEPTOR ANTAGONISTS FOR MIGRAINE PROPHYLAXIS**

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### **MEDICATION(S)**

AIMOVIG AUTOINJECTOR, AIMOVIG AUTOINJECTOR (2 PACK), EMGALITY PEN, EMGALITY SYRINGE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For migraine PROPHYLAXIS to be approved if: Patient must have at least 4 migraine days per month or one or more severe migraines lasting for greater than 12 hours despite use of abortive therapy (e.g. triptan or NSAIDs) AND there is documentation of trial and failure, intolerance, contraindication, or inability (i.e., drug interaction, allergy, adverse reaction, etc.) to at least one agent in any two of the following classes below for at least 4 weeks EACH: (a) antidepressants: amitriptyline, venlafaxine or (b) beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol or (c) calcium channel blocker: verapamil or (d) antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin or (e) Botox (for chronic migraine).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist, headache specialist or pain specialist.

### **COVERAGE DURATION**

Initial: 6 mths Reauth 12mths: positive response to tx (reduction in h/a frequency/intensity).

### **OTHER CRITERIA**

N/A

## **CHOLBAM**

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### **MEDICATION(S)**

CHOLBAM

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of peroxisomal disorder, 2) patient exhibits at least one of the following: a) liver disease (eg, jaundice, elevated serum transaminases), OR b) steatorrhea, OR c) complications from decreased fat-soluble vitamin absorption (eg, poor growth), AND 3) Cholbam will be used as an adjunctive treatment.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All uses (initial): Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.

### **COVERAGE DURATION**

All uses (initial, reauth): 12 months

### **OTHER CRITERIA**

All uses (reauth): documentation of positive clinical response to Cholbam therapy

## **CHORIONIC GONADOTROPIN**

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### **MEDICATION(S)**

CHORIONIC GONAD 10,000 UNIT VL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Prepubertal Cryptorchidism: Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction. Male Hypogonadotropic Hypogonadism (MHH) (initial): Diagnosis of male hypogonadism secondary to pituitary deficiency, and low testosterone (below normal reference value provided by the physician's laboratory) and one of the following: a) low LH (below normal reference value provided by the physician's laboratory) or b) low FSH (below normal reference value provided by the physician's laboratory).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Prepubertal Cryptorchidism: 6 wks. MHH (initial, reauth): 12 months.

### **OTHER CRITERIA**

Excluded if used to promote fertility. MHH (Reauth): Documentation of positive clinical response to therapy.

## **CIMZIA**

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### **MEDICATION(S)**

CIMZIA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Must not be used in combination with other TNF antagonists, non-TNF immunomodulatory drugs: abatacept, anakinra, natalizumab, tofacitinib or rituximab.

### **REQUIRED MEDICAL INFORMATION**

For moderate to severe Crohn's Disease, patient has had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (e.g. 5-ASA products, systemic corticosteroids, or immunosuppressants) AND patient has TF/C/I to Humira (adalimumab). For moderate to severe Rheumatoid Arthritis, patient has had TF/C/I to Humira (adalimumab) AND Enbrel (etanercept). For moderate to severe Psoriatic Arthritis, patient has had TF/C/I to Humira (adalimumab) AND Enbrel (etanercept). For moderate to severe Ankylosing Spondylitis (AS), patient has had TF/C/I to Humira (adalimumab) AND Enbrel (etanercept). For plaque psoriasis patient has had TF/C/I to 1. Humira (adalimumab) OR Enbrel (etanercept) AND 2. Cosentyx (secukinumab). For non-radiographic axial spondyloarthritis, patient has had an inadequate response to, or has a contraindication to conventional therapy [such as NSAID or nonbiologic such as sulfasalazine] OR for continuation of prior CIMZIA (certolizumab) therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a rheumatologist, dermatologist or gastroenterologist.

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

N/A

## **CINRYZE**

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### **MEDICATION(S)**

CINRYZE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis: Hereditary Angioedema, for the routine prophylaxis against angioedema attacks.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

HAE (prophylaxis, treatment): Prescribed by an immunologist, allergist, or rheumatologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **CLOVIQUE**

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### **MEDICATION(S)**

CLOVIQUE, TRIENTINE HCL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Not recommended in cystinuria or rheumatoid arthritis, not indicated for biliary cirrhosis

### **REQUIRED MEDICAL INFORMATION**

Treatment of patients with Wilson disease who are intolerant of penicillamine.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial 6 months Reauth 12 months

### **OTHER CRITERIA**

N/A



## COMETRIQ

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### MEDICATION(S)

COMETRIQ

### PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

Medullary thyroid cancer (MTC): Diagnosis of Metastatic MTC. Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC and positive for RET gene rearrangements.

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

MTC: Prescribed by or in consultation with an oncologist/hematologist or endocrinologist. NSCLC: Prescribed by or in consultation with an oncologist/hematologist.

### COVERAGE DURATION

All uses: 12 months

### OTHER CRITERIA

Approve for continuation of prior therapy.

## **COPIKTRA**

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### **MEDICATION(S)**

COPIKTRA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Chronic lymphocytic leukemia/small lymphocytic lymphoma, relapsed or refractory Treatment of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in adult patients after at least two prior therapies. Follicular lymphoma, relapsed or refractory Treatment of relapsed or refractory follicular lymphoma (FL) in adult patients after at least two prior systemic therapies.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **CORLANOR**

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### **MEDICATION(S)**

CORLANOR

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

BP less than 90/50, severe hepatic impairment, a. fib.

### **REQUIRED MEDICAL INFORMATION**

Chronic heart failure (CHF): Diagnosis of CHF with NYHA Class II, III, or IV symptoms. Left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm with a resting heart rate of greater than or equal to 70 BPM and has been hospitalized for worsening HF in the previous 12 months. Trial and failure, intolerance, or contraindication to maximally tolerated doses of at least one beta-blocker with proven mortality benefit (i.e., carvedilol, bisoprolol, sustained-release metoprolol) AND trial and failure, intolerance, or contraindication to maximally tolerated doses of an ACE inhibitor or ARB OR Treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients ages 6 months and older.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

CHF (initial): Prescribed by or in consultation with a cardiologist

### **COVERAGE DURATION**

Initial, reauth: 12 months

### **OTHER CRITERIA**

CHF (reauth): patient does not have contraindications/exclusions to therapy.

## **COSENTYX**

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### **MEDICATION(S)**

COSENTYX (2 SYRINGES), COSENTYX PEN, COSENTYX PEN (2 PENS), COSENTYX SYRINGE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Must not be used in combination with other IL17 inhibitors or biologic drugs.

### **REQUIRED MEDICAL INFORMATION**

For moderate to severe Ankylosing Spondylitis (AS), patient had an inadequate response to/intolerant of or has a medical contraindication to ONE conventional therapy [such as, NSAIDs or nonbiologic DMARDS such as sulfasalazine]. For moderate to severe plaque psoriasis (Ps), patient had an inadequate response to/intolerant of or has contraindication to other systemic therapy (such as acitretin, cyclosporine or methotrexate). For moderate to severe Psoriatic Arthritis (PsA), patient has had an inadequate response to/intolerant of or has a medical contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine or leflunomide)] OR for continuation of prior COSENTYX therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a rheumatologist or a dermatologist.

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

N/A

## **COTELLIC**

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### **MEDICATION(S)**

COTELLIC

### **PA INDICATION INDICATOR**

3 - 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 an FDA-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with vemurafenib.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **CRINONE**

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### **MEDICATION(S)**

CRINONE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

All indications: Excluded if for fertility uses.

### **REQUIRED MEDICAL INFORMATION**

Secondary amenorrhea: Diagnosis of secondary amenorrhea (the absence of menses in women who have already started menstruation who are not pregnant, breastfeeding, or in menopause).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **CYRAMZA**

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### **MEDICATION(S)**

CYRAMZA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Gastric cancer: All of the following: 1) diagnosis of one of the following: a) gastric adenocarcinoma, OR b) gastro-esophageal junction (GEJ) adenocarcinoma, AND 2) disease is one of the following: a) locally advanced, OR b) metastatic, AND 3) disease has progressed on or after one of the following first-line therapies: a) fluoropyrimidine-containing chemotherapy (eg, fluorouracil, capecitabine), OR b) platinum-containing chemotherapy (eg, cisplatin, carboplatin, oxaliplatin). Non-small cell lung cancer: All of the following: 1) diagnosis of metastatic non-small cell lung cancer, AND 2) used in combination with docetaxel, AND 3) disease has progressed on or after platinum-based chemotherapy (eg, cisplatin, carboplatin, oxaliplatin). Metastatic colorectal cancer (mCRC): 1) Diagnosis of metastatic CRC AND 2) Patient had disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **CYSTARAN**

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### **MEDICATION(S)**

CYSTARAN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Cystinosis: Diagnosis of cystinosis, confirmed by elevated leukocyte cystine levels (LCL), genetic analysis of the CTNS gene or corneal cystine crystal accumulation AND Patient is concomitantly receiving treatment with oral cysteamine

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A



## **DACOGEN**

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### **MEDICATION(S)**

DECITABINE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of myelodysplastic syndrome.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist/oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **DALIRESP**

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### **MEDICATION(S)**

DALIRESP

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Chronic Obstructive Pulmonary Disease (COPD): (Initial) Diagnosis of severe COPD. Patient has chronic bronchitis. Trial and failure, intolerance, or contraindication to two prior therapies for COPD.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

COPD (init, reauth): 12 months

### **OTHER CRITERIA**

COPD (reauth): Documentation of positive clinical response to Daliresp therapy.

## **DANYELZA**

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### **MEDICATION(S)**

DANYELZA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy AND will be in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF).

### **AGE RESTRICTION**

Must be 1 year of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist/oncologist.

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

N/A

## **DARAPRIM**

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### **MEDICATION(S)**

PYRIMETHAMINE 25 MG TABLET

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an infectious disease specialist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Toxoplasmosis only: Approve for continuation of prior therapy.



## **DARZALEX**

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### **MEDICATION(S)**

DARZALEX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Multiple Myeloma (MM): Diagnosis of MM. One of the following: A) Patient has received at least three prior treatment regimens which included both a proteasome inhibitor (eg, bortezomib [Velcade], carfilzomib [Kyprolis]) and an immunomodulatory agent (eg, lenalidomide [Revlimid], thalidomide [Thalomid]) or patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent. OR B) Patient has received at least one prior therapy. Darzalex will be used in combination with either 1) lenalidomide and dexamethasone or 2) bortezomib and dexamethasone

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist/hematologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy

## **DARZALEX FASPRO**

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### **MEDICATION(S)**

DARZALEX FASPRO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of MM. One of the following: A) in combination with bortezomib (Velcade), melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant, B) in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant, C) in patients with relapsed or refractory multiple myeloma who have received at least 1 prior therapy, D) in combination with bortezomib and dexamethasone in patients who have received at least 1 prior therapy, E) as monotherapy, in patients who have received at least 3 prior lines of therapy including a proteasome inhibitor (PI) (eg, bortezomib [Velcade], carfilzomib [Kyprolis]) and an immunomodulatory agent (eg, lenalidomide [Revlimid], thalidomide [Thalomid]) or who are double-refractory to a PI and an immunomodulatory agent.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist/hematologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy

## **DAURISMO**

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### **MEDICATION(S)**

DAURISMO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Acute myeloid leukemia. Treatment of newly diagnosed acute myeloid leukemia (in combination with low-dose cytarabine) in adult patients who are greater than or equal to 75 years of age or who have comorbidities that preclude use of intensive induction chemotherapy.

### **AGE RESTRICTION**

Age greater than or equal to 75 years or has comorbidities that preclude use of intensive induction chemotherapy

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A



## **DEFERASIROX**

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### **MEDICATION(S)**

DEFERASIROX 125 MG TB FOR SUSP, DEFERASIROX 180 MG TABLET, DEFERASIROX 250 MG TB FOR SUSP, DEFERASIROX 360 MG TABLET, DEFERASIROX 500 MG TB FOR SUSP, DEFERASIROX 90 MG TABLET

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older

### **PRESCRIBER RESTRICTION**

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.

## **DEXMETHYLPHENIDATE**

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### **MEDICATION(S)**

DEXMETHYLPHENIDATE HCL, DEXMETHYLPHENIDATE ER 10 MG CP, DEXMETHYLPHENIDATE ER 15 MG CP, DEXMETHYLPHENIDATE ER 20 MG CP, DEXMETHYLPHENIDATE ER 25 MG CP, DEXMETHYLPHENIDATE ER 30 MG CP, DEXMETHYLPHENIDATE ER 35 MG CP, DEXMETHYLPHENIDATE ER 40 MG CP

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

### **AGE RESTRICTION**

PA applies to members 19 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **DEXTROAMPHETAMINE**

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### **MEDICATION(S)**

DEXTROAMPHETAMINE 10 MG TAB, DEXTROAMPHETAMINE 5 MG TAB,  
DEXTROAMPHETAMINE 5 MG/5 ML, DEXTROAMPHETAMINE SULFATE ER

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

### **AGE RESTRICTION**

PA applies to members 19 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **DIACOMIT**

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### **MEDICATION(S)**

DIACOMIT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For the adjunctive treatment of refractory generalized tonic-clonic seizures AND to be used in conjunction with clobazam in patients with Dravet syndrome (previously known as severe myoclonic epilepsy in infancy).

### **AGE RESTRICTION**

Patient must be 2 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by a neurologist or epileptologist.

### **COVERAGE DURATION**

Initial and Reauth: 6 months.

### **OTHER CRITERIA**

N/A

## **DICLOFENAC 3% GEL**

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### **MEDICATION(S)**

DICLOFENAC SODIUM 3% GEL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Dx of Actinic Keratosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **DISPOSABLE EXTERNAL INSULIN PUMP**

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### **MEDICATION(S)**

OMNIPOD, OMNIPOD DASH 5 PACK POD, V-GO 20, V-GO 30, V-GO 40, VGO 20, VGO 30, VGO 40

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Patient must be diagnosed with Type I or Type II Diabetes AND 2. Documentation is submitted stating that patient has utilized one of the following insulin administration methods for at least the last 6 months (a or b): a. Use of an insulin pump OR b. Multiple daily insulin injections (meets i and ii): i. administration of at least 3 injections per day AND ii. History of suboptimal blood sugar control despite appropriate management: one of the following (a-f): a) Repeated hypoglycemic events (BG less than 70 mg/dL) b) Repeated episodes of diabetic ketoacidosis c) Wide fluctuations in blood glucose before mealtime (e.g., pre-prandial blood glucose levels commonly exceed 140 mg/dL d) Hypoglycemia unawareness e) Glycosylated hemoglobin level (HbA1c) greater than or equal to 7.0 f) "Dawn phenomenon" with fasting blood sugars repeatedly greater than 200 g/dL AND 3. Patient has monitored blood glucose at least 4 times a day for at least the last 2 months.

### **AGE RESTRICTION**

Patient age is within the manufacturer recommendations for the requested indication for the requested product.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an endocrinologist.

### **COVERAGE DURATION**

Initial and Reauth 6 months

### **OTHER CRITERIA**

Reauth: Documentation of satisfactory patient response (including current HbA1C).





## **DOJOLVI**

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### **MEDICATION(S)**

DOJOLVI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patient is NOT taking a pancreatic lipase inhibitor (e.g. orlistat) AND Patient will NOT receive an additional medium chain triglyceride while taking triheptanoin.

### **REQUIRED MEDICAL INFORMATION**

Dx of a long-chain fatty acid oxidation disorder (LC-FAOD) confirmed by the following: 1 or more definitive pathogenic mutations in any LC-FAOD gene OR TWO of the following: 1 or more non-definitive pathogenic mutations in any LC-FAOD gene OR Low enzyme activity in cultured fibroblasts OR Disease specific elevations of acylcarnitines on a newborn blood spot or in plasma AND Patient must have severe LC-FAOD confirmed by a history of 1 or more of the following despite therapy: Chronic elevated creatine kinase ([CK] 2 or more times the upper limit of normal) with 2 or more major clinical events (e.g., hospitalizations, hypoglycemia, cardiomyopathy, and rhabdomyolysis) OR Episodic elevated CK with reported muscle dysfunction (e.g., frequent muscle fatigue, exercise intolerance, limitation of exercise OR Highly elevated CK (4 or more times the upper limit of normal) OR Frequent (3 or more within a year or 5 or more within 2 years) severe major clinical events (e.g., hospitalizations, hypoglycemia, cardiomyopathy, and rhabdomyolysis) OR Severe susceptibility to hypoglycemia after short periods of fasting (2 or more events within a year that require ongoing prophylactic management or recurrent symptomatic hypoglycemia requiring intervention 2 or more times per week) OR Evidence of functional cardiomyopathy (echocardiogram documenting poor ejection fraction).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., medical geneticist, genetic metabolic disorders, or a physician with a board

certification in nutrition.

**COVERAGE DURATION**

Initial 6 mths. Reauth 6 mths. -improvement of sx's and reduction in events (e.g. hospitaliz).

**OTHER CRITERIA**

N/A

## **DOPTELET**

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### **MEDICATION(S)**

DOPTELET

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient must have the following: Thrombocytopenia AND ONE of the following: 1. Chronic liver disease AND undergoing a scheduled medical or dental procedure within the next 30 days 2. Chronic immune thrombocytopenia AND patient has had an inadequate response to a previous treatment AND Baseline platelet count less than 50,000 platelets/mcL (50 x 10<sup>9</sup> platelets/L).

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial and Re-Auth: 6 months

### **OTHER CRITERIA**

N/A

## **DOXEPIN, TOPICAL**

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### **MEDICATION(S)**

DOXEPIN 5% CREAM

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patients with untreated narrow angle glaucoma or a tendency to urinary retention

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Pruritis: Short-term (up to 8 days) management of moderate pruritus in adults with atopic dermatitis or lichen simplex chronicus. Medication history includes the use of at least 2 topical corticosteroids, unless contraindicated or clinically significant adverse effects are experienced.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a dermatologist and or allergist.

### **COVERAGE DURATION**

30 days

### **OTHER CRITERIA**

N/A

## **DUOBRII**

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### **MEDICATION(S)**

DUOBRII

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Plaque Psoriasis. Patient has tried and failed or had contraindications to at least two of the following topical medications: halobetasol, tazarotene, calcipotriene, calcipotriene-betamethasone.

### **AGE RESTRICTION**

Patient must be 18 years of age or greater.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a dermatologist or rheumatologist.

### **COVERAGE DURATION**

Initial Auth: 6 months

### **OTHER CRITERIA**

Reauth: Documentation of positive clinical response to therapy. 12 months.

## **DUPIXENT**

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### **MEDICATION(S)**

DUPIXENT PEN, DUPIXENT 200 MG/1.14 ML SYRING, DUPIXENT 300 MG/2 ML SYRINGE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Asthma: Add-on maintenance treatment of moderate to severe asthma in adults and pediatric patients equal to or greater than 12 years of age with an eosinophilic phenotype or with corticosteroid dependent asthma. Limitations of use: Not indicated for the relief of acute bronchospasm or status asthmaticus. Atopic dermatitis: Treatment of moderate to severe atopic dermatitis in adults and pediatric patients equal to or greater than 6 years of age whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Rhinosinusitis (chronic) with nasal polyposis: Add-on maintenance treatment in adults with inadequately controlled chronic rhinosinusitis with nasal polyposis.

### **AGE RESTRICTION**

Atopic Dermatitis: Patient must be 6 years of age and older. Asthma: Patient must be 12 years of age and older. Chronic rhinosinusitis with nasal polyposis: Patient must be 18 years of age and older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **DURYSTA**

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### **MEDICATION(S)**

DURYSTA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For the reduction of Intraocular Pressure (IOP) in Patients with Open-Angle Glaucoma or Ocular Hypertension: patient meets ALL of the following criteria (A, B, and C): The patient is not receiving re-treatment of eye(s) previously treated with Durysta; AND The patient meets the following criteria (i and ii): i) The patient has tried at least two ophthalmic prostaglandins (either as monotherapy or as concomitant therapy) for the treatment of open-angle glaucoma or ocular hypertension. (e.g. bimatoprost 0.03% ophthalmic solution, latanoprost 0.005% ophthalmic solution, travoprost 0.004% ophthalmic solution; Lumigan® (bimatoprost 0.01% ophthalmic solution) AND ii) The patient has tried at least two ophthalmic products (either as monotherapy or as concomitant therapy) from two different pharmacological classes for the treatment of open-angle glaucoma or ocular hypertension (e.g. beta-blockers, alpha-agonist (brimonidine), carbonic anhydrase inhibitors) AND D) For each of the ophthalmic medications that were tried, the patient meets ONE of the following criteria (i or ii): i). The patient has had inadequate efficacy to the previously-tried ophthalmic products, according to the prescriber; OR ii). The patient has experienced adverse event(s) severe enough to warrant discontinuation of the previously-tried ophthalmic products, according to the prescriber.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1-time use/eye (QL 1 implant/eye, lifetime total of QL 2 implants/pt). Duration 12 months QL #2/12

mths.

**OTHER CRITERIA**

Reauth: only for tx of the other eye QL #1 for 12 months.



## **EGRIFTA**

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### **MEDICATION(S)**

EGRIFTA, EGRIFTA SV

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

HIV-associated lipodystrophy (initial): All of the following: 1) diagnosis of HIV-associated lipodystrophy, 2) one of the following: a) waist-circumference of greater than or equal to 95 cm (37.4 inches) in men, OR b) waist-circumference of greater than or equal to 94 cm (37 inches) for women, 3) one of the following: a) Waist-to-hip ratio of greater than or equal to 0.94 for men, OR b) waist-to-hip ratio of greater than or equal to 0.88 for women, 4) body mass index (BMI) greater than 20 kg/m<sup>2</sup>, AND 5) fasting blood glucose (FBG) levels less than or equal to 150 mg/dL (8.33 mmol/L), AND 6) patient has been on a stable regimen of antiretrovirals (eg, NRTIs, NNRTI, Protease Inhibitors, Integrase Inhibitors) for at least 8 weeks.

### **AGE RESTRICTION**

(Initial): 18 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

(initial, reauth): 6 months

### **OTHER CRITERIA**

(reauth): documentation of clinical improvement (eg, improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance, etc) while on Egrifta therapy.

## **ELAPRASE**

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### **MEDICATION(S)**

ELAPRASE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Hunter Syndrome (Mucopolysaccharidosis II (MPS II))

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **ELIGARD**

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### **MEDICATION(S)**

ELIGARD

### **PA INDICATION INDICATOR**

3 - 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 Lupron Depot (7.5 mg, 22.5 mg, 30 mg, and 45 mg).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **EMPLICITI**

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### **MEDICATION(S)**

EMPLICITI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Multiple myeloma: Diagnosis of multiple myeloma. Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist/oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **ENBREL**

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### **MEDICATION(S)**

ENBREL, ENBREL MINI, ENBREL SURECLICK

### **PA INDICATION INDICATOR**

3 - 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. Failure, contraindication, or intolerance to one disease-modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Trial and failure, contraindication, or intolerance to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Trial and failure, contraindication, or intolerance to two NSAIDs. All indications (Initial, reauth): Patient is not receiving Enbrel in combination with a biologic DMARD [eg, Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]. Patient is not receiving Enbrel in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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 indications: Initial: 6 months, Reauth: 12 months

**OTHER CRITERIA**

All indications (Reauth): Documentation of positive clinical response to Enbrel therapy.

## **ENHERTU**

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### **MEDICATION(S)**

ENHERTU

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Pregnancy

### **REQUIRED MEDICAL INFORMATION**

Adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an Oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **EPCLUSA (SOFOSBUVIR-VELPATASVIR)**

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### **MEDICATION(S)**

SOFOBUVIR-VELPATASVIR

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND patient has received baseline evaluation for liver fibrosis to guide appropriate therapy AND patient does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016).

### **AGE RESTRICTION**

Patient must be at least 6 years of age or older or weigh at least 17 kg or more.

### **PRESCRIBER RESTRICTION**

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 guidance.

### **OTHER CRITERIA**

N/A



## **EPIDIOLEX**

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### **MEDICATION(S)**

EPIDIOLEX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS) or tuberous sclerosis complex in patients equal to or greater than 1 year of age. Patient has failed or has developed intolerable side effects to conventional treatment. Conventional treatment includes medications from the following Anticonvulsant Therapeutic Classes: Calcium Channel Modifying Agents, Gamma-aminobutyric Acid (GABA) Augmenting Agents, Glutamate Reducing Agents, Sodium Channel Agents, Anticonvulsants, Other. Dravet syndrome -patient is taking at least 1 concomitant antiepileptic medication AND The patient is refractory on current therapy (i.e. patient has experienced a convulsive seizure [i.e. tonic, atonic, tonic clonic] in the past 28 days). Lennox Gastaut Syndrome - patient has an EEG which has shown a pattern of slow (greater than 2.5 Hz) spike and wave complexes AND The member is taking at least 1 concomitant antiepileptic medication AND The member is refractory on current therapy (e.g. has experienced a drop seizure in the past 28 days, i.e. tonic, atonic, tonic clonic, that led to or could have led to a fall or injury)

### **AGE RESTRICTION**

Patient must be 1 year of age or older.

### **PRESCRIBER RESTRICTION**

Prescribed by a neurologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **EPOETIN ALFA**

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### **MEDICATION(S)**

PROCRIT, RETACRIT

### **PA INDICATION INDICATOR**

3 - 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 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 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 concurrently on chemo, or will receive concomitant chemo for a minimum of 2 mos, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. 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 or peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 30% or Hgb 12 g/dL or less) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa. Anemia in Myelodysplastic Sx (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.

### **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo. MDS:(init) 3mo,(reauth)12mo.  
Preop:1mo.

## **OTHER CRITERIA**

Subject to ESRD review. CKD (Reauth): Dx of CKD. Most recent or average (avg) Hct over 3 months is 33% or less OR most recent or avg Hgb over 3 months is 11 g/dL or less (12g/dL or less for pediatric patients). Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. 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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. HCV (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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. 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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Off-label uses (except MDS): 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. All Uses: PROCRIT Brand will be approved after T/F with biosimilar Retacrit (epoetin alfa-epbx).

# **ERBITUX**

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## **MEDICATION(S)**

ERBITUX 100 MG/50 ML VIAL

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Head and Neck Cancer: Diagnosis of locally or regionally advanced squamous cell head and neck cancer and used in combination with radiation therapy, or diagnosis of recurrent or metastatic squamous cell head and neck cancer and 1 of the following: trial and failure of platinum-based chemotherapy, or used in combination with 1 of the following: cisplatin (Platinol AQ), carboplatin (Paraplatin), cisplatin (Platinol AQ) plus 5-FU (Acrucil), or carboplatin (Paraplatin) plus 5-FU (Acrucil). Colorectal Cancer: Diagnosis of metastatic carcinoma of the colon or rectum. One of the following: Used in combination with either FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan), OR trial and failure or intolerance to irinotecan-based chemotherapy, oxaliplatin-based chemotherapy, or intensive therapy (eg, FOLFOX or FOLFIRI), OR used as monotherapy in patients not appropriate for intensive therapy. Tumor expresses wild-type KRAS gene and wild type NRAS gene. Non-Small Cell Lung Cancer (NSCLC): Diagnosis of recurrent or metastatic NSCLC stage IIIB or IV. One of the following: Used in combination with vinorelbine (Navelbine) and cisplatin (Platinol AQ), OR used as a single-agent for continuation maintenance therapy and Erbitux was given first-line with chemotherapy. ECOG performance status 0-2. Epidermal growth factor receptor (EGFR) expression by immunohistochemistry.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

## **COVERAGE DURATION**

12 months.

**OTHER CRITERIA**

Approve for continuation of prior therapy.

## **ERIVEDGE**

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### **MEDICATION(S)**

ERIVEDGE

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

18 years of age or older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist or dermatologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **ESBRIET**

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### **MEDICATION(S)**

ESBRIET

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Idiopathic pulmonary fibrosis (IPF) (initial): Both of the following: 1) 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

IPF (initial): Prescribed by a pulmonologist

### **COVERAGE DURATION**

initial, reauth: 12 months

### **OTHER CRITERIA**

IPF (reauth): Documentation of positive clinical response to Esbriet therapy



## **EVKEEZA**

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### **MEDICATION(S)**

EVKEEZA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patient does NOT have heterozygous familial hypercholesterolemia

### **REQUIRED MEDICAL INFORMATION**

Patient has 1.) a confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) by any of the following: a) Documented DNA test for functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality OR b) Untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than or equal to 300 mg/dL AND Cutaneous or tendon xanthoma before age 10 years OR untreated LDL-C levels in both parents consistent with HeFH AND 2.) Baseline LDL-C, Total Cholesterol, non-HDL, and apoB labs from within the last 3 months is provided AND 3.) Patient has been receiving stable background lipid lowering therapy for 4 weeks or greater AND 4.) therapy will be used in conjunction with other LDL-lowering therapies AND 5.) Patient has tried and failed at least a 3-month trial of adherent therapy with: combination therapy consisting of the highest available or maximally tolerated dose of atorvastatin OR rosuvastatin, ezetimibe, AND a PCSK9 inhibitor indicated for HoFH (e.g., evolocumab (Repatha)), unless contraindicated AND Despite pharmacological treatment with a PCSK9 inhibitor, statin, and ezetimibe, the patient's LDL-C is greater than or equal to 100 mg/dL (or greater than or equal to 70 mg/dL for patients with ASCVD).

### **AGE RESTRICTION**

Patient is 12 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a cardiologist or a lipid specialist.

### **COVERAGE DURATION**

Initial 3 months and Reauth 6 months.

**OTHER CRITERIA**

N/A

## **EXONDYS 51**

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### **MEDICATION(S)**

EXONDYS-51

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Initial: Diagnosis of Duchenne muscular dystrophy (DMD). Documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping. Patient is ambulatory. Initial/Reauth: Exondys 51 dosing for DMD is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 30 mg/kg infused once weekly.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

(initial, reauth): Prescribed by or in consultation with a neurologist who has experience treating children

### **COVERAGE DURATION**

Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

Reauth: One of the following: 1) All of the following: Patient has been on therapy for less than 12 months, patient is maintaining ambulatory status, and patient is tolerating therapy, OR 2) All of the following: Patient has been on therapy for 12 months or more, Patient is maintaining ambulatory status, patient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients), and patient is tolerating therapy.

## **EYLEA**

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### **MEDICATION(S)**

EYLEA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patient must not have an active ocular or periocular infection.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Diabetic Macular Edema (DME) and has tried and failed or had an intolerance to Avastin OR Diagnosis of Macular Degeneration- Neovascular (wet) age-related macular degeneration and has tried and failed or had an intolerance to Avastin OR Diagnosis of diabetic retinopathy OR Diagnosis of Macular Edema following retinal vein occlusion (RVO).

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by, or in consultation with, an ophthalmologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **FABRAZYME**

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### **MEDICATION(S)**

FABRAZYME 35 MG VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Fabry Disease: Diagnosis of Fabry disease.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Fabry Disease: 12 months

### **OTHER CRITERIA**

N/A

## **FARYDAK**

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### **MEDICATION(S)**

FARYDAK

### **PA INDICATION INDICATOR**

3 - 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 both of the following: Velcade (bortezomib) and dexamethasone. Patient has received at least two prior treatment regimens which included both of the following: Velcade (bortezomib) and an immunomodulatory agent [eg, Revlimid (lenalidomide), Thalomid (thalidomide)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist/hematologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **FENTANYL**

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### **MEDICATION(S)**

FENTANYL CIT OTFC 1,200 MCG, FENTANYL CITRATE OTFC 200 MCG, FENTANYL CITRATE OTFC 600 MCG, FENTANYL CITRATE OTFC 800 MCG

### **PA INDICATION INDICATOR**

3 - 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 mcg per hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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**

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### **MEDICATION(S)**

DEFERIPRONE, FERRIPROX 1,000 MG TABLET, FERRIPROX 100 MG/ML SOLUTION, FERRIPROX (2 TIMES A DAY), FERRIPROX (3 TIMES A DAY)

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Transfusional iron overload due to thalassemia syndromes (Initial): Patient has a diagnosis of transfusional iron overload due to thalassemia syndromes. Absolute neutrophil count (ANC) greater than  $1.5 \times 10^9/L$ . One of the following: A) Patient has failed prior chelation therapy (e.g., Exjade) [failure defined as serum ferritin greater than 2,500 mcg/L] OR B) Patient has a contraindication or intolerance to Desferal (deferioxamine) or Exjade (deferasirox).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

All uses (initial, reauth): 12 months

### **OTHER CRITERIA**

All uses (reauth): Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline. ANC greater than  $0.5 \times 10^9/L$ .



## **FINTEPLA**

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### **MEDICATION(S)**

FINTEPLA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis: Patient has been diagnosed with Dravet syndrome (DS). Fenfluramine (Fintepla) will be added to background antiepileptic therapy. Patient has refractory epilepsy (patient has failed to become seizure-free with adequate trials of antiepileptic drugs [AEDs] that have included at least one of the following drugs: stiripentol or Epidiolex).

### **AGE RESTRICTION**

Patient must be 2 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by a pediatric neurologist, pediatric epileptologist, neurologist or epileptologist.

### **COVERAGE DURATION**

Initial: 6 mths Reauth 6 mths-documented response to tx (dec seizures/stabilization from baseline).

### **OTHER CRITERIA**

N/A

## **FIRAZYR**

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### **MEDICATION(S)**

ICATIBANT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Kalbitor, or Ruconest).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

HAE: Prescribed by an immunologist, allergist, or rheumatologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **FIRDAPSE**

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### **MEDICATION(S)**

FIRDAPSE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Treatment of Lambert-Eaton myasthenic syndrome (LEMS). Patient's diagnosis has been confirmed by either neurophysiology studies OR positive anti-P/Q type voltage-gated calcium channel (VGCC) antibody testing. Patient has been treated with initial pharmacotherapy for LEMS with agents that decrease the action of acetylcholinesterase (i.e. pyridostigmine). Treatment of an associated cancer (if applicable) may also decrease the weakness and other symptoms. If those treatments were not effective, and the patient has relatively mild weakness, aggressive immunotherapy, plasma exchange (PEX) or high-dose IVIG has been tried and failed. Immunosuppressants may include prednisone, azathioprine, and cyclosporine.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **FIRMAGON**

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### **MEDICATION(S)**

FIRMAGON

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of advanced or metastatic prostate cancer.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **FLECTOR PATCH**

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### **MEDICATION(S)**

DICLOFENAC EPOLAMINE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of acute mild pain or moderate pain due to minor strains, sprains, and contusions (initial auth): (Reauthorization): Documentation of clinical benefit from ongoing therapy with generic Flector Patch (diclofenac epolamine topical).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 months

### **OTHER CRITERIA**

N/A

## **FOLOTYN**

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### **MEDICATION(S)**

FOLOTYN 40 MG/2 ML VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Peripheral T-cell lymphoma: Diagnosis of relapsed or refractory PTCL

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **FORTEO**

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### **MEDICATION(S)**

TERIPARATIDE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patient must not use Forteo (teriparatide) in combination with any of the following: Prolia (denosumab), Bisphosphonates, Evista (raloxifene), Miacalcin/Fortical (calcitonin nasal spray), Recalst (zoledronic acid), or Tymlos (abaloparatide).

### **REQUIRED MEDICAL INFORMATION**

Dx: Osteoporosis defined as a BMD T-Score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 OR a Clinical diagnosis based on a history of a low trauma fracture (fragility fracture) at high risk for fracture OR associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5mg or greater of prednisone for at least 3 months) at high risk for fracture. Patient meets one of the following: (A) Patient has been refractory to a trial of an oral bisphosphonate therapy OR (B) Intolerance or contraindications to oral bisphosphonate as defined by having at least one of the following: 1. Hypersensitivity to TWO oral bisphosphonates (one of which must be alendronate) 2. Inability to sit or stand upright for at least 30 minutes, 3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.). 4. Uncorrected hypocalcemia. 5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate. Treatment duration has not exceeded a total of 24 months during the patient's lifetime.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 12 months with one reauth only for a total of 2 years of lifetime treatment.

**OTHER CRITERIA**

N/A



## **FOTIVDA**

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### **MEDICATION(S)**

FOTIVDA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has a diagnosis of renal cell carcinoma (RCC) AND Patient has relapsed or refractory advanced disease with clear cell histology AND Patient has progressed after 2 or more prior systemic therapies. Tivozanib will be used as a single agent.

### **AGE RESTRICTION**

Patient is 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

Reauth: Patient has disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

## **GALAFOLD**

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### **MEDICATION(S)**

GALAFOLD

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Galactosidase alpha gene (GLA) variant based on in vitro assay data.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **GAMASTAN S/D**

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### **MEDICATION(S)**

GAMASTAN S-D

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).

### **REQUIRED MEDICAL INFORMATION**

Immune globulin is being used intramuscularly. The immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Patient requires immunization for hepatitis A, measles, rubella, or varicella.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 months (Approve one dose only)

### **OTHER CRITERIA**

Subject to Part B vs D review.

## **GATTEX**

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### **MEDICATION(S)**

GATTEX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Short Bowel Syndrome (SBS) (Initial) Diagnosis of SBS. Patient is dependent on parenteral nutrition/intravenous (PN/IV) support.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

SBS (Init): 6 months. SBS (Reauth): 12 months.

### **OTHER CRITERIA**

SBS (Reauth): Documentation of positive clinical response to Gattex therapy.

## **GAVRETO**

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### **MEDICATION(S)**

GAVRETO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis: Metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test AND being used as a single agent. Advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy. Advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

### **AGE RESTRICTION**

Patient must be 12 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial: 6 mths Reauth 6 mths

### **OTHER CRITERIA**

Reauth: Patient has experienced disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread.

## **GILENYA**

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### **MEDICATION(S)**

GILENYA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Multiple Sclerosis (MS): Diagnosis of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease with evidence of new brain lesions.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **GILOTRIF**

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### **MEDICATION(S)**

GILOTRIF

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Confirmed diagnosis of 1) First-line treatment of metastatic non-small cell lung cancer (NSCLC) whose tumor has nonresistant epidermal growth factor receptor (EGFR) mutations as detected by a Food and Drug Administration-approved test. OR 2) Treatment of previously treated metastatic squamous cell NSCLC that has progressed following platinum-based chemotherapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **GIVLAARI**

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### **MEDICATION(S)**

GIVLAARI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patient has NOT had or is anticipating a liver transplant and patient will not use in combination with prophylactic IV hemin therapy.

### **REQUIRED MEDICAL INFORMATION**

Patient has a diagnosis of acute hepatic porphyria (AHP), including acute intermittent porphyria, variegate porphyria, hereditary coproporphyria, or ALA dehydratase deficient porphyria, as evidenced by one of the following: patient has had elevated urinary or plasma PBG and ALA levels within the previous year OR patient has a mutation in an affected gene as identified on molecular genetic testing AND Patient has a history of 2 or more documented porphyria attacks (i.e., requirement of hospitalization, urgent healthcare visit, or IV administration of hemin) OR 1 severe attack with central nervous system involvement (e.g., hallucinations, seizures, etc.) during the previous 6 months.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist and/or hepatologist.

### **COVERAGE DURATION**

Initial 6 months, Reauth 12 months

### **OTHER CRITERIA**

For reauth, Patient must continue to meet the above criteria, AND patient must demonstrate disease response as evidenced by a decrease in the frequency of acute porphyria attacks, and/or hospitalizations/urgent care visits, and/or a decrease requirement of hemin IV infusions, AND patient has a reduction/normalization of biochemical markers (e.g., ALA, PBG) compared to baseline.





## **GLATIRAMER ACETATE**

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### **MEDICATION(S)**

GLATIRAMER ACETATE, GLATOPA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, clinically-isolated syndrome, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses, active secondary progressive disease).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **GLEEVEC**

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### **MEDICATION(S)**

IMATINIB MESYLATE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For adults 18 years of age or older, One of the following: A) Diagnosis of Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) AND Patient is found to be Ph+ or BCR-ABL positive as detected by bone marrow cytogenetics, FISH or PCR OR B) Ph+ acute lymphoblastic leukemia (ALL) OR C) Gastrointestinal stromal tumor (GIST) AND one of the following: 1) Patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST, OR 2) Patient had resection of c-KIT (CD117) positive GIST and imatinib will be used as adjuvant therapy 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 associated with platelet-derived growth factor receptor gene rearrangements OR G) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown. For Pediatric patients younger than 18 years of age, One of the following: A) Diagnosis of Ph+ CML that is newly diagnosed in the chronic phase OR B) Diagnosis of newly diagnosed Ph+ALL.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All uses: Prescribed by or in consultation with an oncologist or hematologist

### **COVERAGE DURATION**

All uses: 12 months

**OTHER CRITERIA**

All uses: Approve for continuation of prior therapy.

## **GOCOVRI (AMANTADINE ER CAPSULES)**

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### **MEDICATION(S)**

GOCOVRI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has a diagnosis of Parkinson Disease and is being treated for dyskinesia AND patient is currently receiving levodopa-based therapy (e.g., carbidopa/levodopa), AND patient has tried and failed or was intolerant to immediate-release amantadine capsules, tablets, or oral solution AND OSMOLEX ER tablets (amantadine ER tablets).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

Initial Auth: 12 mths Reauth: Documentation submitted with positive clinical response: 12 mths

### **OTHER CRITERIA**

N/A

## **GRANIX**

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### **MEDICATION(S)**

GRANIX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) patient receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm<sup>3</sup>), AND 2) patients with a history of FN during a previous course of chemotherapy. All indications: History of failure or intolerance to Zarxio (filgrastim-sndz).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All uses: Prescribed by or in consultation with a hematologist/oncologist or infectious disease specialist

### **COVERAGE DURATION**

CFN, secondary prophylaxis of FN: 3mo or duration of tx

### **OTHER CRITERIA**

N/A

## **GRASTEK**

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### **MEDICATION(S)**

GRASTEK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Drug is being used as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis. Clinical notes submitted provide confirmation that diagnosis has been confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. Drug will not be used for the immediate relief of allergy symptoms. First dose will be administered in a healthcare setting with supervision by professional experienced in treatment of allergic diseases and will be monitored for signs or symptoms of severe systemic or severe local allergic reaction for at least 30 minutes. Patient has a history of failure, contraindication, or intolerance to at least two drugs from any of the following drug classes: intranasal antihistamine, intranasal corticosteroid, leukotriene inhibitor, oral antihistamine. Patient has been prescribed auto-injectable epinephrine.

### **AGE RESTRICTION**

Patient must be at least 5 years of age or older and at most 65 years of age or younger.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a professional experienced in the treatment of allergic diseases (Allergist or Immunologist).

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

N/A





## **GROWTH HORMONE**

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### **MEDICATION(S)**

GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPOR, NUTROPIN AQ NUSPIN, OMNITROPE 10 MG/1.5 ML CRTG, OMNITROPE 5 MG/1.5 ML CRTG, SAIZEN, SAIZEN-SAIZENPREP

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

PGHD(initial):less than 4mo w/GD,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)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass),or ht incr at least 2cm/yr over previous yr of tx (doc by previous ht and date and current ht and date) 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, doc grwth velocity less than 25th percentile for bone age. 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):ht incr of at least 2 cm/yr over previous yr of tx (doc by previous ht and date and current ht and date) and expctd adult ht not attained and doc of expctd adult ht goal.

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist.

GFCRI: prescribed by endocrinologist or nephrologist

**COVERAGE DURATION**

All indications (initial, reauth): 12 months

**OTHER CRITERIA**

All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin. 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], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrozole,letrozole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon

at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

## **H.P. ACTHAR GEL**

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### **MEDICATION(S)**

ACTHAR

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Infantile Spasm (West Syndrome): Diagnosis of infantile spasms (West Syndrome). Multiple Sclerosis (MS): Acute exacerbations of MS. Rheumatic disorders: As adjunctive therapy for short-term administration in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis. Collagen diseases: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis). Dermatologic diseases: Severe erythema multiforme, Stevens-Johnson syndrome. Allergic states: Serum sickness. Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as: keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation. Respiratory diseases: Symptomatic sarcoidosis. 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. All indications except for infantile spasms: Trial and failure, contraindication, or intolerance to treatment with two corticosteroids.

### **AGE RESTRICTION**

Infantile spasms: less than 2 years old

### **PRESCRIBER RESTRICTION**

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**

N/A

## **HALAVEN**

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### **MEDICATION(S)**

HALAVEN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Breast Cancer: Diagnosis of recurrent or metastatic breast cancer. Previous treatment with both of the following: one anthracycline [eg, doxorubicin, Ellence (epirubicin)] and one taxane [eg, paclitaxel, Taxotere (docetaxel)]. Liposarcoma: Diagnosis of unresectable or metastatic liposarcoma. Previous treatment with one anthracycline-containing regimen.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All Uses: prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **HARVONI (LEDIPASVIR-SOFOSBUVIR)**

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### **MEDICATION(S)**

LEDIPASVIR-SOFOSBUVIR

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation is provided for a diagnosis of chronic Hepatitis C virus (CHC) infection, which includes Genotype and a positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016).

### **AGE RESTRICTION**

Patient must be 3 years of age or older.

### **PRESCRIBER RESTRICTION**

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 guidance.

### **OTHER CRITERIA**

N/A

## **HERCEPTIN**

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### **MEDICATION(S)**

HERCEPTIN, HERCEPTIN HYLECTA, KANJINTI 150 MG VIAL, OGIVRI 150 MG VIAL, TRAZIMERA 420 MG VIAL

### **PA INDICATION INDICATOR**

3 - 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)-overexpressing breast cancer. One of the following treatment regimens: a) As adjuvant treatment, b) metastatic disease and one of the following: 1) used in combination with a taxane (eg, docetaxel, paclitaxel), or 2) used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease, or c) used in combination with Perjeta (pertuzumab). Gastric Cancer: Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic). Used in combination with one of the following treatment regimens: a) Aduvex (5-fluorouracil), or b) Platinol (cisplatin) and Xeloda (capecitabine)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All uses: Prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy. All Uses: Herceptin Brand will be approved after T/F with dose comparables of biosimilars Kanjinti (Trastuzumab-anns) , Ogivri (Trastuzumab-dkst) and Trazimera (Trastuzumab-qyyp).





## **HETLIOZ**

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### **MEDICATION(S)**

HETLIOZ

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Non-24-Hour Sleep-Wake Disorder (Non-24) (initial): Diagnosis of non-24-hour sleep-wake disorder AND Dx is confirmed by meeting one of the following conditions: i. Assessment of a least one physiologic circadian phase marker (e.g. measurement of urinary melatonin levels, dim light melatonin onset, as measured in blood or saliva), assessment of core body temperature OR ii. If assessment of at least on physiologic circadian phase marker cannot be done, the dx must be confirmed by actigraphy performed for one week or greater plus evaluation of sleep logs recorded for one month or greater AND patient is totally blind (has no light perception).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Non-24 (initial): Prescribed by or in consultation with a specialist in sleep disorders or a neurologist.

### **COVERAGE DURATION**

Non-24 (initial): 6 mo. (reauth): 12 mo

### **OTHER CRITERIA**

Non-24 (reauth): Documentation of positive clinical response to HetlioZ therapy.

# **HIZENTRA**

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## **MEDICATION(S)**

HIZENTRA

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Diagnosis: Treatment of primary humoral immunodeficiency syndromes (congenital agammaglobulinemia, severe combined immunodeficiency syndromes, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome). Treatment of chronic inflammatory demyelinating polyneuropathy. Maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to prevent relapse of neuromuscular disability and impairment. All indications: Previous treatment with immunoglobulin therapy (IVIG).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

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, etc.).

## **COVERAGE DURATION**

6 months

## **OTHER CRITERIA**

Subject to Part B vs. Part D review.

## **HUMIRA**

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### **MEDICATION(S)**

HUMIRA, HUMIRA PEDIATRIC CROHN'S, HUMIRA PEN, HUMIRA PEN CROHN'S-UC-HS, HUMIRA PEN PSOR-UVEITS-ADOL HS, HUMIRA(CF), HUMIRA(CF) PEDIATRIC CROHN'S, HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PEDIATRIC UC, HUMIRA(CF) PEN PSOR-UV-ADOL HS

### **PA INDICATION INDICATOR**

3 - 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. TF/C/I to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to two NSAIDs. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall), or failure (ie, lost response) or intolerance to infliximab. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol, Pentasa, Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. All indications (initial, reauth): Patient is not receiving Humira in combination with a biologic DMARD [eg, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]. Patient is not receiving Humira in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

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 mths. All other Indications Initial: 6 mths, Reauth: 12 mths

**OTHER CRITERIA**

RA, JIA, PsA, Plaque psoriasis, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to Humira therapy. UC (Reauth): For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on Humira therapy for longer than 12 weeks: Documentation of positive clinical response to Humira therapy.

## **HYDROXYPROGESTERONE**

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### **MEDICATION(S)**

HYDROXYPROGEST 250 MG/ML VIAL, HYDROXYPROGESTERONE 1.25 G/5ML

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

All uses (initial): Pregnant patients.

### **REQUIRED MEDICAL INFORMATION**

Amenorrhea: Diagnosis of primary or secondary amenorrhea. Amenorrhea is due to hormonal imbalance in the absence of organic pathology (e.g., submucous fibroids or uterine cancer) Secretory endometrium and desquamation: Used for production of secretory endometrium and desquamation in patients with endometrial disorder. Adenocarcinoma: Diagnosis of Stage III or IV adenocarcinoma of the uterine corpus. Estrogen production test: Used for the testing of endogenous estrogen production.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Adenocarcinoma (initial): Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **IBRANCE**

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### **MEDICATION(S)**

IBRANCE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1)Breast Cancer: Diagnosis of breast cancer. Disease is a) locally advanced or metastatic, b) estrogen-receptor (ER)-positive, and c) human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) and patient is a postmenopausal woman, OR b) all of the following: used in combination with Faslodex (fulvestrant), disease has progressed following endocrine therapy, and one of the following: 1) patient is a postmenopausal woman OR 2) both of the following: patient is a premenopausal or perimenopausal woman and patient is receiving a luteinizing hormone-releasing hormone (LHRH) agonist [eg, Zoladex (goserelin)]. OR 2)men with hormone receptor-positive, human epidermal growth factor receptor 2-negative advance or metastatic breast cancer when used in combination with an aromatase inhibitor.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **ICLUSIG**

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### **MEDICATION(S)**

ICLUSIG

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Chronic myelogenous leukemia: Diagnosis of chronic myelogenous leukemia AND One of the following: A) Trial and failure, resistance, relapse, contraindication, or intolerance to at least TWO other tyrosine kinase inhibitors (i.e., Gleevec [imatinib], Sprycel, Tasigna, and Bosulif) or B) Patient has the T315I mutation. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) AND One of the following: A) Trial and failure, resistance relapse, contraindication, or intolerance to at least TWO other FDA-approved tyrosine kinase inhibitors (i.e., Gleevec [imatinib], Sprycel), or B) Patient has the T315I mutation.

### **AGE RESTRICTION**

All Uses: 18 years of age or older

### **PRESCRIBER RESTRICTION**

All Uses: Prescribed by or in consultation with an oncologist or hematologist

### **COVERAGE DURATION**

All uses: 12 months

### **OTHER CRITERIA**

All uses: Approve for continuation of prior therapy.



# ILARIS

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## MEDICATION(S)

ILARIS

## PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Periodic Fever Syndromes (Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF)). (Initial) Diagnosis of one of the autoinflammatory Periodic Fever Syndromes: CAPS (including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS)), TRAPS, HIDS/MKD, or FMF, AND The medication will not be used in combination with another biologic agent. Systemic juvenile idiopathic arthritis (sJIA) (Initial): Diagnosis of active sJIA AND The medication will not be used in combination with another biologic

## AGE RESTRICTION

SJIA (initial): 2 years of age or older

## PRESCRIBER RESTRICTION

Periodic Fever Syndromes (CAPS, TRAPS, HIDS/MKD, FMF) (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist

## COVERAGE DURATION

All indications (initial, reauth): 12 months

## OTHER CRITERIA

Periodic Fever Syndrome (CAPS, TRAPS, HIDS/MKD, FMF) ((Reauth) and SJIA (Reauth): Documentation of positive clinical response to therapy.

## **IMBRUVICA**

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### **MEDICATION(S)**

IMBRUVICA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Mantle cell lymphoma (MCL): Diagnosis of MCL AND patient has relapsed or is refractory to at least one prior therapy for the treatment of MCL. Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Waldenstrom's macroglobulinemia: Diagnosis of Waldenstroms macroglobulinemia/lymphoplasmacytic lymphoma. Small lymphocytic lymphoma (SLL): Diagnosis of SLL. Marginal zone lymphoma (MZL): Diagnosis of MZL AND patient has received at least one prior anti-CD20-based therapy for MZL [e.g., Rituxan (rituximab), Zevalin (ibritumomab), Gazyva (obinutuzumab, etc.)]. Chronic graft-versus-host disease (cGVHD) (refractory): Diagnosis of cGVHD (refractory).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All uses: Prescribed by or in consultation with an oncologist, hematologist or transplant specialist.

### **COVERAGE DURATION**

All Uses: 12 months

### **OTHER CRITERIA**

All Uses: Approve for continuation of prior therapy.

## **IMFINZI**

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### **MEDICATION(S)**

IMFINZI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Urothelial carcinoma: 1) Diagnosis of locally advanced or metastatic urothelial carcinoma AND 2) One of the following: a) Patient has experienced disease progression during or following platinum-containing chemotherapy OR b) Patient has experienced disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy

## **IMLYGIC**

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### **MEDICATION(S)**

IMLYGIC

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Treatment (local) of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery

### **AGE RESTRICTION**

Patient must be at least 6 years of age and no greater than 17 years of age.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

N/A

## **IMPAVIDO**

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### **MEDICATION(S)**

IMPAVIDO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient must have one of the following diagnoses: 1. visceral Leishmaniasis (caused by *Leishmania donovani*) AND patient has tried and failed or has a contraindication to Amphoterecin B liposomal (Ambisome), 2. cutaneous Leishmaniasis (caused by *L. braziliensis*, *L. guyanensis*, and *L. panamensis*), 3. mucosal leishmaniasis (caused by *L. braziliensis*). Patient must weigh at least 30 kg.

### **AGE RESTRICTION**

Patient is 12 years of age or older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an infectious disease specialist.

### **COVERAGE DURATION**

28 days

### **OTHER CRITERIA**

N/A

## **INBRIJA**

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### **MEDICATION(S)**

INBRIJA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has developed OFF periods due to disease progression despite optimal treatment with oral doses of carbidopa/levodopa.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **INFLECTRA**

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### **MEDICATION(S)**

INFLECTRA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Dx of moderately to severely active CD or FCD. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. Rheumatoid arthritis (RA) (initial): Diagnosis (Dx) of moderately to severely active RA. Ankylosing spondylitis (AS) (initial): Dx of active AS. Psoriatic arthritis (PsA) (initial): Dx of active PsA. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. CD, FCD (initial): Trial and failure, contraindication or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). UC (initial): TF/C/I to one of the following conventional therapies: corticosteroids, aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine/Sulfazine)], azathioprine (Imuran), 6-mercaptopurine (Purinethol). RA (initial): Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), or TF/C/I to methotrexate. AS (initial): TF/C/I to two or more NSAIDs. All indications (Initial): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

RA, AS: Prescribed or recommended by a rheumatologist. PsA: Prescribed or recommended by rheumatologist or dermatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed or recommended by a gastroenterologist. Plaque Psoriasis: Prescribed or recommended by a

dermatologist

**COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

**OTHER CRITERIA**

Reauthorization for all indications: Documentation of positive clinical response to infliximab therapy. All indications (re-auth): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].



## **INGREZZA**

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### **MEDICATION(S)**

INGREZZA, INGREZZA INITIATION PACK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Must not be taken with other VMAT2 inhibitors, such as Xenazine (tetrabenazine).

### **REQUIRED MEDICAL INFORMATION**

Initial Auth: Clinically diagnosed with tardive dyskinesia, If tardive dyskinesia is related to drug use, and if appropriate for this patient, the causative drug must be discontinued or tried at a lower dose, Failure/intolerance/contraindication to a benzodiazepine, such as clonazepam (Klonopin) or tetrabenazine (Xenazine), Baseline evaluation of TD using one of the following: Abnormal Involuntary Movement Scale (AIMS) greater than or equal to 10 or Clinical Global Impression of Severity (CGI-S) score greater than or equal to 4. Reauth: Patients therapy has been re-evaluated within the last 12 month AND Patient is tolerating treatment AND Patient has disease stabilization or improvement in disease as defined by one of the following scores: AIMS decrease from baseline by at least 2 points Clinical Global Impression of Severity (CGI-S) score less than or equal to 2.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist or psychiatrist

### **COVERAGE DURATION**

3 months, Reauth 12 months

### **OTHER CRITERIA**

N/A

## **INLYTA**

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### **MEDICATION(S)**

INLYTA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

First-line treatment (in combination with avelumab??or??pembrolizumab) of advanced renal cell carcinoma OR Treatment (as a single-agent) of advanced renal cell carcinoma after failure of 1 prior systemic therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **INQOVI**

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### **MEDICATION(S)**

INQOVI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Dx: myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following FrenchAmerican-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System (IPSS) groups

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist/hematologist.

### **COVERAGE DURATION**

Initial and Reauth: 6 months

### **OTHER CRITERIA**

N/A

## **INREBIC**

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### **MEDICATION(S)**

INREBIC

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).

### **AGE RESTRICTION**

Patient must be 18 years of age or greater.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist/oncologist.

### **COVERAGE DURATION**

Duration: 12 months

### **OTHER CRITERIA**

N/A

## **INTRON A**

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### **MEDICATION(S)**

INTRON A 10 MILLION UNITS VIAL, INTRON A 18 MILLION UNIT/3 ML, INTRON A 50 MILLION UNITS VIAL

### **PA INDICATION INDICATOR**

3 - 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: Diagnosis of chronic hepatitis C, patient without decompensated liver disease, patient has not previously been treated with interferon, and one of the following - 1) used in combination with ribavirin or 2) contraindication or intolerance to ribavirin. Metastatic renal cell carcinoma (RCC): diagnosis of metastatic RCC, used in combination with Avastin (bevacizumab). Other: diagnosis of condylomata acuminata (genital or perianal), diagnosis of hairy cell leukemia, diagnosis of AIDS-related Kaposi sarcoma, diagnosis of malignant melanoma, diagnosis of Stage III or IV follicular Non-Hodgkins Lymphoma, as maintenance therapy for the treatment of multiple myeloma.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

RCC: Prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

HepB, HepC: 48 wks. Condylomata acuminata (genital or perianal): 6 wks. Other: 12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

# **IRESSA**

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## **MEDICATION(S)**

IRESSA

## **PA INDICATION INDICATOR**

3 - 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 an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

## **COVERAGE DURATION**

12 months

## **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **ISOTRETINOIN**

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### **MEDICATION(S)**

CLARAVIS, ISOTRETINOIN, MYORISAN, ZENATANE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Acne (initial): Diagnosis of acne. Trial and failure, contraindication or intolerance to an adequate trial (at least 30 days) of at least TWO of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin)] b) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)] OR c) topical antibiotic [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Acne (Initial): Prescribed by a dermatologist

### **COVERAGE DURATION**

Acne (initial, reauth): 5 months

### **OTHER CRITERIA**

Acne (reauth): One of the following: A) After more than 2 months off therapy, persistent or recurring severe recalcitrant nodular acne is still present, OR B) the total cumulative dose is less than 150 mg/kg (will be approved up to a total of 150 mg/kg).

## **ISTODAX**

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### **MEDICATION(S)**

ROMIDEPSIN 10 MG KIT, ROMIDEPSIN 10 MG VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Patient has tried and had an inadequate response, intolerance or contraindication to at least one prior therapy (eg, retinoids, corticosteroids).  
Peripheral T-cell lymphoma (PTCL): Diagnosis of PTCL. Patient has tried and had an inadequate response, intolerance or contraindication to at least one prior therapy (eg, conventional chemotherapy such as CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone), Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin), HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone) alternating with high-dose methotrexate and cytarabine).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

CTCL, PTCL: Prescribed by or in consultation with an oncologist/hematologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.



## **ISTURISA**

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### **MEDICATION(S)**

ISTURISA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Cushing's disease AND Pituitary surgery was not curative or patient is not a candidate for surgery.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an endocrinologist.

### **COVERAGE DURATION**

6 months

### **OTHER CRITERIA**

N/A

## **IVIG**

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### **MEDICATION(S)**

BIVIGAM, FLEBOGAMMA DIF 10% VIAL, GAMMAGARD LIQUID, GAMMAGARD S-D, GAMMAKED 1 GRAM/10 ML VIAL, GAMMAKED 10 GRAM/100 ML VIAL, GAMMAKED 20 GRAM/200 ML VIAL, GAMMAKED 5 GRAM/50 ML VIAL, GAMMAPLEX 10 GRAM/200 ML VIAL, GAMMAPLEX 20 GRAM/400 ML VIAL, GAMMAPLEX 5 GRAM/100 ML VIAL, GAMUNEX-C, OCTAGAM, PANZYGA, PRIVIGEN

### **PA INDICATION INDICATOR**

3 - 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). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. Gammaplex only: Hereditary intolerance to fructose. Infants for whom sucrose or fructose tolerance has not been established.

### **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 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  $10 \times 10^9/L$ . 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/mm<sup>3</sup>. Continued in Other Criteria Section.

### **AGE RESTRICTION**

HIV (initial): patient is less than or equal to 12 years of age.

### **PRESCRIBER RESTRICTION**

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, etc.).

### **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 and 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, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., bzds, 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 transplant 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, Gammagard Liquid, Gammaked 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's age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both

strategies) for maintenance therapy.

# JAKAFI

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## MEDICATION(S)

JAKAFI

## PA INDICATION INDICATOR

3 - 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.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a hematologist/oncologist

## COVERAGE DURATION

Myelofibrosis, Polycythemia vera, graft-versus-host disease: 12 months.

## OTHER CRITERIA

Approve for continuation of prior therapy.

## **JEMPERLI**

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### **MEDICATION(S)**

JEMPERLI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has a diagnosis of endometrial carcinoma AND patient has disease that is mismatch repair deficient (dMMR) as determined by an FDA-approved test AND Patient has advanced or recurrent disease AND Patient has progressed on or following prior treatment with a platinum-containing regimen.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial: 6mths. Reauth: 6 months

### **OTHER CRITERIA**

Reauth Criteria: Patient must continue to meet the above criteria AND Disease response with treatment as defined by stabilization of disease OR decrease in size of tumor or tumor spread.

## **JEVTANA**

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### **MEDICATION(S)**

JEVTANA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Prostate Cancer: Diagnosis of castration-resistant metastatic prostate cancer AND patient has been previously treated with a docetaxel-containing regimen AND patient is receiving concurrent prednisone

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **JUXTAPID**

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### **MEDICATION(S)**

JUXTAPID

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Homozygous familial hypercholesterolemia (HoFH) (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. Patient has had trial and failure or intolerance to ONE LDL-C lowering prescription therapy. Patient has had trial and failure or intolerance to Repatha therapy. One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: LDL-C greater than or equal to 70 mg/dL with ASCVD OR LDL-C greater than or equal to 130 mg/dL without ASCVD. Not used in combination with Kynamro (mipomersen). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient is not pregnant. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests. Patient is not concomitantly on moderate or strong CYP 3A4 inhibitors (eg, clarithromycin).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

HoFH (initial, reauth): Prescribed by a cardiologist, endocrinologist, or lipid specialist.

### **COVERAGE DURATION**

HoFH (initial): 6 months. (reauth): 12 months



**OTHER CRITERIA**

HoFH (reauthorization): Patient continues to receive statin at the maximally tolerated dose (or other LDL-C lowering prescription therapy if patient is unable to take a statin). Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior Juxtapid therapy) while on Juxtapid therapy. Not used in combination with Kynamro (mipomersen). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient is not pregnant. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests. Patient is not concomitantly on moderate or strong CYP 3A4 inhibitors (eg, clarithromycin).

## **JYNARQUE**

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### **MEDICATION(S)**

JYNARQUE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Use is contraindicated in patients who are anuric. Use is contraindicated in patients with significant hepatic impairment or disease (or a history of). Concurrent use of strong CYP3A4 inhibitors (eg, ketoconazole, clarithromycin, ritonavir, saquinavir)

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Autosomal dominant polycystic kidney disease

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 Months

### **OTHER CRITERIA**

N/A

## **KADCYLA**

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### **MEDICATION(S)**

KADCYLA 100 MG VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Breast cancer: A) Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive recurrent or metastatic breast cancer AND B) Patient has been previously treated with Herceptin (trastuzumab) and a taxane (eg, docetaxel, paclitaxel).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **KALYDECO**

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### **MEDICATION(S)**

KALYDECO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Confirmed diagnosis of Cystic Fibrosis (CF) in patients 6 months of age or older who have 1 mutation in the CF transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bidirectional sequencing when recommended by the mutation test instructions for use

### **AGE RESTRICTION**

CF (Initial): 6 months of age and older

### **PRESCRIBER RESTRICTION**

CF (Initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or a 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).

## **KANUMA**

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### **MEDICATION(S)**

KANUMA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Lysosomal acid lipase deficiency: Diagnosis of lysosomal acid lipase deficiency (LAL-D). Diagnosis was confirmed by an enzymatic blood (e.g., dried blood spot test) or genetic test.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, gastroenterologist, or lipidologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **KEVEYIS**

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### **MEDICATION(S)**

KEVEYIS

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

All Uses (Initial and Reauth): Hepatic insufficiency (e.g., Child-Pugh class A). Severe pulmonary disease [e.g., severe chronic obstructive pulmonary disease]. Concomitant use with high dose aspirin (i.e., greater than 100 mg per day).

### **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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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 Keveyis therapy.

## **KEVZARA**

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### **MEDICATION(S)**

KEVZARA

### **PA INDICATION INDICATOR**

3 - 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. Patient has had a T/F, CI to one or more non-biologic DMARD AND T/F, CI to both Enbrel (etanercept) and Humira (adalimumab), or for continuation of prior Kevzara therapy. (Initial, Reauth): Patient is not receiving Kevzara in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Initial: Prescribed by or in consultation with a rheumatologist

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

RA (reauth): Documentation of positive clinical response to Kevzara therapy

## **KEYTRUDA**

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### **MEDICATION(S)**

KEYTRUDA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Melanoma: Diagnosis (dx) of melanoma and disease is unresectable or metastatic. Non-Small Cell Lung Cancer (NSCLC): Dx of metastatic NSCLC. One of the following: A) Tumors express high PD-L1 [Tumor Proportion Score (TPS) greater than or equal to 50%]] as determined by an FDA-approved test, absence of epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations, and used as first-line treatment. OR B) Tumors express PD-L1 [Tumor Proportion Score (TPS) greater than or equal to 1%] as determined by an FDA-approved test, patient had a trial and failure, contraindication, or intolerance to platinum-containing therapy (eg, cisplatin, carboplatin), AND one of the following: 1) absence of EGFR mutation or ALK rearrangement, OR 2) both of the following: presence of EGFR or ALK genomic tumor aberrations AND trial and failure, contraindication, or intolerance to FDA-approved therapy for these aberrations [e.g., Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib), Xalkori (crizotinib)]. Recurrent or metastatic head and neck squamous cell carcinoma (HNSCC): Patient has a diagnosis of recurrent or metastatic HNSCC AND patient has disease progression on or after platinum-containing therapy. Classical Hodgkin lymphoma: Diagnosis of classical Hodgkin lymphoma AND One of the following: A) disease is refractory or B) disease has relapsed after 3 or more prior lines of therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**



12 months

**OTHER CRITERIA**

Approve for continuation of prior therapy.

## **KINERET**

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### **MEDICATION(S)**

KINERET

### **PA INDICATION INDICATOR**

3 - 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. Patient has had T/F, CI to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Kineret therapy. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID AND dx of NOMID has been confirmed by one of the following: NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation OR evidence of active inflammation including both of the following: clinical symptoms (eg, rash, fever, arthralgia) and elevated acute phase reactants (eg, ESR, CRP). All Uses (initial, reauth): Patient is not receiving Kineret in combination with a biologic disease modifying antirheumatic drug (DMARD) [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Kineret in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

RA (initial): Prescribed by or in consultation with a rheumatologist. NOMID (initial): Prescribed by or in consultation with allergist/immunologist or rheumatologist or pediatrician.

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

All Uses (Reauth): Documentation of positive clinical response to Kineret therapy.

## **KISQALI**

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### **MEDICATION(S)**

KISQALI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of advanced or metastatic breast cancer: Patient has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer (in combination with an aromatase inhibitor) in pre/perimenopausal or postmenopausal women as initial endocrine-based therapy. Treatment of HR-positive, HER2-negative advanced or metastatic breast cancer (in combination with fulvestrant) in postmenopausal women as initial endocrine-based therapy or following disease progression on endocrine therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy

## **KISQALI-FEMARA PACK**

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### **MEDICATION(S)**

KISQALI FEMARA CO-PACK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Breast cancer, advanced or metastatic as initial endocrine-based therapy for the treatment of hormone receptor-positive, human epidermal growth factor receptor 2-negative in pre/perimenopausal or postmenopausal women.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy

## **KORLYM**

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### **MEDICATION(S)**

KORLYM

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Initial: Prescribed by or in consultation with an endocrinologist.

### **COVERAGE DURATION**

Initial, reauth: 6 months

### **OTHER CRITERIA**

Reauthorization: Documentation of one of the following: patient has improved glucose tolerance while on Korlym therapy or patient has stable glucose tolerance while on Korlym therapy.

## **KOSELUGO**

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### **MEDICATION(S)**

KOSELUGO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Pediatric patient has diagnosis of neurofibromatosis type 1. Patient is symptomatic and has inoperable plexiform neurofibromas.

### **AGE RESTRICTION**

Pediatric patient must be 2 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial: 6 months Reauth: 12 months with positive response.

### **OTHER CRITERIA**

N/A

## **KUVAN**

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### **MEDICATION(S)**

SAPROPTERIN DIHYDROCHLORIDE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient is a new start to Kuvan (sapropterin dihydrochloride). Patient will have blood Phe levels measured after 1 week of therapy and periodically for up to 2 months of therapy to determine response.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

PKU (Init): 2 months (Reauth): 12 months

### **OTHER CRITERIA**

PKU (reauth): Patient is currently on therapy with Kuvan (sapropterin dihydrochloride). Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline. Patient will continue to have blood Phe levels measured periodically during therapy.



## **KYNMOBI**

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### **MEDICATION(S)**

KYNMOBI 10 MG SL FILM, KYNMOBI 15 MG SL FILM, KYNMOBI 20 MG SL FILM, KYNMOBI 25 MG SL FILM, KYNMOBI 30 MG SL FILM

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant use of at 5HT 3 antagonist.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Parkinson Disease (PD). Patient is experiencing acute intermittent hypomobility (defined as OFF episodes characterized by muscle stiffness, slow movements, or difficulty starting movements for at least 2 hours per day on average) AND Patient is on a stable levodopa-based therapy AND patient has tried and failed an adequate trial (at least 2 drugs) of adjunct therapies (e.g., dopamine agonists, subcutaneous apomorphine, levodopa extended-release, catechol-O-methyl transferase [COMT] inhibitors, monoamine oxidase B [MAO-B] inhibitors, amantadine derivatives).

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist

### **COVERAGE DURATION**

Initial and Reauth: 6 months

### **OTHER CRITERIA**

Reauth: Pt is benefitting from treatment.

## **KYPROLIS**

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### **MEDICATION(S)**

KYPROLIS

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Multiple Myeloma (MM): Diagnosis of MM. Disease is relapsed or refractory. Patient has received at least one prior therapy for MM.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist/hematologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **LARTRUVO**

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### **MEDICATION(S)**

LARTRUVO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Soft Tissue Sarcoma (STS): Diagnosis of STS. All of the following: A) One of the following: 1) Disease is not amenable to curative treatment with radiotherapy or 2) Disease is not amenable to curative treatment with surgery AND B) Used in combination with doxorubicin for the first 8 cycles of treatment

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy

## **LENVIMA**

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### **MEDICATION(S)**

LENVIMA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Differentiated thyroid cancer (DTC): Diagnosis of DTC. Disease is locally recurrent or metastatic. Patient has symptomatic or progressive disease. Disease is refractory to radioactive iodine treatment. Renal Cell Carcinoma (RCC): Diagnosis of advanced RCC following one prior anti-angiogenic therapy. Used in combination with everolimus. Hepatocellular carcinoma (HCC): Diagnosis of unresectable (HCC). Endometrial carcinoma, advanced: Diagnosis of advanced endometrial carcinoma (in combination with pembrolizumab) that is not microsatellite instability-high or mismatch repair deficient, in patients who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## LETAIRIS

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### MEDICATION(S)

AMBRISENTAN

### PA INDICATION INDICATOR

3 - 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 RESTRICTION

N/A

### PRESCRIBER RESTRICTION

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.

## LEUKINE

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### MEDICATION(S)

LEUKINE

### PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

Bone marrow/stem cell transplant (BMSCT): One of the following: 1) patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT, OR 2) for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, OR 3) for peripheral stem cell transplant (PSCT) patients who have received myeloablative chemotherapy. Acute myeloid leukemia (AML): patients with AML following induction or consolidation chemotherapy, AND age greater than or equal to 55 years. Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) patient receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm<sup>3</sup>), AND 2) patients with a history of FN during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) Patient is receiving National Cancer Institutes Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm<sup>3</sup>), AND 2) patients with FN at high risk for infection-associated complications.

### AGE RESTRICTION

N/A

**PRESCRIBER RESTRICTION**

(Initial): Prescribed by hematologist/oncologist except HIVN: Prescribed by hematologist/oncologist or infectious disease specialist

**COVERAGE DURATION**

BMSCT, AML, CFN, FN (prophylaxis), NDDC:3mo or duration of tx. HIVN:6mo. FN (tx):1 mo. H-ARS:3 mths.

**OTHER CRITERIA**

HIV-related neutropenia (HIVN)(off-label): Patients infected with HIV, and ANC less than or equal to 1000 (cells/mm<sup>3</sup>).

## **LIBTAYO**

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### **MEDICATION(S)**

LIBTAYO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has 1. metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC AND patient is not a candidate for curative surgery or curative radiation or 2. locally advanced basal cell carcinoma (laBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate 3. metastatic basal cell carcinoma (mBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate 4. non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (tumor proportion score [TPS] greater than 50 percent as determined by an FDA-approved test, with no EGFR, ALK, or ROS1 aberrations, and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation OR metastatic or 5. locally advanced or metastatic BCC previously treated with a hedgehog pathway inhibitor (HHI) or for whom an HHI is not appropriate.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial Auth and Reauth: 6 months.

### **OTHER CRITERIA**

N/A



## **LIDOCAINE**

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### **MEDICATION(S)**

LIDOCAINE 5% OINTMENT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 Months

### **OTHER CRITERIA**

N/A

## **LIDODERM**

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### **MEDICATION(S)**

LIDOCAINE 5% PATCH

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of post-herpetic neuralgia

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **LINEZOLID**

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### **MEDICATION(S)**

LINEZOLID

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Confirmed vancomycin-resistant enterococcus faecium (VRE) infection. Confirmed methicillin-resistant *S. aureus* (MRSA), methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Streptococcus agalactiae*, or *Streptococcus pyogenes* infection AND individual has had a trial and inadequate response or intolerance to or has contraindications to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: vancomycin, TMP-SMX, clindamycin, doxycycline, tetracycline (Based on 2011 IDSA MRSA guideline recommendations)). Individual started treatment with LINEZOLID in the hospital and requires continued outpatient therapy. Isolates of MRSA have a vancomycin minimum inhibitory concentration (MIC) of greater than 2.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **LONSURF**

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### **MEDICATION(S)**

LONSURF

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1) Colorectal Cancer: Diagnosis of metastatic colorectal cancer 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., Avastin) AND One of the following: A) patient has KRAS wild-type tumors and trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux) OR Patient has KRAS mutant tumors. 2) Gastric Cancer: Diagnosis of Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/NEU-targeted therapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **LORBRENA**

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### **MEDICATION(S)**

LORBRENA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Non-small cell lung cancer, metastatic Treatment of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) in patients whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease, or progressed on alectinib as the first ALK inhibitor therapy for metastatic disease, or progressed on ceritinib as the first ALK inhibitor therapy for metastatic disease.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **LOTRONEX**

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### **MEDICATION(S)**

ALOSETRON HCL

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

Initial: 18 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

IBS (initial): 12 weeks. IBS (reauth): 6 mo.

### **OTHER CRITERIA**

IBS (reauthorization): Symptoms of IBS continue to persist, AND documentation of positive clinical response to alosetron therapy.

## **LUCEMYRA**

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### **MEDICATION(S)**

LUCEMYRA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Congenital long QT syndrome, severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of covered use

### **AGE RESTRICTION**

18 years of age or older

### **PRESCRIBER RESTRICTION**

n/a

### **COVERAGE DURATION**

14 days

### **OTHER CRITERIA**

N/A

# **LUCENTIS**

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## **MEDICATION(S)**

LUCENTIS

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Patient must not have an active ocular or periocular infection.

## **REQUIRED MEDICAL INFORMATION**

Diagnosis of Diabetic Macular Edema (DME) and has tried and failed or had an intolerance to Avastin OR Diagnosis of Macular Degeneration- Neovascular (wet) age-related macular degeneration and has tried and failed or had an intolerance to Avastin OR Diagnosis of diabetic retinopathy OR Diagnosis of Myopic choroidal neovascularization OR Diagnosis of Macular Edema following retinal vein occlusion (RVO).

## **AGE RESTRICTION**

Patient must be 18 years of age or older

## **PRESCRIBER RESTRICTION**

Must be prescribed by, or in consultation with, an ophthalmologist.

## **COVERAGE DURATION**

12 months

## **OTHER CRITERIA**

N/A



## **LUMAKRAS**

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### **MEDICATION(S)**

LUMAKRAS

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Nonsmall cell lung cancer, locally advanced or metastatic, KRAS G12C-mutated: Treatment of KRAS G12C-mutated locally advanced or metastatic nonsmall cell lung cancer (NSCLC), as determined by an FDA-approved test, in patients who have received at least 1 prior systemic therapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial: 6mths. Reauth: 6 months

### **OTHER CRITERIA**

Reauth Criteria: Patient must continue to meet the above criteria AND Disease response with treatment.

## **LUMIZYME-MYOZYME**

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### **MEDICATION(S)**

LUMIZYME

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Pompe disease: Diagnosis of Pompe disease [acid alpha-glucosidase (GAA) deficiency].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **LUPANETA PACK**

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### **MEDICATION(S)**

LUPANETA PACK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Endometriosis (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID or one oral contraceptive. Trial and failure, contraindication, or intolerance to Lupron Depot (7.5 mg, 22.5 mg, 30 mg, and 45 mg).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Endomet (init, reauth): 6 months

### **OTHER CRITERIA**

Endometriosis (reauthorization): Patient is experiencing recurrence of symptoms after an initial course of therapy.

## **LUPKYNIS**

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### **MEDICATION(S)**

LUPKYNIS

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has active lupus nephritis and will be used in combination with a background immunosuppressive therapy regimen AND patient has had trial and failure or contraindication to belimumab (BENLYSTA).

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an immunologist, rheumatologist or nephrologist.

### **COVERAGE DURATION**

Initial Auth and Reauth: 6 months.

### **OTHER CRITERIA**

N/A

# **LUPRON**

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## **MEDICATION(S)**

LEUPROLIDE 2WK 14 MG/2.8 ML KT, LEUPROLIDE 2WK 14 MG/2.8 ML VL

## **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prostate Cancer:(initial, reauth): Prescribed by or in consultation with an oncologist.

## **COVERAGE DURATION**

Prostate CA (initial, reauth): 12 months

## **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **LUPRON DEPOT**

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### **MEDICATION(S)**

LUPRON DEPOT, LUPRON DEPOT (LUPANETA), LUPRON DEPOT-PED 11.25 MG 3MO, LUPRON DEPOT-PED 7.5 MG KIT

### **PA INDICATION INDICATOR**

3 - 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) (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID and one oral contraceptive. 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Prostate CA: 12 mo. Endomet (init, reauth):6mo. UL (anemia):3 mo (fibroids):4 mo

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **LUPRON DEPOT PED**

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### **MEDICATION(S)**

LUPRON DEPOT-PED 11.25 MG KIT, LUPRON DEPOT-PED 15 MG KIT, LUPRON DEPOT-PED 30 MG 3MO KIT

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.

### **COVERAGE DURATION**

CPP (init, reauth): 12 months

### **OTHER CRITERIA**

CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.

## **LYNPARZA**

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### **MEDICATION(S)**

LYNPARZA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1st -Line Maint. BRCAm Adv. Ovarian CA (AOCA): maint. tx of adult pts w/ deleterious or susp. deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) adv. epithelial ovarian, fallopian tube, or primary peritoneal CA who are in complete or PR to 1st -line platinum-based chemo. 1st -Line Maint. HRD-Positive AOCA in Combination w/ Bevacizumab: In comb. w/ bevacizumab for the maint. tx of adult pts w/ adv. Epith. ovarian, fallopian tube or primary peritoneal CA who are in complete or PR to 1st -line platinum-based chemo and whose CA is assoc. w/ homologous recomb. deficiency (HRD) pos. status defined by either: a deleterious or susp. deleterious BRCA mutation, and/or genomic instability. Maint. Recurrent OCA: For the maint. tx of adult pts w/ recurrent epithelial ovarian, fallopian tube, or primary peritoneal CA, who are in complete or PR to platinum-based chemo. Adv. gBRCAm OCA: For the tx of adult pts w/ deleterious or susp. deleterious germline BRCA-mutated (gBRCAm) AOCA who have been tx w/ 3 or more prior lines of chemo. gBRCAm, HER2-Neg Metastatic Breast CA: For the tx of adult pts w/ deleterious or susp. deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast CA who have been tx w/ chemo in the neoadj., adj, or metastatic setting. Pts w/ hormone receptor (HR)-pos breast CA should have been tx w/ a prior endocrine therapy or considered inappropriate for endocrine tx. 1st -Line Maint. gBRCAm Metastatic Pancreatic CA: For the maint. tx of adult pts w/ deleterious or susp. deleterious gBRCAm metastatic pancreatic adenoCA whose disease has not progressed on at least 16 wks of a 1st -line platinum-based chemo regimen. HRR Gene-mutated Metastatic Castration-Resistant Prostate CA: For the tx of adult pts w/ deleterious or susp. deleterious germline or somatic homologous recomb. repair (HRR) gene-mutated metastatic castration-resistant prostate CA (mCRPC) who have progressed following prior tx w/ enzalutamide or abiraterone.

### **AGE RESTRICTION**



N/A

**PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

**COVERAGE DURATION**

12 months

**OTHER CRITERIA**

Approve for continuation of prior therapy.

## **MARINOL**

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### **MEDICATION(S)**

DRONABINOL

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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.

## **MAYZENT**

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### **MEDICATION(S)**

MAYZENT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

A CYP2C9\*3/\*3 genotype?? Patient must not have experienced in the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemia attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure ?? Patient must not have presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker

### **REQUIRED MEDICAL INFORMATION**

Inadequate response, or intolerance, to first-line agents such as fingolimod (GILENYA) and dimethyl fumarate (TECFIDERA).

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by a neurologist or in consultation with a neurologist.

### **COVERAGE DURATION**

Initial Auth: 12 months

### **OTHER CRITERIA**

Reauth: Documentation of positive clinical response to therapy. 12 months.

## **MEGESTROL**

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### **MEDICATION(S)**

MEGESTROL 625 MG/5 ML SUSP, MEGESTROL ACET 40 MG/ML SUSP, MEGESTROL ACET 400 MG/10 ML

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

All Medically Accepted indications not otherwise excluded by Part D.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

6 months

### **OTHER CRITERIA**

N/A

## **MEKINIST**

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### **MEDICATION(S)**

MEKINIST

### **PA INDICATION INDICATOR**

3 - 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 an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **MEKTOVI**

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### **MEDICATION(S)**

MEKTOVI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

CRITERIA: Melanoma, unresectable or metastatic Treatment of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with encorafenib, as detected by an FDA-approved test.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **METADATE ER-RITALIN SR**

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### **MEDICATION(S)**

METHYLPHENIDATE ER 10 MG TAB, METHYLPHENIDATE ER 20 MG TAB

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

### **AGE RESTRICTION**

PA applies to members 19 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **METHYLIN CHEW**

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### **MEDICATION(S)**

METHYLPHENIDATE 10 MG CHEW TAB, METHYLPHENIDATE 2.5 MG CHEW TB,  
METHYLPHENIDATE 5 MG CHEW TAB

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

### **AGE RESTRICTION**

PA applies to members 19 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A



## **METHYLPHENIDATE**

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### **MEDICATION(S)**

METHYLPHENIDATE 10 MG TABLET, METHYLPHENIDATE 10 MG/5 ML SOL,  
METHYLPHENIDATE 20 MG TABLET, METHYLPHENIDATE 5 MG TABLET, METHYLPHENIDATE 5  
MG/5 ML SOLN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

### **AGE RESTRICTION**

PA applies to members 19 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **METHYLPHENIDATE ER**

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### **MEDICATION(S)**

METHYLPHENIDATE ER 10 MG CAP, METHYLPHENIDATE ER 15 MG CAP, METHYLPHENIDATE ER 18 MG TAB, METHYLPHENIDATE ER 20 MG CAP, METHYLPHENIDATE ER 27 MG TAB, METHYLPHENIDATE ER 30 MG CAP, METHYLPHENIDATE ER 36 MG TAB, METHYLPHENIDATE ER 40 MG CAP, METHYLPHENIDATE ER 50 MG CAP, METHYLPHENIDATE ER 54 MG TAB, METHYLPHENIDATE ER 60 MG CAP, METHYLPHENIDATE ER(LA) 30MG CP, METHYLPHENIDATE HCL CD, METHYLPHENIDATE HCL ER (CD), METHYLPHENIDATE LA 30 MG CAP, METHYLPHENIDATE LA 60 MG CAP

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

### **AGE RESTRICTION**

PA applies to members 19 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

# **METHYLTESTOSTERONE**

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## **MEDICATION(S)**

METHYLTESTOSTERONE

## **PA INDICATION INDICATOR**

3 - 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 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). 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. Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC, GID: 12 mo. DP: 6 mo.

## **OTHER CRITERIA**

HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) 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: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

## **MIRVASO**

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### **MEDICATION(S)**

MIRVASO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Rosacea (init): Diagnosis of rosacea. Patient has moderate to severe persistent (nontransient) facial erythema.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Rosacea (init, reauth): 12 months

### **OTHER CRITERIA**

Rosacea (reauth) Documentation of positive clinical response to Mirvaso therapy.

## **MONJUVI**

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### **MEDICATION(S)**

MONJUVI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Dx: relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma AND the drug will be used in combination with lenalidomide AND patient is not eligible for autologous stem cell transplant.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist/oncologist.

### **COVERAGE DURATION**

Initial: 6 months Reauth: 12 months.

### **OTHER CRITERIA**

Reauth: Pt is benefitting from treatment.

## **MOTTEGRITY**

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### **MEDICATION(S)**

MOTTEGRITY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient must have a diagnosis of chronic idiopathic constipation, Patient must have experienced an inadequate response after a 14-day trial of lactulose or polyethylene glycol (PEG-3350) at a maximum tolerated dose, OR have a documented intolerance or contraindication to both lactulose and polyethylene glycol (PEG-3350), Patient must not have a known or suspected mechanical gastrointestinal obstruction.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a gastroenterologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **MOZOBIL**

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### **MEDICATION(S)**

MOZOBIL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Hematopoietic Stem Cell (HSC) Mobilization: Patient with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM) who will be undergoing autologous HSC transplantation. Used in combination with granulocyte-colony stimulating factor (G-CSF).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist/oncologist

### **COVERAGE DURATION**

One course of therapy up to 4 days

### **OTHER CRITERIA**

N/A



## **MS INTEFERONS**

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### **MEDICATION(S)**

AVONEX 30 MCG VIAL KIT, AVONEX PREFILLED SYR 30 MCG KT, AVONEX PEN, BETASERON, PLEGRIDY 125 MCG/0.5 ML SYRING, PLEGRIDY PEN, REBIF, REBIF REBIDOSE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Multiple Sclerosis (MS): Diagnosis of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease with evidence of new brain lesions.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **MYALEPT**

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### **MEDICATION(S)**

MYALEPT

### **PA INDICATION INDICATOR**

3 - 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: a) Patient has hypertriglyceridemia and is refractory or intolerant to at least two formulary triglyceride lowering agents at highest tolerated doses (i.e. atorvastatin, simvastatin, pravastatin, rosuvastatin, fenofibrate, ezetimibe, gemfibrozil) OR b) Patient has Diabetes Mellitus or insulin resistance with persistent hyperglycemia despite optimized insulin therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Initial: Prescribed by or in consultation with an endocrinologist

### **COVERAGE DURATION**

Initial and reauth: 12 months

### **OTHER CRITERIA**

Lipodystrophy (reauth): Patient has experienced an objective response to therapy, such as A) Sustained reduction in hemoglobin A1c (HbA1c) level from baseline OR B) Sustained reduction in triglyceride (TG) levels from baseline

## **NAGLAZYME**

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### **MEDICATION(S)**

NAGLAZYME

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Mucopolysaccharidosis (MPS VI): Diagnosis of MPS VI (Maroteaux-Lamy Syndrome)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

MPS VI: 12 months

### **OTHER CRITERIA**

N/A

## **NAMENDA XR (INCLUDING TITRATION PACK), MEMANTINE (TABLETS, SOLUTION AND TITRATION PACK)**

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### **MEDICATION(S)**

MEMANTINE 5-10 MG TITRATION PK, MEMANTINE HCL 10 MG TABLET, MEMANTINE HCL 2 MG/ML SOLUTION, MEMANTINE HCL 5 MG TABLET, MEMANTINE HCL ER

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Members that are 50 years of age or older are NOT subject to the prior authorization requirements. Prior Authorization applies to members that are 49 years of age or younger.

### **REQUIRED MEDICAL INFORMATION**

Individual has a diagnosis of moderate to severe dementia of the Alzheimers type.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **NATESTO**

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### **MEDICATION(S)**

NATESTO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Dx: Hypogonadism (hypogonadotropic) or hypogonadism (primary) (males) AND labwork within the past 12 months of low testosterone level measured on at least two occasions is provided AND patient has tried and failed at least 2 other formulary alternative testosterone given by other routes of administration such as transdermally or intramuscularly.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial and Reauth 6 mths

### **OTHER CRITERIA**

N/A

## **NATPARA**

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### **MEDICATION(S)**

NATPARA

### **PA INDICATION INDICATOR**

3 - 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. NATPARA is not being used in the setting of acute post-surgical hypoparathyroidism. Patient does not have a known calcium-sensing receptor mutation. Patient is not at an increased risk for osteosarcoma.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Hypocalcemia (Initial): Prescribed by or in consultation with an endocrinologist.

### **COVERAGE DURATION**

Initial: 4 months. Reauth: 12 months

### **OTHER CRITERIA**

N/A

## **NAYZILAM**

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### **MEDICATION(S)**

NAYZILAM

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (e.g., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and greater.

### **AGE RESTRICTION**

Patient must be 12 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by a neurologist or in consultation with a neurologist.

### **COVERAGE DURATION**

3 months.

### **OTHER CRITERIA**

N/A

# NEULASTA

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## MEDICATION(S)

FULPHILA, NEULASTA, NEULASTA ONPRO, UDENYCA, ZIEXTENZO

## PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) patient receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm<sup>3</sup>), AND 2) patients with a history of FN during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) patient is receiving National Cancer Institutes Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm<sup>3</sup>), AND 2) patients with FN at high risk for infection-associated complications. Acute radiation syndrome (ARS): Patient was acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

All uses (initial): Prescribed by a hematologist/oncologist

## COVERAGE DURATION



FN (treatment), ARS: 1 mo. CFN, NDDC, FN (prophylaxis): 3 mo or duration of tx.

**OTHER CRITERIA**

All Uses: Neulasta Brand will be approved after T/F with at least two formulary alternative biosimilars- Udenyca (pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez) and Fulphila (pegfilgrastim-jmdb).

## NEUPOGEN

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### MEDICATION(S)

NEUPOGEN

### PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

Bone marrow/stem cell transplant (BMSCT): One of the following: 1) pts with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT, OR 2) for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, OR 3) for peripheral stem cell transplant (PSCT) pts who have received myeloablative chemotherapy. Acute myeloid leukemia (AML): patients with AML following induction or consolidation chemotherapy. Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) Pt is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) Pt receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) Pts receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm<sup>3</sup>), AND 2) Pts with a history of FN during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) Pt is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) Pt is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Severe chronic neutropenia (SCN): Pts with SCN (ie, congenital, cyclic, and idiopathic neutropenias with chronic ANC less than or equal to 500 cells/mm<sup>3</sup>). Treatment of FN (off-label): Both of the following: 1) Pts receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm<sup>3</sup>), AND 2) Pts with FN at high risk for infection-associated complications. Acute radiation syndrome (ARS): Pt is/was acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrom

### AGE RESTRICTION

N/A

**PRESCRIBER RESTRICTION**

Prescribed by hematologist/oncologist except HIVN: Prescribed by hematologist/oncologist or infectious disease specialist

**COVERAGE DURATION**

BMSCT,AML,CFN,secondary ppx of FN,NDDC:3mo or tx duration. SCN:12mo. HIVN:6mo .ARS,FN  
Tx:1 mo.

**OTHER CRITERIA**

HIV-related neutropenia (HIVN)(off-label): Patients infected with HIV, and ANC less than or equal to 1000 (cells/mm<sup>3</sup>). For the following uses: AML following induction or consolid chemo, Bone marrow transplants, chemo induced myelosupp in nonmyeloid malignancy, peripheral blood progenitor cell collection and tx, or severe chronic neutropenia, NEUPOGEN Brand will be approved after failure with biosimilar products Nivestym (filgrastim-aafi) and Zarxio (filgrastim-sndz).

## **NEXAVAR**

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### **MEDICATION(S)**

NEXAVAR

### **PA INDICATION INDICATOR**

3 - 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: Relapsed disease OR both medically/surgically unresectable tumor and dx of Stage IV disease. Hepatocellular carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or both of the following: patient is not a transplant candidate and disease is unresectable. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC (ie, follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma). One of the following: locally recurrent disease or metastatic 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. Patient has symptomatic disease. Trial and failure, contraindication, or intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

RCC, DTC, MTC: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **NEXLETOL**

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### **MEDICATION(S)**

NEXLETOL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis: 1) ASCVD, established: Treatment of established ASCVD (as confirmed by e.g. acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA or PAD, all of presumed atherosclerotic origin), as an adjunct to maximally tolerated statin therapy (OR The member is determined to have statin-associated muscle symptoms or myalgias that have included rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of statin-associated muscle symptoms or myalgias despite both lowering of statin strength AND attempting a different statin), in adult patients who require additional lowering of LDL-C. 2) Heterozygous familial hypercholesterolemia (HeFH): Treatment of HeFH, as an adjunct to maximally tolerated statin therapy (OR The member is determined to have statin-associated muscle symptoms or myalgias that have included rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of statin-associated muscle symptoms or myalgias despite both lowering of statin strength AND attempting a different statin), in adult patients who require additional lowering of LDL-C.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 6 mths. Reauth: 12 mths.

### **OTHER CRITERIA**

Reauth: Submission of LDL-C labs demonstrating improvement from baseline.

## **NEXLIZET**

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### **MEDICATION(S)**

NEXLIZET

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis: 1) ASCVD, established: Treatment of established ASCVD (as confirmed by e.g. acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA or PAD, all of presumed atherosclerotic origin), as an adjunct to maximally tolerated statin therapy (OR The member is determined to have statin-associated muscle symptoms or myalgias that have included rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of statin-associated muscle symptoms or myalgias despite both lowering of statin strength AND attempting a different statin), in adult patients who require additional lowering of LDL-C. 2) Heterozygous familial hypercholesterolemia (HeFH): Treatment of HeFH, as an adjunct to maximally tolerated statin therapy (OR The member is determined to have statin-associated muscle symptoms or myalgias that have included rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of statin-associated muscle symptoms or myalgias despite both lowering of statin strength AND attempting a different statin), in adult patients who require additional lowering of LDL-C. OR Patient has a dx of ASCVD, established or HeFH and has tried and failed tx with NEXLETOLE (bempedoic acid).

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 6 mths. Reauth: 12 mths. Lab values show sustained LDL-C reduction from pre-tx baseline.



**OTHER CRITERIA**

N/A

## **NINLARO**

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### **MEDICATION(S)**

NINLARO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Multiple myeloma: Diagnosis of multiple myeloma. Used in combination with Revlimid (lenalidomide) and dexamethasone. Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist/oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **NIVESTYM**

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### **MEDICATION(S)**

NIVESTYM

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Acute myeloid leukemia following induction or consolidation chemotherapy - To reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy in adults with acute myeloid leukemia (AML) Bone marrow transplantation To reduce the duration of neutropenia and neutropenia-related events (eg, neutropenic fever) in patients with nonmyeloid malignancies receiving myeloablative chemotherapy followed by bone marrow transplantation. Ref Myelosuppressive chemotherapy recipients with nonmyeloid malignancies To decrease the incidence of infection (neutropenic fever) in patients with nonmyeloid malignancies receiving myelosuppressive chemotherapy associated with a significant incidence of severe neutropenia with fever. Peripheral blood progenitor cell collection and therapy Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for apheresis collection. Severe chronic neutropenia Long-term administration to reduce the incidence and duration of neutropenic complications (eg, fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. All indications: History of failure or intolerance to Zarxio (filgrastim-sndz).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

**OTHER CRITERIA**

N/A

## **NON-PREFERRED TIRF**

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### **MEDICATION(S)**

ABSTRAL

### **PA INDICATION INDICATOR**

3 - 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 mcg per hour, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day). Trial and failure or intolerance to generic fentanyl lozenge.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

## **NORTHERA**

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### **MEDICATION(S)**

NORTHERA

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

## **NOURIANZ**

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### **MEDICATION(S)**

NOURIANZ

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis is Parkinson's disease. Patient is experiencing off episodes. Nourianz is being prescribed as adjunctive treatment to levodopa/carbidopa.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

# NOVANTRONE

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## MEDICATION(S)

MITOXANTRONE HCL

## PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Multiple Sclerosis (MS) (init): Diagnosis (dx) of one of the following: secondary progressive MS: gradually worsening disability with or without superimposed relapses, progressive relapsing MS: progression of disability from the onset with superimposed relapses, or worsening relapsing-remitting MS: neurological status remains significantly abnormal in between MS relapses. Disease progression despite one of the following therapies: Avonex, Aubagio, Betaseron, Copaxone, Glatopa, Extavia, Gilenya, Lemtrada, Rebif, Tecfidera, Tysabri. Left ventricular ejection fraction (LVEF) greater than or equal to 50%. Neutrophil count greater than or equal to 1500 cell/mm<sup>3</sup>. Lifetime cumulative dose less than 140 mg/m<sup>2</sup>. Prostate Cancer (PC) (init): Dx of advanced hormone-refractory (castration-resistant) PC. Used in combination with corticosteroids (eg, prednisone, methylprednisolone). LVEF greater than or equal to 50%. Neutrophil count greater than or equal to 1500 cell/mm<sup>3</sup>. Acute Non-Lymphocytic Leukemia (ANLL) (init): Dx of ANLL (eg, myelogenous, promyelocytic, monocytic, and erythroid). Used in combination with other medications used for the treatment of ANLL. LVEF greater than or equal to 50%.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

All Uses: 12 weeks



**OTHER CRITERIA**

Approve for continuation of prior therapy.

## **NOXAFIL DR 100MG TABLET**

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### **MEDICATION(S)**

POSACONAZOLE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **NP HUMAN GROWTH HORMONE**

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### **MEDICATION(S)**

ZOMACTON

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

PGHD(initial):less than 4mo w/GD,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, doc grwth velocity less than 25th percentile for bone age. 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 RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist.  
GFCRI: prescribed by endocrinologist or nephrologist

## **COVERAGE DURATION**

All indications (initial, reauth): 12 months

## **OTHER CRITERIA**

Trial and failure or intolerance to Genotropin and Nutropin. 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], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrozole,letrozole) or androgens(eg,testosterone cypionate). 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 structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3). IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).



## **NUBEQA**

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### **MEDICATION(S)**

NUBEQA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Treatment of nonmetastatic castration-resistant prostate cancer.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist or urologist

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

## **NUCALA (MEPOLIZUMAB)**

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### **MEDICATION(S)**

NUCALA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Severe Asthma: 1. Pt has documented dx of severe asthma with an eosinophilic phenotype 2. Pt has a pre-tx serum eosinophil count of greater than or equal to 150 cells per mcL OR historical level of greater than or equal to 300 cells per mcL in the last 12 mths if pt is on oral steroids. 3. Pt must have been treated with high dose inhaled corticosteroids plus LABAs, leukotriene modifiers, theophylline or oral corticosteroids for at least 4 mths OR 4. Pt is intolerant or has a C/I to any of these medications. 5. Patient has experienced at least 2 of the following in the past 12 mths: Two or more exacerbations requiring oral steroid tx, Two or more exacerbations requiring hospitalization or ER visit, airflow limitation (FEV1 less than 60 percent predicted), daily sx's such as cough, wheezing, chest tightness or difficulty breathing. Eosinophilic granulomatosis with polyangiitis: 1. Pt has a documented dx of eosinophilic granulomatosis with polyangiitis based on the presence of at least four of the following dx criteria: a) Asthma b) Eosinophilia c) Mononeuropathy or polyneuropathy d) Migratory or transient pulmonary infiltrates on chest x-rays e) Paranasal sinus abnormalities f) Bx containing a blood vessel with extravascular eosinophils 1. Pt is 18 years of age or older 2. Pt is stable or TF/C/I on corticosteroids 3. Documentation of severe disease (e.g., vasculitis with cerebral, cardiac, renal, or gastrointestinal involvement) or disease flares with tapering of corticosteroid therapy 4. Pt has TF/C/I with at least one of the following immunosuppressants: azathioprine, cyclophosphamide, or methotrexate OR prescriber has submitted clinical information why these medications are not appropriate.

### **AGE RESTRICTION**

Severe Asthma. Patient must be 6 years of age or older. Eosinophilic Granulomatosis with Polyangiitis. Patient must be 18 years of age or older.

**PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an allergist, immunologist, rheumatologist or pulmonologist.

**COVERAGE DURATION**

Initial Auth 6 mths Reauth: 12 mths: Pt. has continued to experience a positive clinical response.

**OTHER CRITERIA**

N/A



## **NUEDEXTA**

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### **MEDICATION(S)**

NUEDEXTA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Pseudobulbar affect (PBA) (initial): Diagnosis of PBA. (Reauthorization): Documentation of clinical benefit from ongoing therapy with Nuedexta.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

6 months

### **OTHER CRITERIA**

N/A

## **NULOJIX**

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### **MEDICATION(S)**

NULOJIX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Kidney transplant: The medication is being used for prevention of kidney transplant organ rejection AND The patient is immune to the Epstein-Barr virus (i.e. EBV seropositive) AND The patient is prescribed concurrent therapy with mycophenolate and corticosteroids

### **AGE RESTRICTION**

Kidney transplant: 18 years of age or older

### **PRESCRIBER RESTRICTION**

Kidney transplant: Prescriber is experienced in immunosuppressive therapy and management of transplant patients

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Subject to Part B vs. Part D review. Approve for continuation of prior therapy.

## **NUPLAZID**

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### **MEDICATION(S)**

NUPLAZID

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **NUVIGIL**

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### **MEDICATION(S)**

ARMODAFINIL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Obstructive sleep apnea/hypopnea syndrome (OSAHS) (Initial): Diagnosis (dx) of OSAHS 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 sleep disorder (SWSD) (Initial): Dx of SWSD confirmed by 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 sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). No other medical condition or medication accounts for the symptoms. Narcolepsy (initial): Dx of narcolepsy as confirmed by sleep study (unless prescriber provides justification confirming that a sleep study is not feasible).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

OSAHS (Initial): 3 months (Reauth): 12 months. SWSD (Initial, Reauth): 3 months. Other:12 months

**OTHER CRITERIA**

OSAHS (Reauth): Documentation of positive clinical response to prior therapy. SWSD (Reauth): Documentation of positive clinical response to prior therapy. Patient still requires treatment for SWSD. Narcolepsy (reauth): Documentation of positive clinical response to prior therapy.

## **NUZYRA**

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### **MEDICATION(S)**

NUZYRA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Nuzyra tablets: Community-Acquired Bacterial Pneumonia (CABP) Diagnosis: CABP caused by designated susceptible microorganisms, AND patient has had T/F or CI or is not a good candidate for at least two of the following available treatment options 1. appropriate beta-lactam (i.e. ceftriaxone, cefotaxime, ertapenem, ampicillin/sulbactam) in combination with a macrolide (i.e. azithromycin, clarithromycin) or doxycycline, or 2. monotherapy with a respiratory fluoroquinolone (i.e. levofloxacin). Acute Bacterial Skin and Skin Structure Infections (ABSSSI) Diagnosis: ABSSSI caused by designated susceptible microorganisms, AND patient has had T/F or CI or is not a good candidate for at least two of the following treatment options: vancomycin, linezolid, doxycycline, trimethoprim/sulfamethoxazole. Nuzyra vials: Patient-specific, clinically significant reason why the member cannot use the oral tablet formulation.

### **AGE RESTRICTION**

Age 18 years of age or greater.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

14 days

### **OTHER CRITERIA**

N/A

## **OCALIVA**

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### **MEDICATION(S)**

OCALIVA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Individual has a diagnosis of primary biliary cholangitis (PBC) as confirmed by TWO of the following (Lindor, 2009): a) Elevated alkaline phosphatase. b) Positive antimitochondrial antibodies (AMA) titer. C) Liver biopsy with findings consistent with PBC.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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 Ocaliva therapy) while on Ocaliva therapy.

# **OCREVUS**

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## **MEDICATION(S)**

OCREVUS

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Diagnosis of hepatitis B virus infection or hepatitis C virus infection or another active infection at initiation of therapy OR History of life-threatening infusion reaction of ocrelizumab OR treating systemic lupus erythematosus or rheumatoid arthritis OR concurrent use with other MS disease modifying agents.

## **REQUIRED MEDICAL INFORMATION**

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that patient has met all approval criteria. Patient must have ONE of the following: 1. Relapsing Multiple Sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease AND patient has had failure (ineffective response due to continued clinical relapse) of two or more formulary MS drugs (e.g. Copaxone/Glatopa (glatiramer), Aubagio, Gilenya, Mayzent, Tecfidera, Avonex, betaseron, Rebif, Plegridy) up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced . 2. Primary Progressive Multiple Sclerosis (PPMS).

## **AGE RESTRICTION**

Patient must be 18 years of age or older.

## **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist.

## **COVERAGE DURATION**

Initial: 6 mths Reauth Criteria: Slow of dx progress, stable (no dec in EDSS or MRI): 6 mths

## **OTHER CRITERIA**

N/A





## **ODACTRA**

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### **MEDICATION(S)**

ODACTRA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Drug is being used as immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis. Clinical notes submitted provide that diagnosis has been confirmed by in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* HDMs, or skin testing to licensed HDM allergen extracts. First dose will be administered in a healthcare setting with supervision by professional experienced in treatment of allergic diseases and will be monitored for signs or symptoms of severe systemic or severe local allergic reaction for at least 20 to 30 minutes. Patient has a history of failure, contraindication, or intolerance to at least two drugs from any of the following drug classes: intranasal antihistamine, intranasal corticosteroid, leukotriene inhibitor, oral antihistamine. Patient has been prescribed auto-injectable epinephrine.

### **AGE RESTRICTION**

Patient must be at least 18 years of age or older and at most 65 years of age or younger.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a professional experienced in the treatment of allergic diseases (Allergist or Immunologist).

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

N/A

## **ODOMZO**

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### **MEDICATION(S)**

ODOMZO

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist or dermatologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **OFEV**

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### **MEDICATION(S)**

OFEV

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Idiopathic pulmonary fibrosis (IPF): 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. Chronic fibrosing interstitial lung diseases with a progressive phenotype: Diagnosis of chronic fibrosing interstitial lung diseases (ILD) with a progressive phenotype. Systemic sclerosis-associated interstitial lung disease: Diagnosis of systemic sclerosis-associated ILD to slow the rate of decline in pulmonary function.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

IPF (initial): Prescribed by a pulmonologist

### **COVERAGE DURATION**

Initial, reauth: 12 months

### **OTHER CRITERIA**

IPF (reauth): Documentation of positive clinical response to Ofev therapy.

## **OLUMIANT**

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### **MEDICATION(S)**

OLUMIANT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Must not be used in combination with other JAK inhibitors (such as Xeljanz), biologic drugs (such as but not limited to, TNF agents, anti-CD20 monoclonal antibodies, IL-1R antagonists, selective co-stimulation modulators) or potent immunosuppressants (such as azathioprine and cyclosporine).

### **REQUIRED MEDICAL INFORMATION**

For moderate to severe RA, patient has had a T/F, CI to Enbrel(etanercept) AND Humira(adalimumab) OR for continuation of prior baricitinib therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a rheumatologist.

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

N/A

## **ONCASPAR**

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### **MEDICATION(S)**

ONCASPAR

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

History of serious thrombosis with prior L-asparaginase therapy. History of pancreatitis with prior L-asparaginase therapy. History of serious hemorrhagic events with prior L-asparaginase therapy.

### **REQUIRED MEDICAL INFORMATION**

Patient is using Oncaspar as a component of a multi-agent chemotherapeutic regimen AND is using for Acute lymphoblastic lymphoma or acute lymphocytic leukemia (ALL) or Extranodal natural killer T-cell lymphoma, nasal type (ENKL).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist/oncologist.

### **COVERAGE DURATION**

Initial and Reauth: 6 months.

### **OTHER CRITERIA**

N/A

## **ONGENTYS**

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### **MEDICATION(S)**

ONGENTYS

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis is Parkinsons disease. Patient is experiencing off episodes. Drug will be given as adjunctive treatment to levodopa/carbidopa. Patient has tried and failed entacapone tablet.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

Initial and Reauth: 6 months.

### **OTHER CRITERIA**

N/A

## **ONMEL**

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### **MEDICATION(S)**

ONMEL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

All of the following: 1) Diagnosis of onychomycosis of the toenail as confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, AND 2) patient condition is causing debility or a disruption in their activities of daily living, AND 3) patient has had a trial and inadequate response, intolerance or hypersensitivity to oral terbinafine.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 months

### **OTHER CRITERIA**

N/A



## **ONUREG**

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### **MEDICATION(S)**

ONUREG

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For the continued treatment of adult patients with acute myeloid leukemia (AML) who achieved first complete remission (CR) or CR with incomplete blood count recovery (CRi) following intensive induction chemotherapy and who are not able to complete intensive curative therapy.

### **AGE RESTRICTION**

Must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by an oncologist.

### **COVERAGE DURATION**

Initial: 6mths. Reauth: 6 months

### **OTHER CRITERIA**

For Reauth: Patient demonstrates disease response with treatment as defined by stabilization of disease or improvement as evidenced by a complete response (CR) (e.g. morphologic, cytogenic, or molecular CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, quantitative polymerase chain reaction (QPCR), or fluorescence in situ hybridization (FISH).

## **OPDIVO**

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### **MEDICATION(S)**

OPDIVO 100 MG/10 ML VIAL, OPDIVO 240 MG/24 ML VIAL, OPDIVO 40 MG/4 ML VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Dx: In combination with chemotherapy for: (1) the neoadjuvant treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer (2) the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence. In combination with docetaxel for the treatment of adult patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial: 6 mths. Reauth: 6 mths (maximum total tx time 1 yr).

### **OTHER CRITERIA**

N/A

## **OPSUMIT**

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### **MEDICATION(S)**

OPSUMIT

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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.

## **ORENCIA IV**

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### **MEDICATION(S)**

ORENCIA 250 MG VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Must not be used in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Orencia in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

### **REQUIRED MEDICAL INFORMATION**

For RA, patient has had an inadequate response to ONE conventional therapy [non-biologic DMARD (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] or a tumor necrosis factor (TNF) antagonist AND has TF/C/I to Humira (adalimumab) AND Enbrel (etanercept). For PsA, patient has had an inadequate response to ONE conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, or leflunomide)] or a tumor necrosis factor antagonist AND has had a TF/C/I to Humira (adalimumab) AND Enbrel (etanercept) AND Cosentyx (Secukinumab). For JIA, patient has had an inadequate response to, is intolerant of, or has a contraindication to ONE conventional Therapy [non-biologic DMARD such as methotrexate] AND has had a TF/C/I to Humira (adalimumab) AND Enbrel (etanercept) OR for continuation of prior Orencia IV therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a rheumatologist or a dermatologist.

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

N/A



## **ORENCIA SC**

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### **MEDICATION(S)**

ORENCIA 125 MG/ML SYRINGE, ORENCIA 50 MG/0.4 ML SYRINGE, ORENCIA 87.5 MG/0.7 ML SYRINGE, ORENCIA CLICKJECT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Must not be used in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Orencia in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

### **REQUIRED MEDICAL INFORMATION**

For RA, patient has had TF/C/I to Humira (adalimumab) AND Enbrel (etanercept). For PsA, patient has had TF/C/I to Humira (adalimumab) AND Enbrel (etanercept) . For JIA, patient has had TF/C/I to Humira (adalimumab) AND Enbrel (etanercept) OR for continuation of prior Orencia SC therapy OR prior maintenance therapy of at least 4 weeks with Orencia IV. .

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a rheumatologist or a dermatologist.

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

N/A

## **ORENITRAM**

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### **MEDICATION(S)**

ORENITRAM ER

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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**

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### **MEDICATION(S)**

ORGOVYX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has androgen-sensitive advanced prostate cancer AND patient must have T/F and or have a CI to one GnRH antagonist (degarelix, Firmagon) or one GnRH agonist (leuprolide, Lupron, Eligard, triptorelin, Trelstar).

### **AGE RESTRICTION**

Patient is 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an urologist or an oncologist.

### **COVERAGE DURATION**

Initial and Reauth: 6 months.

### **OTHER CRITERIA**

N/A



## **ORKAMBI**

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### **MEDICATION(S)**

ORKAMBI

### **PA INDICATION INDICATOR**

3 - 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. The presence of the mutation was documented by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments-approved facility.

### **AGE RESTRICTION**

CF (Initial): Patient is 2 years of age or older

### **PRESCRIBER RESTRICTION**

CF (Initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or a 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)

## **OSMOLEX ER**

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### **MEDICATION(S)**

OSMOLEX ER 129 MG TABLET, OSMOLEX ER 193 MG TABLET, OSMOLEX ER 258 MG TABLET

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient must have a diagnosis of Parkinson Disease and is experiencing drug-induced extrapyramidal symptoms. Patient must have trial and failure of use of at least TWO generically available immediate-release formulations of amantadine (e..g. AMANTADINE 100 MG CAPSULE, AMANTADINE 100 MG TABLET, AMANTADINE 50 MG/5 ML SOLUTION, AMANTADINE 100 MG/10 ML SOLN).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **OTEZLA**

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### **MEDICATION(S)**

OTEZLA 28 DAY STARTER PACK, OTEZLA 30 MG TABLET

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For Psoriatic Arthritis (PsA), patient has had TF/C/I to: Humira (adalimumab) AND Enbrel (etanercept).  
For plaque psoriasis (Ps), patient has had TF/C/I to: 1. Humira (adalimumab) OR Enbrel (etanercept)  
AND 2. Cosentyx (Secukinumab), OR for continuation of prior Otezla (premilast) therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a rheumatologist or a dermatologist.

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

N/A

## **OXANDRIN**

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### **MEDICATION(S)**

OXANDROLONE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Promote weight gain (initial): Medication will be used as an adjunct therapy to promote weight gain AND One of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons. Counterbalance protein catabolism (initial): Oxandrin will be used to counterbalance protein catabolism associated with chronic corticosteroid administration. Bone pain (initial): Diagnosis of bone pain associated with osteoporosis.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

bone pain (initial, reauth): 1 month. Others (initial, reauth): 3 months

### **OTHER CRITERIA**

All diagnoses (reauth): patient has experienced an objective improvement (i.e. weight gain, increase in lean body mass, or reduction in muscle pain/weakness)

## **OXERVATE**

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### **MEDICATION(S)**

OXERVATE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis Neurotrophic Keratitis.

### **AGE RESTRICTION**

Greater than or equal to 2 years.

### **PRESCRIBER RESTRICTION**

Must be prescribed by an ophthalmologist

### **COVERAGE DURATION**

Initial: 8 weeks. Re Auth: Documentation supports positive response to therapy Duration 8 weeks

### **OTHER CRITERIA**

N/A

## **OXLUMO**

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### **MEDICATION(S)**

OXLUMO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a nephrologist or urologist.

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

N/A

## **PADCEV**

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### **MEDICATION(S)**

PADCEV

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of locally advanced or metastatic urothelial cancer in adults who have previously received a programmed death receptor-1 or programmed death-ligand 1 inhibitor (eg Keytruda, Opdivo, Bavencio, Imfinzi, Tecentriq), and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

Initial and Reauth: 12 months

### **OTHER CRITERIA**

N/A

## **PALYNZIK**

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### **MEDICATION(S)**

PALYNZIQ

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Labs showing uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 YEAR

### **OTHER CRITERIA**

N/A



## PART D VS PART B

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### MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10% VIAL, ACETYLCYSTEINE 20% VIAL, ACYCLOVIR 1,000 MG/20 ML VIAL, ACYCLOVIR 500 MG/10 ML VIAL, ALBUTEROL 100 MG/20 ML SOLN, ALBUTEROL 15 MG/3 ML SOLUTION, ALBUTEROL 2.5 MG/0.5 ML SOL, ALBUTEROL 20 MG/4 ML SOLUTION, ALBUTEROL 5 MG/ML SOLUTION, ALBUTEROL SUL 0.63 MG/3 ML SOL, ALBUTEROL SUL 1.25 MG/3 ML SOL, ALBUTEROL SUL 2.5 MG/3 ML SOLN, AMBISOME, AMINOSYN II 10% IV SOLUTION, AMINOSYN II 7% IV SOLUTION, AMINOSYN WITH ELECTROLYTES, AMINOSYN-HBC, AMINOSYN-PF, AMINOSYN-RF, AMPHOTERICIN B, APREPITANT, ARFORMOTEROL TARTRATE, ASTAGRAF XL, AZASAN, AZATHIOPRINE 50 MG TABLET, BETHKIS, BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CINACALCET HCL, CLINIMIX 4.25%-10% SOLUTION, CLINIMIX 4.25%-20% SOLUTION, CLINIMIX 4.25%-25% SOLUTION, CLINIMIX 4.25%-5% SOLUTION, CLINIMIX 5%-15% SOLUTION, CLINIMIX 5%-25% SOLUTION, CLINIMIX E 2.75%-10% SOLUTION, CLINIMIX E 2.75%-5% SOLUTION, CLINIMIX E 4.25%-10% SOLUTION, CLINIMIX E 4.25%-25% SOLUTION, CLINIMIX E 4.25%-5% SOLUTION, CLINIMIX E 5%-15% SOLUTION, CLINIMIX E 5%-20% SOLUTION, CLINIMIX E 5%-25% SOLUTION, CROMOLYN 20 MG/2 ML NEB SOLN, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 25 MG TABLET, CYCLOPHOSPHAMIDE 50 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG TABLET, CYCLOSPORINE, CYCLOSPORINE MODIFIED, EMEND 125 MG POWDER PACKET, ENGERIX-B 20 MCG/ML SYRN, ENGERIX-B PEDIATRIC-ADOLESCENT, FLUOROURACIL 1 GRAM/20 ML VIAL, FLUOROURACIL 2.5 GRAM/50 ML VL, FLUOROURACIL 5 GRAM/100 ML VL, FLUOROURACIL 500 MG/10 ML VIAL, FORMOTEROL FUMARATE, FREAMINE HBC, GENGRAF, GRANISETRON HCL 1 MG TABLET, HEPARIN 10,000 UNIT/10 ML VIAL, HEPARIN 30,000 UNIT/30 ML VIAL, HEPARIN 50,000 UNIT/10 ML VIAL, HEPARIN SOD 1,000 UNIT/ML VIAL, HEPARIN SOD 20,000 UNIT/ML VL, HEPARIN SOD 5,000 UNIT/ML VIAL, HEPATAMINE, IMOVAX RABIES VACCINE, INTRALIPID 20% IV FAT EMUL, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, LEVALBUTEROL CONCENTRATE, LEVALBUTEROL HCL, MIACALCIN, MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLATE 500 MG VIAL, MYCOPHENOLIC ACID, NEPHRAMINE, NUTRILIPID, ONDANSETRON 4 MG/5 ML SOLUTION, ONDANSETRON HCL 24 MG TABLET, ONDANSETRON HCL 4 MG TABLET, ONDANSETRON HCL 8 MG TABLET, ONDANSETRON ODT, PAMIDRONATE 30 MG/10 ML VIAL, PAMIDRONATE 60 MG/10 ML VIAL, PAMIDRONATE 90 MG/10 ML VIAL, PARICALCITOL 1 MCG CAPSULE, PARICALCITOL 2 MCG CAPSULE, PARICALCITOL 4 MCG CAPSULE, PENTAMIDINE 300 MG INHAL POWDR, PREMASOL 10% IV SOLUTION, PROCALAMINE, PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 1 MG GRANULE PACKET, PROGRAF 5 MG/ML AMPULE, PROSOL,

RABAVERT, RECOMBIVAX HB 10 MCG/ML SYR, RECOMBIVAX HB 10 MCG/ML VIAL, RECOMBIVAX HB 40 MCG/ML VIAL, RECOMBIVAX HB 5 MCG/0.5 ML SYR, SIROLIMUS 0.5 MG TABLET, SIROLIMUS 1 MG TABLET, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TABLET, TACROLIMUS 0.5 MG CAPSULE (IR), TACROLIMUS 1 MG CAPSULE (IR), TACROLIMUS 5 MG CAPSULE (IR), TOBRAMYCIN 300 MG/4 ML AMPULE, TOBRAMYCIN 300 MG/5 ML AMPULE, TRAVASOL, TREANDA 100 MG VIAL, TRIMETHOBENZAMIDE HCL, TROPHAMINE 10% IV SOLUTION

## **DETAILS**

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

## **PEGASYS**

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### **MEDICATION(S)**

PEGASYS, PEGASYS PROCLICK

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

HepB: 48 wks. HepC: Initial: 28 wks. Reauth: 20 wks.

### **OTHER CRITERIA**

N/A

## **PEMAZYRE**

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### **MEDICATION(S)**

PEMAZYRE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For the treatment of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma in adults with a fibroblast growth factor receptor 2 fusion or other rearrangement. Must provide documentation of detection by an FDA-approved test.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial: 6 months Reauth: 12 months with positive response.

### **OTHER CRITERIA**

N/A

## **PENNSAID**

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### **MEDICATION(S)**

PENNSAID

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Initial, reauth: History of severe allergic-type reactions after taking aspirin or other non-steroidal anti-inflammatory (NSAIDs), including urticaria and asthma (aspirin-sensitive asthma).

### **REQUIRED MEDICAL INFORMATION**

Osteoarthritis of the knees (initial): Diagnosis of osteoarthritis of the knees and diclofenac will not be used in the treatment of peri-operative pain in the setting of coronary artery bypass graft surgery AND Patient must have tried and failed diclofenac sodium 1.5 % transdermal solution AND diclofenac sodium 1% gel.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial 3 months, reauth: 6 months

### **OTHER CRITERIA**

Osteoarthritis of the knees (reauth): Patient has experienced a response to therapy (e.g., improvement in pain symptoms of osteoarthritis).

## **PEPAXTO**

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### **MEDICATION(S)**

PEPAXTO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Not indicated and not recommended for use as a conditioning regimen for transplant outside of controlled clinical trials

### **REQUIRED MEDICAL INFORMATION**

In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody.

### **AGE RESTRICTION**

Patient is 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist or hematologist.

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

N/A

## **PERJETA**

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### **MEDICATION(S)**

PERJETA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Metastatic breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer. One of the following: a) patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease AND used in combination with Herceptin (trastuzumab) and a taxane (eg, docetaxel, paclitaxel), OR b) patient was previously treated with chemotherapy and Herceptin (trastuzumab) without Perjeta AND used in combination with Herceptin (trastuzumab). Non-metastatic breast cancer: One of the following diagnoses: HER2-positive early stage breast cancer, HER2-positive locally advanced breast cancer, or HER2-positive inflammatory breast cancer. Used in combination with both Herceptin (trastuzumab) and a taxane (eg, docetaxel, paclitaxel).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All Uses: Prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **PHESGO**

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### **MEDICATION(S)**

PHESGO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patient did NOT receive prior allogeneic hematopoietic stem cell transplantation (HSCT).

### **REQUIRED MEDICAL INFORMATION**

Patient has mantle cell lymphoma (MCL) that is relapsed or refractory disease AND Patient has a greater than or equal to measurable MCL lesion AND Patient must have received previous systemic therapy which included 1 or more agents from each of the following categories for MCL: Bruton tyrosine kinase (BTK) inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib) AND Anti-CD20 monoclonal antibody (e.g., rituximab) AND Anthracycline OR Bendamustine-containing chemotherapy.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist/hematologist.

### **COVERAGE DURATION**

Initial: 1 treatment course (1 dose), Reauth: n/a

### **OTHER CRITERIA**

N/A



## **POLIVY**

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### **MEDICATION(S)**

POLIVY 140 MG VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (in combination with bendamustine and a rituximab product) not otherwise specified, after at least two prior therapies.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by an oncologist or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **POMALYST**

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### **MEDICATION(S)**

POMALYST

### **PA INDICATION INDICATOR**

3 - 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. Patient has received two prior therapies, including Revlimid (lenalidomide) and a proteasome inhibitor [eg, Velcade (bortezomib) or Kyprolis (carfilzomib)] or has a contraindication or intolerance to Revlimid and proteasome inhibitors. Patient has experienced disease progression on or within 60 days of completion of last therapy. Kaposi sarcoma (KS): Diagnosis of KS. Treatment of AIDS-related Kaposi sarcoma in adults after failure of highly active antiretroviral therapy (HAART). Treatment of Kaposi sarcoma in HIV-negative adults.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist/hematologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **PORTRAZZA**

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### **MEDICATION(S)**

PORTRAZZA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Not indicated for treatment of non-squamous NSCLC

### **REQUIRED MEDICAL INFORMATION**

First-line treatment of metastatic squamous non-small cell lung cancer (NSCLC) in combination with gemcitabine and cisplatin.

### **AGE RESTRICTION**

Patient is 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist or hematologist.

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

N/A

## **PRALUENT**

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### **MEDICATION(S)**

PRALUENT PEN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Submission of medical records (eg, chart notes, laboratory values) documenting one of the following diagnoses: 1) Primary Hyperlipidemia (PH), including heterozygous familial hyperlipidemia (HeFH): Initial Authorization: as adjunctive therapy to maximally tolerated high intensity statin therapy (e.g. atorvastatin or rosuvastatin) in members that have failed to achieve goal LDLC reduction OR The member is determined to have statin associated muscle symptoms or myalgias that have included rhabdomyolysis OR Member has failed to achieve goal LDLC reduction because of statin associated muscle symptoms or myalgias despite both lowering of statin strength AND attempting a different statin. Reauthorization: maintenance of a reduction in LDLC from baseline. Requires submission of medical records (eg, laboratory values) documenting a sustained LDLC reduction from pre-treatment baseline (ie, prior to Praluent therapy) while on Praluent therapy. 2) Clinical Atherosclerotic Cardiovascular Disease (ASCVD): Initial Authorization. The member must have documentation of ASCVD (as confirmed by e.g. acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack or peripheral arterial disease, all of presumed atherosclerotic origin). Reauthorization: Maintenance of a reduction in LDLC from baseline. Requires submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior to Praluent therapy) while on Praluent therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Initial, reauth: Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist

**COVERAGE DURATION**

Initial: 6 months. Reauth: 12 months

**OTHER CRITERIA**

One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: (1) LDL-C greater than or equal to 70 mg/dL with ASCVD. (2) LDL-C greater than or equal to 100 mg/dL without ASCVD. Initial, reauth: Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.

## **PRETOMANID**

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### **MEDICATION(S)**

PRETOMANID

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Not indicated for drug-sensitive tuberculosis, latent infection due to *Mycobacterium tuberculosis*, or multidrug-resistant TB that is not treatment-intolerant or nonresponsive to standard therapy. Must be used in combination with bedaquiline and linezolid.

### **AGE RESTRICTION**

Patient must be 18 years of age or greater.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

6 months

### **OTHER CRITERIA**

N/A

## **PREVYMIS**

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### **MEDICATION(S)**

PREVYMIS

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant administration with pimozide or ergot alkaloids, concomitant administration with pitavastatin and simvastatin when coadministered with cyclosporine.

### **REQUIRED MEDICAL INFORMATION**

Cytomegalovirus (prophylaxis): Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

4 months

### **OTHER CRITERIA**

N/A

## **PROCYSBI**

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### **MEDICATION(S)**

PROCYSBI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Nephropathic cystinosis: Diagnosis of nephropathic cystinosis, confirmed by elevated leukocyte cystine levels (LCL) or genetic analysis of the CTNS gene AND Trial and failure or intolerance to therapy with Cystagon (immediate-release cysteamine bitartrate).

### **AGE RESTRICTION**

Patient must be 1 year of age or older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A



## **PROLIA**

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### **MEDICATION(S)**

PROLIA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Postmenopausal osteoporosis (PMO) (initial): Diagnosis (dx) of PMO. History (hx) of vertebral compression fractures (fx), or fx of the hip, or distal radius resulting from minimal trauma, or bone mineral density score (BMD) indicative of osteoporosis (OP): T-score less than or equal to -2.5 (2.5 standard deviations [SD] or greater below the mean for young adults). PMO, prophylaxis (initial): For prevention of PMO. BMD scan indicative of osteopenia: T-score -1.0 to -2.5. Nonmetastatic prostate cancer (NMPC) bone loss (initial): Dx of NMPC. Pt is 70 years or older, or less than 70 years old with BMD T-score below -1.0 (1.0 SD or greater below the mean for young adults) or hx of vertebral compression fx or fx of the hip or distal radius resulting from minimal trauma. NMPC (reauth): No evidence of metastases. Breast cancer (BC) bone loss (initial): Dx of BC. BMD T-score below -1.0 (1.0 SD or greater below the mean for young adults) or hx of vertebral compression fx or fx of the hip or distal radius resulting from minimal trauma. OP in men (initial): Pt is a male with OP. Hx of vertebral compression fx or fx of the hip or distal radius resulting from minimal trauma, or BMD indicative of OP: T-score less than or equal to -2.0 (2.0 SD or greater below the mean for young adults). Treatment of glucocorticoid-induced osteoporosis in patients at high risk of fracture who are initiating or continuing systemic glucocorticoids at a daily dose equivalent to 7.5 mg of prednisone for an anticipated duration of at least 6 months (high risk defined as osteoporotic fracture history, multiple risk factors for fracture, or failure of or intolerance to other available osteoporosis therapy).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

All uses (initial, reauth): 12 months

**OTHER CRITERIA**

NMPC bone loss (initial and reauth): Receiving androgen deprivation therapy (ADT) from luteinizing hormone/gonadotropin releasing hormone (LHRH/GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), Zoladex (goserelin)] or bilateral orchiectomy (i.e., surgical castration). BC bone loss (initial and reauth): Pt is receiving aromatase inhibitor (AI) therapy [e.g., Arimidex (anastrozole), Aromasin (exemestane), Femara (letrozole)]. All indications except NMPC (initial): One of the following A) Patient has a documented trial and therapeutic failure with a bisphosphonate, where therapeutic failure is defined as new fractures in compliant patients on therapy for at least 6 months, failure to produce a clinically significant change in a biochemical marker(s) of bone turnover, or significant loss of bone mineral density on follow-up scans after 12 to 24 months of therapy or B) Patient has a documented contraindication or intolerance to bisphosphonate therapy, or is unable to comply with appropriate administration recommendations for oral or injectable bisphosphonate therapy. All indications (renewal): The patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, or improved biochemical markers, etc.)

## **PROMACTA**

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### **MEDICATION(S)**

PROMACTA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Chronic immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of relapsed/refractory chronic ITP for greater than 6 months. Baseline platelet count is less than 50,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. One of the following: A) Trial and failure, intolerance, contraindication to corticosteroids or immune globulin OR B) Trial and failure or contraindication to splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C. Patient has thrombocytopenia defined as platelets less than 90,000/mcL for initiation (pre-treatment) of interferon therapy. Diagnosis of Severe aplastic anemia (initial): Patient has a platelet count less than 30,000/mcL. 1. First-line treatment (in combination with standard immunosuppressive therapy) of severe aplastic anemia in patients greater than or equal to 2 years of age, or 2. treatment of severe (refractory) aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy. Trial and failure, intolerance, or contraindication to immunosuppressive therapy with antithymocyte globulin and cyclosporine.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

ITP (init, reauth): 12mo. HepC: 9wks (init), 24wks (reauth). Aplas anemia (init, reauth): 16wks.

### **OTHER CRITERIA**

ITP (reauth): After at least 4 weeks of therapy at the maximum weekly dose (10 mcg/kg), the platelet count increased to a sufficient level to avoid clinically important bleeding. Hepatitis C (reauth): Platelets less than 75,000/mcL for maintenance of optimal interferon-based therapy. Aplastic anemia (reauth): Patient has experienced an increase in platelet count.

## **PROVIGIL**

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### **MEDICATION(S)**

MODAFINIL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Obstructive sleep apnea/hypopnea syndrome (OSAHS) (Initial): Diagnosis (dx) of OSAHS defined by one of the following: 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), and 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work sleep disorder (SWSD) (Initial): Dx of SWSD confirmed by 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 sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). No other medical condition or medication accounts for the symptoms. Narcolepsy (initial): Dx of narcolepsy as confirmed by 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.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

OSAHS/MS/dep(init), SWSD (init,reauth): 3 mo.OSAHS/dep(reauth): 12mo. MS (reauth): 6mo. Other: 12mo

**OTHER CRITERIA**

OSAHS (Reauth): Documentation of positive clinical response to prior therapy. SWSD (Reauth):

Documentation of positive clinical response to prior therapy. Patient still requires treatment for SWSD.

Narcolepsy (reauth): Documentation of positive clinical response to prior therapy. MS Fatigue (reauth):

Patient is experiencing relief of fatigue with modafinil therapy. Idiopathic Hypersomnia (reauth):

Documentation of positive clinical response to modafinil therapy. Depression (reauth): Documentation of positive clinical response to modafinil therapy. Used as adjunctive therapy.

## **PULMOZYME**

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### **MEDICATION(S)**

PULMOZYME

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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).

## **QINLOCK**

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### **MEDICATION(S)**

QINLOCK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Gastrointestinal stromal tumor, advanced. Treatment of advanced GIST in adults who have previously received treatment with 3 or more kinase inhibitors, including imatinib.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A



## **QUALAQUIN**

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### **MEDICATION(S)**

QUININE SULFATE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **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. Not used for the treatment or prevention of nocturnal leg cramps.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

7 days

### **OTHER CRITERIA**

N/A

## **RASUVO- METHOTREXATE SC AUTOINJECTOR**

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### **MEDICATION(S)**

RASUVO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA) and have had T/F or CI to methotrexate oral tablets AND intramuscular methotrexate injectable vial. 2. Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are intolerant of/have a contraindication to or have had T/F or CI to methotrexate oral tablets AND methotrexate injectable prefilled syringe (pf) (REDITREX) OR for continuation of Rasuvo therapy.

### **AGE RESTRICTION**

Must be 18 year of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a rheumatologist or dermatologist.

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

N/A

## **RAVICTI**

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### **MEDICATION(S)**

RAVICTI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Urea cycle disorders (UCDs) (Initial): Diagnosis of UCDs.

### **AGE RESTRICTION**

UCDs (Initial): 2 months of age and older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

UCDs (Initial, reauth): 12 months

### **OTHER CRITERIA**

UCDs (reauth): Documentation of positive clinical response to Ravicti therapy.

## **RAYALDEE**

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### **MEDICATION(S)**

RAYALDEE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Rayaldee is not indicated for the treatment of secondary hyperparathyroidism in patients with stage 5 chronic kidney disease or in patients with end-stage renal disease on dialysis.

### **REQUIRED MEDICAL INFORMATION**

Initial Authorization: Diagnosis of secondary hyperparathyroidism AND the patient has Stage 3 or 4 chronic kidney disease AND the patient has a serum total 25-hydroxyvitamin D level less than 30ng/mL AND the patient's most recent serum calcium level is less than 9.8 mg/dL AND the patient has had previous treatment, intolerance, or contraindication to TWO generic vitamin D analogs (i.e. calcitriol, paricalcitol, or doxercalciferol). ReAuthorization: Intact PTH is NOT persistently abnormally low AND serum calcium is consistently within the normal limits AND serum 25-hydroxyvitamin D is NOT consistently greater than 100 ng/mL.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a nephrologist.

### **COVERAGE DURATION**

Initial Authorization: 3 months. ReAuth: 12 months

### **OTHER CRITERIA**

N/A

## **REBLOZYL**

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### **MEDICATION(S)**

REBLOZYL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Adults patient with anemia of beta thalassemia who require regular red blood cell (RBC) transfusions.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist.

### **COVERAGE DURATION**

6 months

### **OTHER CRITERIA**

N/A

## **REDITREX- METHOTREXATE INJ PREFILLED SYR (PF)**

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### **MEDICATION(S)**

REDITREX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA) and have had T/F or CI to methotrexate oral tablets AND intramuscular methotrexate injectable vial. 2. Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are intolerant of/have a contraindication to or have had T/F or CI to methotrexate oral tablets AND intramuscular methotrexate injectable vial OR for continuation of Reditrex therapy.

### **AGE RESTRICTION**

Must be 18 year of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a rheumatologist or dermatologist.

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

N/A

## **REGRANEX**

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### **MEDICATION(S)**

REGRANEX

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

5 months

### **OTHER CRITERIA**

N/A

## **RELISTOR**

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### **MEDICATION(S)**

RELISTOR 12 MG/0.6 ML SYRINGE, RELISTOR 12 MG/0.6 ML VIAL, RELISTOR 8 MG/0.4 ML SYRINGE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Opioid-induced constipation (OIC) (Initial): Diagnosis of OIC. Patient has used opioid medication for a minimum of 4 weeks. Patient is experiencing fewer than 3 bowel movements in a week or no bowel movement for longer than 2 days. One of the following: A) Patient is an adult with a diagnosis of chronic non-cancer pain AND patient had a trial and failure, contraindication, or intolerance to Amitiza (lubiprostone), OR B) Patient is receiving palliative care for an advanced illness.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

OIC (initial, reauth): 4 months

### **OTHER CRITERIA**

OIC (Reauth): Diagnosis of OIC. One of the following: A) Patient is an adult with a diagnosis of chronic non-cancer pain, OR B) Both of the following: Patient is receiving palliative care for an advanced illness AND Patient has responded to therapy (e.g., increase in bowel movements).



## REMODULIN

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### MEDICATION(S)

TREPROSTINIL

### PA INDICATION INDICATOR

3 - 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 RESTRICTION

N/A

### PRESCRIBER RESTRICTION

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.

## **RENFLEXIS**

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### **MEDICATION(S)**

RENFLEXIS

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Dx of moderately to severely active CD or FCD. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. Rheumatoid arthritis (RA) (initial): Diagnosis (Dx) of moderately to severely active RA. Ankylosing spondylitis (AS) (initial): Dx of active AS. Psoriatic arthritis (PsA) (initial): Dx of active PsA. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. CD, FCD (initial): Trial and failure, contraindication or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). UC (initial): TF/C/I to one of the following conventional therapies: corticosteroids, aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine/Sulfazine)], azathioprine (Imuran), 6-mercaptopurine (Purinethol). RA (initial): Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), or TF/C/I to methotrexate. AS (initial): TF/C/I to two or more NSAIDs. All indications (Initial): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

RA, AS: Prescribed or recommended by a rheumatologist. PsA: Prescribed or recommended by rheumatologist or dermatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed or recommended by a gastroenterologist. Plaque Psoriasis: Prescribed or recommended by a

dermatologist

**COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

**OTHER CRITERIA**

Reauthorization for all indications: Documentation of positive clinical response to infliximab therapy. All indications (re-auth): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

## **REPATHA**

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### **MEDICATION(S)**

REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Submission of medical records (chart, labs) w/ one of the following dx: 1) Primary Hyperlipidemia (PH), including heterozygous familial hyperlipidemia (HeFH): Initial Auth: as adjunctive treatment to max tolerated high intensity statin therapy in members who have failed to achieve goal LDL-C reduction OR had statin-associated myalgias (SAMs) that have included rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of SAMs despite both lowering of statin strength AND attempting a different statin. 2) Homozygous familial hypercholesterolemia (HoFH): defined by at least one of the following: Genetic confirmation of 2 mutant alleles at the LDL receptor, alleles at the LDL receptor, ApoB, PCSK9, or ARH adaptor protein gene locus OR an untx LDL-C greater than 500 mg/dL (13 mmol/L) or tx LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) or tx non-HDL cholesterol greater than or equal to 330 mg/dL (8.5 mmol/L) w/ at least one of the following: Cutaneous or tendon xanthoma before age 10 yrs OR Elevated LDL cholesterol levels before lipid lowering consistent w/ HeFH in both parents [untx total cholesterol greater than 290 mg/dL (7.5 mmol/L) or untx LDL-C greater than 190 mg/dL (4.9 mmol/L)]. Initial Auth: as adj. therapy to max tolerated high intensity statin therapy in members who have failed to achieve goal LDL-C reduction OR had SAMs that have included rhabdomyolysis OR has failed to achieve goal LDL-C reduction because of SAMs despite both lowering of statin strength AND attempting a diff statin. 3) Clinical Atherosclerotic Cardiovascular Disease (ASCVD): Initial Auth: documentation of ASCVD (as confirmed by e.g. acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA or PAD, all of presumed atherosclerotic origin). PH/HeFH/HoFH/ASCVD: Reauth: Maintenance of a reduction in LDL-C from baseline.

### **AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

HeFH/ASCVD/HoFH (init, reauth): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist

**COVERAGE DURATION**

PH/HeFH/ASCVD/HoFH (init): 6 mon. PH/HeFH/ASCVD/HoFH (reauth): 12 mon.

**OTHER CRITERIA**

PH/HeFH/ASCVD/HoFH (Initial, reauth): Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. HoFH (Initial, reauth): Not used in combination with Juxtapid (lomitapide) or Kynamro (mipomersen).

## **RETEVMO**

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### **MEDICATION(S)**

RETEVMO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

One of the following Diagnoses: 1) Non-small cell lung cancer (NSCLC), metastatic, advanced or metastatic RET fusion-positive, 2) advanced or metastatic RET-mutant medullary thyroid cancer (MTC) in patients who require systemic therapy, 3) advanced or metastatic RET fusion-positive thyroid cancer in patients who require systemic therapy and who are refractory to radioactive iodine (if radioactive iodine is appropriate).

### **AGE RESTRICTION**

Patient must be 12 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

## REVATIO

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### MEDICATION(S)

SILDENAFIL 10 MG/12.5 ML VIAL, SILDENAFIL 10 MG/ML ORAL SUSP, SILDENAFIL 20 MG TABLET

### PA INDICATION INDICATOR

3 - 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. For sildenafil oral suspension only (initial, reauth): One of the following: A) Intolerance to sildenafil 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 RESTRICTION

N/A

### PRESCRIBER RESTRICTION

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

## **REVLIMID**

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### **MEDICATION(S)**

REVLIMID

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Multiple myeloma (MM): Diagnosis of MM. Either used as 1) combination therapy with dexamethasone, or 2) maintenance therapy following autologous hematopoietic stem cell transplantation (auto-HSCT). Myelodysplastic syndromes (MDS): Patient has transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q (del 5q) cytogenetic abnormality with or without additional cytogenetic abnormalities. Mantle cell lymphoma (MCL): Diagnosis of MCL. Disease has relapsed, refractory, or progressed after at least one prior therapy (eg, bortezomib, bendamustine, cladribine, rituximab). Follicular lymphoma (previously treated): Treatment of previously treated follicular lymphoma (in combination with a rituximab product) in adults. Marginal zone lymphoma (previously treated): Treatment of previously treated marginal zone lymphoma (in combination with a rituximab product).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist/hematologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.



## **REZUROCK**

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### **MEDICATION(S)**

REZUROCK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Histologic relapse of underlying cancer or post-transplant lymphoproliferative disease

### **REQUIRED MEDICAL INFORMATION**

Patient has diagnosis of chronic graft-versus-host disease (cGVHD) AND Patient has failed at least 2 previous lines of systemic therapy for the treatment of cGVHD (e.g., corticosteroids and immunosuppressants such as prednisone, cyclosporine, tacrolimus, sirolimus, mycophenolate mofetil).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 6 months Reauth: 6months

### **OTHER CRITERIA**

Reauth: Patient continues to meet the initial criteria AND Patient has a response to therapy with an improvement in one or more of the following: Clinician assessments (e.g., NIH Skin Score, Upper GI Response Score, NIH Lung Symptom Score) AND/OR Patient-reported symptoms (e.g., Lee Symptom Scale).

## **RILUTEK**

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### **MEDICATION(S)**

RILUZOLE

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

ALS: 12 months

### **OTHER CRITERIA**

N/A

## **RITUXAN**

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### **MEDICATION(S)**

RIABNI, RITUXAN, RUXIENCE, TRUXIMA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Rheumatoid Arthritis (RA) (init): Patient is not receiving Rituxan (rituximab) in combination with a biologic DMARD [eg, Enbrel (etanercept), Orencia (abatacept), Kineret (anakinra)]. Patient is not receiving Rituxan (rituximab) in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

### **REQUIRED MEDICAL INFORMATION**

Non-Hodgkin's Lymphoma (NHL): As first-line treatment of diffuse large B-cell, CD20-positive, NHL in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens, or as first-line treatment of follicular, CD20-positive, B-cell NHL in combination with chemotherapy, or as a single-agent maintenance therapy for the treatment of follicular, CD20-positive, B-cell NHL in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, or for the treatment of low-grade, CD20-positive, B-cell NHL in patients with stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/prednisone) chemotherapy or who achieve a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/prednisone) chemotherapy, or diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma. Rheumatoid Arthritis (RA) (init): Concurrently on or contraindication, or intolerance to methotrexate. Trial and failure, contraindication, or intolerance (TF/C/I) to a TNF antagonist (eg, adalimumab, etanercept, infliximab). Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): Patient is concurrently on glucocorticoids (eg, prednisone) OR contraindication or intolerance to glucocorticoids (eg, prednisone). Immune or idiopathic thrombocytopenic purpura (ITP): TF/C/I to one of the following: corticosteroids, immunoglobulins, or splenectomy. Documented platelet count of less than  $50 \times 10^9 /L$ .

### **AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

ITP: Prescribed by or in consultation with a hematologist or oncologist. RA: Prescribed by or in consultation with a rheumatologist. WG, MPA: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist.

**COVERAGE DURATION**

All uses except RA, WG, MPA: 6 mos. RA: 3 months. WG, MPA: 3 months only.

**OTHER CRITERIA**

Approve for continuation of prior therapy. All Uses: Rituxan Brand will be approved after T/F with biosimilar Ruxience (rituximab-pvvr ).

## **ROZLYTREK**

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### **MEDICATION(S)**

ROZLYTREK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1 positive. Adult and pediatric patients 12 years of age and older with solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have either progressed following treatment or have no satisfactory alternative therapy.

### **AGE RESTRICTION**

Patient must be 12 years of age or greater.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **RUBRACA**

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### **MEDICATION(S)**

RUBRACA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Ovarian cancer: advanced Treatment of deleterious germline and/or somatic BRCA mutation associated (as detected by an approved test) ovarian cancer in patients who have been treated with 2 or more prior lines of chemotherapy or Diagnosis of Ovarian cancer, recurrent (maintenance) Maintenance treatment of recurrent Ovarian cancer (epithelial, fallopian tube, or primary peritoneal) in patients who are in complete or partial response to platinum-based chemotherapy. Prostate cancer, metastatic, castration-resistant (BRCA-mutated): Treatment of deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer in adults who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy

## **RUCONEST**

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### **MEDICATION(S)**

RUCONEST

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Firazyr, or Kalbitor).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

HAE: Prescribed by an immunologist, allergist, or rheumatologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **RYBREVANT**

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### **MEDICATION(S)**

RYBREVANT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Non–small cell lung cancer, locally advanced or metastatic: Treatment of locally advanced or metastatic non–small cell lung cancer in adults with epidermal growth factor receptor exon 20 insertion mutations (as detected by an approved test), with disease progression on or after platinum-based chemotherapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial: 6mths. Reauth: 6 months

### **OTHER CRITERIA**

Reauth Criteria: Patient must continue to meet the above criteria AND Disease response with treatment.



## **RYDAPT**

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### **MEDICATION(S)**

RYDAPT

### **PA INDICATION INDICATOR**

3 - 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, 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All indications: Prescribed by or in consultation with a hematologist or oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy

## **SABRIL**

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### **MEDICATION(S)**

VIGABATRIN, VIGADRONE

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **SANDOSTATIN**

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### **MEDICATION(S)**

OCTREOTIDE 1,000 MCG/5 ML VIAL, OCTREOTIDE ACET 0.05 MG/ML VL, OCTREOTIDE ACET 100 MCG/ML AMP, OCTREOTIDE ACET 100 MCG/ML VL, OCTREOTIDE ACET 200 MCG/ML VL, OCTREOTIDE ACET 50 MCG/ML AMP, OCTREOTIDE ACET 50 MCG/ML VIAL, OCTREOTIDE ACET 500 MCG/ML AMP, OCTREOTIDE ACET 500 MCG/ML VL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) History of failure to surgical resection and/or pituitary irradiation OR B) patient is not a candidate for surgical resection or pituitary irradiation AND Trial and failure 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 and flushing episodes. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

All Uses (Initial and reauth): 12 months

### **OTHER CRITERIA**

Acromegaly (reauth): Patient has had a 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 and flushing episodes. Vasoactive intestinal peptide tumor (reauth): patient has improvement in number of diarrhea episodes.

## **SANDOSTATIN LAR**

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### **MEDICATION(S)**

SANDOSTATIN LAR DEPOT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) Failure to surgical resection and/or pituitary irradiation OR B) patient is not a candidate for surgical resection or pituitary irradiation AND Trial and failure or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses AND Patient had a trial of short-acting octreotide and responded to and tolerated therapy. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea and flushing episodes AND Patient had a trial of short-acting octreotide and responded to and tolerated therapy. Vasoactive peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea AND Patient had a trial of short-acting octreotide and responded to and tolerated therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

All Uses (Initial and reauth): 12 months

### **OTHER CRITERIA**

Acromegaly (reauth): Patient has had a 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 and flushing episodes. Vasoactive intestinal peptide tumor (reauth):

patient has improvement in number of diarrhea episodes.

## **SARCLISA**

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### **MEDICATION(S)**

SARCLISA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis: Multiple myeloma (relapsed or refractory); Treatment of multiple myeloma (in combination with pomalidomide and dexamethasone) in adults who have received 2 or more prior therapies including lenalidomide and a proteasome inhibitor (e.g. Velcade, Ninlaro, Kyprolis).

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial: 6 months Reauth: 12 months with positive response.

### **OTHER CRITERIA**

N/A

## **SEROSTIM**

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### **MEDICATION(S)**

SEROSTIM

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

HIV wasting (Initial): Diagnosis of HIV-associated wasting syndrome or cachexia, and one of the following: unintentional weight loss greater than 10% over the last 12 months, or unintentional weight loss greater than 7.5% over the last 6 months, or loss of 5% body cell mass (BCM) within 6 months, or body mass index (BMI) less than 20 kg/m<sup>2</sup>, or patient is male and has BCM less than 35% of total body weight (TBW) and BMI less than 27 kg/m<sup>2</sup>, or patient is female and has BCM less than 23% of TBW and BMI less than 27 kg/m<sup>2</sup>. Nutritional evaluation since onset of wasting first occurred. Anti-retroviral tx has been optimized to decrease the viral load. Patient has not had weight loss as a result of other underlying treatable conditions (eg, depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes). Patient has tried and had an inadequate response or intolerance to dronabinol or megestrol acetate.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Initial, Reauth: Prescribed by or in consultation with an infectious disease specialist.

### **COVERAGE DURATION**

Initial: 3 months, Reauth: 6 months

### **OTHER CRITERIA**

HIV wasting (reauth): Evidence of positive response to therapy. One of the following targets or goals



has not been achieved: weight, BCM, BMI. Patient is currently receiving treatment with antiretrovirals.

## **SIGNIFOR**

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### **MEDICATION(S)**

SIGNIFOR

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Cushing's disease (initial): Diagnosis of Cushings disease AND failure to or patient is not a candidate for pituitary surgery.

### **AGE RESTRICTION**

Initial: 18 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 3 months. Reauth: 12 months.

### **OTHER CRITERIA**

Cushing's disease (reauth): a clinically meaningful reduction in 24-hour urinary free cortisol levels or improvement in signs or symptoms of the disease

## **SILIQ**

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### **MEDICATION(S)**

SILIQ

### **PA INDICATION INDICATOR**

3 - 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. Patient has had T/F, CI to 1. Enbrel (etanercept) OR Humira (adalimumab) AND 2. Cosentyx (Secukinumab), OR for continuation of prior Siliq therapy. Patient is not receiving Siliq in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

N/A

## **SIMPONI**

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### **MEDICATION(S)**

SIMPONI

### **PA INDICATION INDICATOR**

3 - 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 and patient has had T/F, CI to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi therapy. For Psoriatic Arthritis, patient has had a T/F, CI to Humira (adalimumab) AND Enbrel (etanercept). For Ankylosing Spondylitis, patient has had T/F, CI to Humira (adalimumab) AND Enbrel (etanercept). For UC, patient has had T/F, CI to ONE conventional therapy (such as 6-mercaptopurine, azathioprine, oral aminosalicylates, or oral corticosteroids) OR demonstrated dependence on corticosteroids AND patient has had T/F, CI to Humira (adalimumab). Patient is not receiving Simponi in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]. Patient is not receiving Simponi in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

RA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. UC (Initial): Prescribed by or in consultation with a gastroenterologist.

### **COVERAGE DURATION**

UC (Initial): 12 weeks. UC (Reauth): 12 months. RA, AS, PsA Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

All indications (Reauth): Documentation of positive clinical response to Simponi therapy.

## **SIMPONI ARIA**

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### **MEDICATION(S)**

SIMPONI ARIA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate, OR with another immunosuppressive agent if T/F, CI to methotrexate AND patient has had T/F, CI to ONE nonbiologic DMARD AND for One of the following: T/F, CI to Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi Aria therapy. For Psoriatic Arthritis, T/F, CI to ONE conventional therapy (such as non-biologic DMARDs) AND patient has had a T/F, CI to Humira (adalimumab) AND Enbrel (etanercept) AND Cosentyx (Secukinumab). For Ankylosing Spondylitis, patient has had T/F/CI to ONE conventional therapy (e.g. NSAIDs or nonbiologic DMARDs) AND patient has had T/F, CI to Humira (adalimumab) AND Enbrel (etanercept) AND Cosentyx (Secukinumab). Patient is not receiving Simponi Aria in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]. Patient is not receiving Simponi Aria in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

RA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. UC (Initial): Prescribed by or in consultation with a gastroenterologist.

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

**OTHER CRITERIA**

All indications (Reauth): Documentation of positive clinical response to Simponi Aria therapy.

# SKYRIZI

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## MEDICATION(S)

SKYRIZI 150 MG/ML SYRINGE, SKYRIZI (2 SYRINGES) KIT, SKYRIZI PEN

## PA INDICATION INDICATOR

3 - 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. Patient has had T/F, CI to ONE systemic therapy (for example acitretin, methotrexate, cyclosporine) AND T/F, CI to 1. Enbrel (etanercept) OR Humira (adalimumab) AND 2. Cosentyx (Secukinumab), OR for continuation of prior Skyrizi therapy.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Plaque psoriasis: Prescribed by or in consultation with a dermatologist or rheumatologist.

## COVERAGE DURATION

Initial and Reauth: 6 months

## OTHER CRITERIA

Plaque psoriasis (Reauth): Documentation of positive clinical response to Skyrizi therapy. Patient is not receiving Skyrizi in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)].



## **SOMATULINE DEPOT**

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### **MEDICATION(S)**

SOMATULINE DEPOT 60 MG/0.2 ML, SOMATULINE DEPOT 90 MG/0.3 ML

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) Failure to one of the following: surgery or radiotherapy, OR B) not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (initial): Diagnosis of unresectable, well- or moderately-differentiated, locally advanced or metastatic GEP-NETs

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

All Indications (Initial and reauth): 12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **SOMATULINE DEPOT 2**

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### **MEDICATION(S)**

SOMATULINE DEPOT 120 MG/0.5 ML

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) Failure to one of the following: surgery or radiotherapy, OR B) not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (initial): Diagnosis of unresectable, well- or moderately-differentiated, locally advanced or metastatic GEP-NETs

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

All Indications (Initial and reauth): 12 months

### **OTHER CRITERIA**

Applies to New Starts only. Approve for continuation of prior therapy.

## **SOMAVERT**

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### **MEDICATION(S)**

SOMAVERT

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial and reauth: 12 months

### **OTHER CRITERIA**

Acromegaly (reauth): Patient has experienced an objective response to therapy (biochemical control, decrease or normalization of IGF-1 levels).

## **SOVALDI**

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### **MEDICATION(S)**

SOVALDI 400 MG TABLET

### **PA INDICATION INDICATOR**

3 - 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. For genotype (GT) 1 patients. All GT1 (except Sovaldi plus Daklinza therapy in post-liver transplant (tx) patients) and GT4: 1) trial and failure, intolerance or contraindication (TF/I/C) to both of the following: Harvoni and Zepatier therapy OR 2) For continuation of prior Sovaldi therapy. For GT2 (except in 1) post-liver tx patients, or 2) patients 12 to 17 years of age or 3) both of the following: a) patients weighing at least 35 kg and b) less than 18 years of age) or GT3 patients (except in 1) patients 12 to 17 years of age or 2) both of the following: a) patients weighing at least 35 kg and b) less than 18 years of age), using Sovaldi plus ribavirin: TF/I/C to Epclusa OR for continuation of prior Sovaldi therapy. All Sovaldi plus Daklinza therapy: One of the following: 1) Patient has not failed a prior HCV NS5A-containing regimen (eg, Daklinza) therapy, OR 2) patient has failed prior therapy with an NS5A-containing regimen AND submission of medical records (eg, chart notes) documenting that the patient does not have NS5A inhibitor resistance-associated variants detected using commercially available assays. For GT2 and GT3 (except post-liver tx patients) patients, using Sovaldi plus Daklinza: TF/I/C to Epclusa OR for continuation of prior Sovaldi therapy. For GT1 post-liver tx patients using Sovaldi plus Daklinza, TF/I/C to Harvoni OR for continuation of prior Sovaldi therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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 48 wks. Criteria will be applied consistent with current AASLD/IDSA guideline

**OTHER CRITERIA**

N/A

## **SPORANOX**

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### **MEDICATION(S)**

ITRACONAZOLE 10 MG/ML SOLUTION, ITRACONAZOLE 100 MG CAPSULE

### **PA INDICATION INDICATOR**

3 - 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) patient is resistant to topical antifungal treatment and has one of the following diagnoses: a) tinea corporis (ringworm), OR b) tinea cruris (jock itch), OR c) tinea pedis (athletes foot), OR d) tinea capitis (scalp ringworm), OR e) pityriasis versicolor, OR 3) 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) culture, OR iii) histology, AND b) patient has had a trial and inadequate response, intolerance or hypersensitivity to oral terbinafine, OR 4) patient has a diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole (ORAL SOLUTION ONLY).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Systemic fungal fxn:6mo, candidiasis:1 mo., fingernail onycho: 5 weeks, toenail onycho, other:3mo.

### **OTHER CRITERIA**

N/A

## **SPRAVATO**

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### **MEDICATION(S)**

SPRAVATO 56 MG DOSE PACK, SPRAVATO 84 MG DOSE PACK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Treatment of treatment-resistant depression (TRD) in adults, in conjunction with an oral antidepressant.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a psychiatrist.

### **COVERAGE DURATION**

Initial: 1 months Reauth: 12 months

### **OTHER CRITERIA**

Will only be available to be administered in certified treatment centers in accordance with the REMS.

## **SPRYCEL**

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### **MEDICATION(S)**

SPRYCEL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML): Diagnosis of Ph+ CML. Ph+ acute lymphoblastic leukemia (ALL): Diagnosis of Ph+ ALL.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All Uses: Prescribed by or in consultation with an oncologist or hematologist

### **COVERAGE DURATION**

All Uses: 12 months

### **OTHER CRITERIA**

All Uses: Approve for continuation of prior therapy.



## **STELARA**

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### **MEDICATION(S)**

STELARA 130 MG/26 ML VIAL, STELARA 45 MG/0.5 ML SYRINGE, STELARA 90 MG/ML SYRINGE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Crohn Disease: Dx of moderately to severely active Crohns disease and one of the following: TF/C/I to Humira (adalimumab) AND TF/C/I to treatment with at least one immunomodulator or corticosteroid [e.g., Purinethol (6-mercaptopurine), Imuran (azathioprine), Sandimmune (cyclosporine A), Prograf (tacrolimus), MTX (methotrexate)], OR for continuation of prior Stelara therapy. Plaque Psoriasis: Dx of moderate to severe plaque psoriasis and patient has had 1. TF/C/I to Humira (adalimumab) OR TF/C/I to Enbrel (etanercept) AND 2. TF/C/I to Cosentyx (secukinumab) OR for continuation of prior Stelara therapy. Psoriatic Arthritis: Dx of active Psoriatic Arthritis and patient has had TF/C/I to Enbrel (etanercept) AND TF/C/I to Humira (adalimumab) OR for continuation of prior Stelara therapy. Ulcerative Colitis: Dx of ulcerative colitis AND TF/C/I to Humira (adalimumab) OR for continuation of prior Stelara therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a rheumatologist, dermatologist or gastroenterologist.

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

N/A

## **STIVARGA**

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### **MEDICATION(S)**

STIVARGA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Colorectal cancer, metastatic- Treatment of metastatic colorectal cancer in patients previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, antivascular endothelial growth factor (VEGF) therapy (e.g. Avastin [bevacizumab]) and antiepidermal growth factor receptor (EGFR) therapy [e.g. Vectibix (panitumumab), Erbitux (cetuximab)] (if RAS gene [HRAS, KRAS, NRAS] wild type) Gastrointestinal stromal tumors- Treatment of locally advanced, unresectable or metastatic gastrointestinal stromal tumors (GIST) in patients previously treated with imatinib and sunitinib. Liver Carcinoma- Treatment of Hepatocellular carcinoma in patients previously treated with sorafenib.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **STRENSIQ**

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### **MEDICATION(S)**

STRENSIQ

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Hypophosphatasia: Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia AND for patients requesting the 80 mg/0.8 mL vial only: Patient's weight is greater than or equal to 40 kg

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Hypophosphatasia: Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism or endocrinologist

### **COVERAGE DURATION**

Hypophosphatasia: 12 months

### **OTHER CRITERIA**

N/A

## **SUTENT**

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### **MEDICATION(S)**

SUNITINIB MALATE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Renal cell carcinoma: Adjuvant treatment of adults at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy or treatment of advanced RCC. Gastrointestinal stromal tumor (GIST): Diagnosis of GIST after disease progression on or intolerance to imatinib. Pancreatic neuroendocrine tumors: Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumor that is unresectable locally advanced or metastatic disease.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All Indications: Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

All Indications: 12 months

### **OTHER CRITERIA**

All Indications: Approve for continuation of prior therapy

## **SYLATRON**

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### **MEDICATION(S)**

SYLATRON

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Melanoma: Diagnosis of melanoma with microscopic or gross nodal involvement AND The prescribed medication will be used as adjuvant therapy within 84 days of definitive surgical resection, including complete lymphadenectomy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy

## **SYLVANT**

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### **MEDICATION(S)**

SYLVANT 100 MG VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Multicentric Castleman's disease (MCD) (Initial): Diagnosis of MCD. Patient is human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

MCD (Initial): Prescribed by or in consultation with hematologist/oncologist or rheumatologist.

### **COVERAGE DURATION**

MCD (initial, reauth): 6 months

### **OTHER CRITERIA**

MCD (reauth): Documentation of positive clinical response to Sylvant therapy. Patient is HIV negative and HHV-8 negative.

## **SYMLIN**

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### **MEDICATION(S)**

SYMLINPEN 120, SYMLINPEN 60

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Gastroparesis.

### **REQUIRED MEDICAL INFORMATION**

One of the following diagnoses: A) Type 1 diabetes OR B) Type 2 diabetes.

### **AGE RESTRICTION**

18 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **SYNAGIS**

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### **MEDICATION(S)**

SYNAGIS 50 MG/0.5 ML VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient will use palivizumab for immunoprophylaxis of respiratory syncytial virus (RSV) during the peak months of infection in the patients geographic region AND Patient meets one of the following criteria: 1) Infants born at 28 weeks, six days gestation or earlier and who are younger than 12 months of age at the start of the RSV season OR 2) Diagnosis of chronic lung disease of prematurity, born before 32 weeks, 0 days gestation, received greater than 21% oxygen for at least the first 28 days after birth, and one of the following: a) 12 months of age or younger at the start of the RSV season OR b) greater than 12 months of age to 24 months of age at the start of the RSV season and received medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) within 6 months before the start of the second RSV season. OR 3) Patient is 12 months of age or younger at the start of the RSV season and has one of the following: a) acyanotic heart failure that will require a cardiac surgical procedure and the patient is receiving medication to control congestive heart failure, OR b) moderate to severe pulmonary hypertension OR c) cyanotic heart defect. OR 4) patient is younger than 24 months of age and will or has undergone a cardiac transplantation during the RSV season. OR 5) Patient is 12 months of age or younger at the start of the RSV season with a congenital abnormality or neuromuscular disorder and has an impaired ability to clear secretions from the upper airway due to an ineffective cough. OR 6) Patient is younger than 24 months of age with a lymphocyte count below the normal range for patients age and has received or will receive a solid organ transplant, hematopoietic stem cell transplant recipient, or chemotherapy during the RSV season.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**



Prescribed by or in consultation with a pediatric specialist (i.e., pulmonologist, neonatologist, neurologist, cardiologist, pediatric intensivist, or infectious disease specialist).

**COVERAGE DURATION**

12 months

**OTHER CRITERIA**

Approve 5 doses based on patient body weight for all other indications.

## **SYNRIBO**

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### **MEDICATION(S)**

SYNRIBO

### **PA INDICATION INDICATOR**

3 - 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 AND Patient has tried and has had resistance, relapse, inadequate response, intolerance or is contraindicated to TWO tyrosine kinase inhibitors (i.e., Gleevec [imatinib], Sprycel, Tasigna, and Bosulif, Iclusig)

### **AGE RESTRICTION**

CML: 18 years of age or older

### **PRESCRIBER RESTRICTION**

CML: Prescribed by or in consultation with a hematologist/oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy

## **TABRECTA**

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### **MEDICATION(S)**

TABRECTA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Dx: Non-small cell lung cancer, metastatic (with mesenchymal-epithelial transition exon 14 skipping mutation)

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

## **TACROLIMUS OINTMENT**

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### **MEDICATION(S)**

TACROLIMUS 0.03% OINTMENT, TACROLIMUS 0.1% OINTMENT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

For tacrolimus 0.03 percent, individual is 2 years of age and older. For tacrolimus 0.1 percent, individual is 16 years of age and older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Individual had a trial of and inadequate response or intolerance to one topical prescription strength corticosteroid.

## **TADALAFIL 5 MG FOR BPH**

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### **MEDICATION(S)**

TADALAFIL 5 MG TABLET

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has a diagnosis of Benign Prostatic Hypertrophy.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **TAFINLAR**

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### **MEDICATION(S)**

TAFINLAR

### **PA INDICATION INDICATOR**

3 - 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 an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **TAGRIS**

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### **MEDICATION(S)**

TAGRIS

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1)Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Tumors are positive for epidermal growth factor receptor (EGFR) T790M mutation. The patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib). 2)First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

# TALTZ

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## MEDICATION(S)

TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE

## PA INDICATION INDICATOR

3 - 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. Patient has had T/F, CI to 1. Enbrel (etanercept) OR Humira (adalimumab) AND 2. Cosentyx (Secukinumab), OR for continuation of prior Taltz therapy. Diagnosis of Psoriatic Arthritis. Patient has had T/F, CI to 1. Enbrel (etanercept) OR Humira (adalimumab) AND 2. Cosentyx (Secukinumab), OR for continuation of prior Taltz therapy. Diagnosis of Ankylosing Spondylitis. Patient has had T/F, CI to 1. Enbrel (etanercept) OR Humira (adalimumab) AND 2. Cosentyx (Secukinumab), OR for continuation of prior Taltz therapy. Patient is not receiving Taltz in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist.

## COVERAGE DURATION

All indications: Initial: 6 months, Reauth: 12 months

## OTHER CRITERIA

Plaque psoriasis (Reauth): Documentation of positive clinical response to Taltz therapy. Patient is not receiving Taltz in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].





## **TALZENNA**

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### **MEDICATION(S)**

TALZENNA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

CRITERIA: Breast cancer, locally advanced or metastatic (BRCA-mutated, HER2-negative) Treatment of deleterious or suspected deleterious germline BRCA-mutated, HER2-negative locally advanced or metastatic breast cancer in adults (as detected by an approved test)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **TARCEVA**

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### **MEDICATION(S)**

ERLOTINIB HCL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1) 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 an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility. 2) Pancreatic Cancer: Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer AND erlotinib will be used in combination with gemcitabine.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All Indications: Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

All Indications: 12 months

### **OTHER CRITERIA**

All Indications: Approve for continuation of prior therapy.

# **TARGRETIN**

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## **MEDICATION(S)**

BEXAROTENE, TARGRETIN 1% GEL

## **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist or dermatologist

## **COVERAGE DURATION**

12 months

## **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **TASIGNA**

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### **MEDICATION(S)**

TASIGNA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Chronic myelogenous leukemia (CML): Diagnosis of Ph+ CML

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist or hematologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **TAVALISSE**

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### **MEDICATION(S)**

TAVALISSE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of covered use.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

## TAZORAC

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### MEDICATION(S)

TAZAROTENE 0.1% CREAM, TAZORAC 0.05% CREAM, TAZORAC 0.05% GEL, TAZORAC 0.1% GEL

### PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

Acne vulgaris (initial): Diagnosis of acne vulgaris AND History of failure or intolerance to at least two topical acne products (e.g., tretinoin, adapalene, benzoyl peroxide, clindamycin, erythromycin, or azelaic acid). Plaque psoriasis (initial): Diagnosis of stable moderate to severe plaque psoriasis AND Patient has body surface area (BSA) involvement of less than 20 percent AND History of failure or intolerance to at least two topical psoriasis product (e.g., medium to high potency corticosteroids and/or vitamin D analogs).

### AGE RESTRICTION

Acne (initial): 12 years of age or older

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

All uses (Initial and reauth): 12 months

### OTHER CRITERIA

Acne, Plaque psoriasis (reauth): Documentation of positive clinical response to therapy .

## **TAZVERIK**

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### **MEDICATION(S)**

TAZVERIK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Epithelioid sarcoma, metastatic or locally advanced: Treatment of metastatic or locally advanced epithelioid sarcoma not eligible for complete resection in adults and adolescents 16 years of age or older. Follicular lymphoma, relapsed/refractory: Treatment of relapsed or refractory follicular lymphoma in adults whose tumors are positive for an EZH2 mutation (as detected by an approved test) and who have received at least 2 prior systemic therapies. Treatment of relapsed or refractory follicular lymphoma in adults who have no satisfactory alternative treatment options.

### **AGE RESTRICTION**

Patient must be 16 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial and Reauth: 12 months

### **OTHER CRITERIA**

N/A



## **TECFIDERA**

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### **MEDICATION(S)**

DIMETHYL FUMARATE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Multiple Sclerosis (MS): Diagnosis of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease with evidence of new brain lesions.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **TEGSEDI**

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### **MEDICATION(S)**

TEGSEDI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of hereditary transthyretin (hATTR) amyloidosis or familial amyloid polyneuropathy (FAP) AND has a TTR mutation confirmed by genotyping AND has associated mild to moderate polyneuropathy AND has a baseline platelet count greater than or equal to  $100 \times 10^9/L$  AND has a urinary protein to creatinine ratio (UPCR) greater than or equal to 1000 mg/g.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **TEPEZZA**

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### **MEDICATION(S)**

TEPEZZA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Thyroid Eye Disease (must meet all): 1) Diagnosis of Graves' disease with associated TED (i.e., Graves' ophthalmopathy, Graves' orbitopathy), 2) Member has active TED with a clinical activity score (CAS) of 4 or greater, 3) Member is euthyroid or mildly hypo/hyper-thyroid with a free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50 percent above or below the normal limits, 4) Member does not require surgical ophthalmological intervention, 5) Failure of a 4 week trial of a systemic corticosteroid (e.g. prednisone, methylprednisolone), unless contraindicated or clinically significant adverse effects are experienced, 6) Dose does not exceed a single 10 mg/kg dose followed by seven 20 mg/kg infusions given every 3 weeks.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an ophthalmologist.

### **COVERAGE DURATION**

"Initial: 6 months (up to 7 total 20 mg/kg infusions, not including the initial 10 mg/kg first infusion)

Reauthorization (must meet all) 6 months (up to 7 total 20 mg/kg infusions): 1) member has previously met initial approval criteria, 2) Member is responding positively to therapy as evidenced by a 2) point or greater reduction in CAS from baseline, 3) Member continues to have active TED with a clinical activity score (CAS) of 3 or greater, 4) Member has not received 7 or greater infusions (not including the initial 10 mg/kg first infusion).

**OTHER CRITERIA**

N/A

## **TEPMETKO**

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### **MEDICATION(S)**

TEPMETKO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has metastatic nonsmall cell lung cancer harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations. Medical chart information is provided by the prescriber.

### **AGE RESTRICTION**

Patient is 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist or oncologist.

### **COVERAGE DURATION**

Initial and Reauth: 6 months.

### **OTHER CRITERIA**

N/A

## **THALOMID**

---

### **MEDICATION(S)**

THALOMID

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

MM: Prescribed by or in consultation with an oncologist/hematologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

# THIOLA

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## MEDICATION(S)

THIOLA EC, TIOPRONIN

## PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial Authorization: Patient has a diagnosis of cystinuria, AND Diagnosis is confirmed by nephrolithiasis and 1 of the following: family history of cystinuria, stone analysis confirming cystine stone, or elevated cystine output, AND Patient is greater than 20 kg, Reauthorization Criteria: Patient continues to meet criteria identified above, AND Patient has an improvement in cystinuria, documented by prescriber based on laboratory analysis (e.g., urine cystine) or lack of stone formation, AND Patient has not experienced any treatment-restricting adverse effects (e.g., hypersensitivity, proteinuria), AND Prescriber monitors cystine levels every 3 months to maintain a urinary cystine concentration less than 250 mg/L, AND Prescriber assesses for proteinuria every 3 to 6 months during treatment.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial auth: 6 months. Reauth: 12 months

## OTHER CRITERIA

N/A

## **TIBSOVO**

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### **MEDICATION(S)**

TIBSOVO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an approved test.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A



## **TOPICAL RETINOID**

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### **MEDICATION(S)**

TRETINOIN 0.01% GEL, TRETINOIN 0.025% CREAM, TRETINOIN 0.025% GEL, TRETINOIN 0.05% CREAM, TRETINOIN 0.05% GEL, TRETINOIN 0.1% CREAM, TRETINOIN MICROSPHERE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

One of the following: Acne: Diagnosis of acne.

### **AGE RESTRICTION**

PA applies to members 26 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **TRACLEER**

---

### **MEDICATION(S)**

BOSENTAN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Bosentan is contraindicated in pregnancy, use with cyclosporine A, use with glyburide, and hypersensitivity to bosentan or any of its components.

### **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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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.

## **TRANSMUCOSAL FENTANYL CITRATE**

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### **MEDICATION(S)**

FENTANYL CITRATE OTFC 400 MCG

### **PA INDICATION INDICATOR**

3 - 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 g/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

## **TRELSTAR**

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### **MEDICATION(S)**

TRELSTAR 22.5 MG VIAL

### **PA INDICATION INDICATOR**

3 - 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 Lupron Depot (7.5 mg, 22.5 mg, 30 mg, and 45 mg).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **TRELSTAR 3.75 AND 11.25MG**

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### **MEDICATION(S)**

TRELSTAR 11.25 MG VIAL, TRELSTAR 3.75 MG VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Following radical prostatectomy as adjuvant therapy when lymph node metastases are present OR Locally advanced disease OR Other advanced, recurrent, or metastatic disease.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **TRETINOIN/CLINDAMYCIN**

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### **MEDICATION(S)**

CLINDAMYCIN PHOS-TRETINOIN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Acne: Diagnosis of acne.

### **AGE RESTRICTION**

PA applies to members 26 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **TRIKAFTA**

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### **MEDICATION(S)**

TRIKAFTA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient must have diagnosis of Cystic fibrosis (CF) and have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a Pulmonologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **TRODELVY**

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### **MEDICATION(S)**

TRODELVY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis is metastatic triple-negative breast cancer (mTNBC). Patient has received 2 or more prior therapies for metastatic disease.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial: 6 months Reauth: 12 months with positive response.

### **OTHER CRITERIA**

N/A



## TRUSELTIQ

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### MEDICATION(S)

TRUSELTIQ

### PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

Treatment of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma in patients with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

Must be prescribed by or in consultation with an oncologist.

### COVERAGE DURATION

Initial: 6mths. Reauth: 6 months

### OTHER CRITERIA

Reauth Criteria: Patient must continue to meet the above criteria AND Disease response with treatment.

# **TUKYSA**

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## **MEDICATION(S)**

TUKYSA

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Patient must have a diagnosis of advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer. It will be used in combination with trastuzumab and capecitabine. Patient has received 1 or more prior anti-HER2-based regimens in the metastatic setting.

## **AGE RESTRICTION**

Patient must be 18 years of age or older

## **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

## **COVERAGE DURATION**

Initial: 6 months Reauth: 12 months with positive response.

## **OTHER CRITERIA**

N/A

## **TURALIO**

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### **MEDICATION(S)**

TURALIO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Treatment of symptomatic tenosynovial giant cell tumor associated with severe morbidity or functional limitations and not amenable to improvement with surgery in adults.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Auth: 12 months

### **OTHER CRITERIA**

N/A

## **TYKERB**

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### **MEDICATION(S)**

LAPATINIB

### **PA INDICATION INDICATOR**

3 - 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: Herceptin (trastuzumab), Xeloda (capecitabine), or aromatase inhibitors [eg, Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **TYMLOS**

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### **MEDICATION(S)**

TYMLOS

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patient has utilized abaloparatide and a parathyroid hormone analog (e.g., teriparatide [Forteo]) for a combined total lifetime duration of 2 years or longer. Patient is using Tymlos in combination with any of the following: (1) Prolia (denosumab) OR (2) Bisphosphonate OR (3) Evista (raloxifene) OR (4) Miacalcin/Fortical (calcitonin nasal spray) OR (5) Reclast (zoledronic acid) OR (6) Forteo (teriparatide).

### **REQUIRED MEDICAL INFORMATION**

Patient is a postmenopausal female with one of the following: (A) dx of osteoporosis (defined as a bone mineral density [BMD] T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 OR (B) dx of osteoporosis based on history of an osteoporotic low trauma fracture (fragility fracture) and considered at high risk for additional fracture AND patient has had a trial and failure or has a contraindication to an oral or IV bisphosphonate AND denosumab. Duration has not exceeded a total of 24 months during the patient's lifetime.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 12 months with one reauth only for a total of 2 years of lifetime treatment

### **OTHER CRITERIA**

Reauth: patient is responding positively to treatment.

# **TYSABRI**

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## **MEDICATION(S)**

TYSABRI

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses). Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone or Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Rebif (interferon beta-1a), or Tecfidera (dimethyl fumarate). Patient is not taking Tysabri in combination with another MS agent [eg, Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone (glatiramer acetate), Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Rebif (interferon beta-1a), or Tecfidera (dimethyl fumarate)]. Crohn's Disease (CD) (initial): Diagnosis of moderate to severe CD with evidence of inflammation (eg, elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes). Inadequate response or intolerance to one of the following conventional therapies: corticosteroids, 6-mercaptopurine (6MP [Purinethol], azathioprine (Imuran), methotrexate, aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine). Inadequate response or intolerance to a TNF-inhibitor (eg, Cimzia [certolizumab pegol], Humira [adalimumab], Remicade [infliximab]). CD (initial and reauth): Patient is not taking Tysabri in combination with an immunosuppressant (eg, 6-MP, azathioprine, cyclosporine, or methotrexate) or a TNF-inhibitor (eg, Enbrel [etanercept], Humira [adalimumab], or Remicade [infliximab]).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

MS: 12mo. CD (Init): 3 mo. CD (Reauth): 6 mo if not on steroids. Otherwise, 3 mo.

**OTHER CRITERIA**

CD (reauth): Diagnostic and/or clinical documentation (eg, improved disease activity index) that indicates patient has experienced clinical benefit from receiving (induction) Tysabri therapy by week 12.

## **UBRELVY**

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### **MEDICATION(S)**

UBRELVY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patient must NOT be concurrently using a strong CYP3A4 inhibitor AND Patient must NOT have end-stage renal disease (creatinine clearance [CrCl] less than 15 mL/min). Patient is not being treated for prevention of migraine.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of migraine, with or without aura. Patient must have tried and failed 1 or more of the following: NSAID, non-opioid analgesic, OR caffeinated analgesic combination, AND Patient must have tried and failed, or have contraindication to at least 1 formulary triptan (eg. rizatriptan, sumatriptan, zolmitriptan, naratriptan, frovatriptan, almotriptan). REAUTH: patient continues to meet the above criteria and demonstrates resolution in headache pain or reduction in headache severity, as assessed by prescriber.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

Initial: 6 months. Reauth: 12 months

### **OTHER CRITERIA**

N/A



## **UKONIQ**

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### **MEDICATION(S)**

UKONIQ

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has a diagnosis of 1. Follicular lymphoma, relapsed or refractory and has received at least 3 prior lines of systemic therapy or 2. relapsed or refractory marginal zone lymphoma and has received at least 1 prior anti-CD20-based regimen.

### **AGE RESTRICTION**

Patient is 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist or oncologist.

### **COVERAGE DURATION**

Initial and Reauth: 6 months.

### **OTHER CRITERIA**

N/A

## **UPTRAVI**

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### **MEDICATION(S)**

UPTRAVI

### **PA INDICATION INDICATOR**

3 - 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 Patient 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. One of the following: a) History of trial and failure, contraindication, or intolerance to a PDE5 inhibitor (ie, Adcirca, Revatio) or Adempas (riociguat), and History of 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 Uptravi therapy. Not taken in combination with a prostanoid/prostacyclin analogue (eg, epoprostenol, iloprost, treprostinil).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist

### **COVERAGE DURATION**

Initial: 6 months Reauth: 12 months

### **OTHER CRITERIA**

PAH (Reauth): Documentation of positive clinical response to Uptravi therapy. Not taken in combination with a prostanoid/prostacyclin analogue (eg, epoprostenol, iloprost, treprostinil)

## **VALCHLOR**

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### **MEDICATION(S)**

VALCHLOR

### **PA INDICATION INDICATOR**

3 - 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), topical nitrogen mustard, etc.].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist or dermatologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **VANCOMYCIN CAPSULE**

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### **MEDICATION(S)**

VANCOMYCIN 250 MG/5 ML SOLN, VANCOMYCIN HCL 125 MG CAPSULE, VANCOMYCIN HCL 250 MG CAPSULE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Individual is being treated for enterocolitis caused by Staphylococcal aureus including methicillin-resistant strains. Individual is being treated for Clostridium difficile-associated diarrhea.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

14 days

### **OTHER CRITERIA**

N/A

## VELCADE

---

### MEDICATION(S)

VELCADE

### PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

Multiple myeloma (MM): Diagnosis of MM. Mantle cell lymphoma (MCL): Diagnosis of MCL.

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

MM, MCL: Prescribed by or in consultation with an oncologist/hematologist

### COVERAGE DURATION

12 months

### OTHER CRITERIA

Approve for continuation of prior therapy.

## **VENCLEXTA**

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### **MEDICATION(S)**

VENCLEXTA, VENCLEXTA STARTING PACK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL,  
2) Acute Myeloid Leukemia (AML): Diagnosis of AML in combination with azacitidine, or decitabine, or low-dose cytarabine in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist or oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **VENTAVIS**

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### **MEDICATION(S)**

VENTAVIS

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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.

## **VERQUVO**

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### **MEDICATION(S)**

VERQUVO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Pregnancy

### **REQUIRED MEDICAL INFORMATION**

Patient has a diagnosis of symptomatic chronic heart failure AND ejection fraction is less than 45 percent AND patient meets 1 or more of the following criteria: patient has required the use of at least one IV diuretic (e.g. furosemide, bumetanide) as an outpatient in the past 3 months OR patient was recently hospitalized for heart failure within the last 6 months AND patient is on at least ONE drug for heart failure from any of the following classes, unless contraindicated (beta-blocker {e.g. metoprolol, carvedilol, bisoprolol}, ACE inhibitor {e.g. captopril, enalapril, lisinopril}, ARB {e.g. valsartan, olmesartan, telmisartan, irbesartan, losartan}, aldosterone receptor antagonist {e.g. eplerenone}) AND patient is NOT taking another soluble guanylate cyclase (sGC) stimulator or PDE-5 inhibitor.

### **AGE RESTRICTION**

Patient is 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a cardiologist.

### **COVERAGE DURATION**

Initial and Reauth 6 months

### **OTHER CRITERIA**

Reauth: patient is responding positively to treatment.



# **VERZENIO**

---

## **MEDICATION(S)**

VERZENIO

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

As initial endocrine-based therapy (in combination with an aromatase inhibitor) for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in postmenopausal females. In combination with fulvestrant for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in females with disease progression following endocrine therapy. As monotherapy for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in patients with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

## **AGE RESTRICTION**

Must be 18 years of age or older.

## **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **VISUDYNE**

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### **MEDICATION(S)**

VISUDYNE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patient must not have a diagnosis of porphyria.

### **REQUIRED MEDICAL INFORMATION**

Dx: predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration (classic wet AMD), pathologic myopia, or presumed ocular histoplasmosis. For neovascularization due to age-related macular degeneration, patient has tried, failed or had a CI to Avastin.

### **AGE RESTRICTION**

Must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an ophthalmologist.

### **COVERAGE DURATION**

Initial and Reauth: 3 mths. Reevaluated every 3 mths. if choroidal neovascular leakage detected, tx can be repeated.

### **OTHER CRITERIA**

N/A

## **VITRAKVI**

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### **MEDICATION(S)**

VITRAKVI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Solid tumors. Treatment of solid tumors (in adult and pediatric patients) that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity and have no satisfactory alternative treatments or that have progressed following treatment.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **VIZIMPRO**

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### **MEDICATION(S)**

VIZIMPRO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

First-line treatment of metastatic non-small cell lung cancer (NSCLC) in patients with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an approved test.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **VOSEVI**

---

### **MEDICATION(S)**

VOSEVI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with rifampin.

### **REQUIRED MEDICAL INFORMATION**

Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a genotype and positive HCV RNA result (AASLD/IDSA 2017, CDC 2013) AND patient has received baseline evaluation for liver fibrosis to guide appropriate therapy AND patient does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016). Trial and failure, contraindication, or intolerance to generic Harvoni (Ledipasvir/Sofosbuvir) and generic Epclusa (Sofosbuvir-Velpatasvir).

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

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 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.

### **OTHER CRITERIA**

N/A

## **VOTRIENT**

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### **MEDICATION(S)**

VOTRIENT

### **PA INDICATION INDICATOR**

3 - 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 and patient received at least one prior chemotherapy (e.g., ifosfamide, doxorubicin, cisplatin, dacarbazine, docetaxel, oxaliplatin, etc.)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All Uses: Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **VPRIV**

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### **MEDICATION(S)**

VPRIV

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Gaucher disease: Diagnosis of type 1 Gaucher disease. Patient has evidence of symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Gaucher disease: 12 months

### **OTHER CRITERIA**

N/A

## **VUMERITY**

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### **MEDICATION(S)**

VUMERITY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Moderate to severe impairment of kidney function, pregnancy

### **REQUIRED MEDICAL INFORMATION**

Treatment of relapsing forms of multiple sclerosis (confirmed diagnosis of MS as documented by lab report such as an MRI), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a Neurologist.

### **COVERAGE DURATION**

Initial and Reauth 12 months

### **OTHER CRITERIA**

For Reauth, patient continues to meet initial approval criteria AND absence of toxicities from the drug AND chart notes indicating monitoring of response to therapy has been positive.



## **VYNDAQEL/VYNDAMAX**

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### **MEDICATION(S)**

VYNDAMAX, VYNDAQEL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Chart notes indication diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

### **AGE RESTRICTION**

Patient must be 18 years of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by a cardiologist or in consultation with a cardiologist.

### **COVERAGE DURATION**

Initial Auth: 12 months

### **OTHER CRITERIA**

Reauth: Documentation of positive clinical response to therapy. 12 months.

## **WELIREG**

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### **MEDICATION(S)**

WELIREG

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Immediate need for surgical intervention for tumor treatment or evidence of metastatic disease. Use in combination with erythropoiesis stimulating agents (ESAs). Pregnancy.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis is von Hippel-Lindau disease and patient requires therapy for associated 1 or more of the following: 1. renal cell carcinoma (RCC), 2. CNS hemangioblastomas, or 3. pancreatic neuroendocrine tumors. Women of child-bearing age must have a confirmed negative pregnancy test prior to treatment.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial: 6 months. Reauth: 6 months

### **OTHER CRITERIA**

Reauth Criteria: Patient continues to meet initial criteria and treatment has resulted in disease response as defined by stabilization of disease or decrease in tumor size or spread.

## **XALKORI**

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### **MEDICATION(S)**

XALKORI

### **PA INDICATION INDICATOR**

3 - 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 IIIB or IV) NSCLC AND One of the following: A) Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility or B) Patient has MET amplification- or ROS1 rearrangements-positive tumor as detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

NSCLC: Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy

## **XCOPRI**

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### **MEDICATION(S)**

XCOPRI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For the treatment of partial-onset seizures in adult patients.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

Initial: 6 mths. Reauth: 12 mths.

### **OTHER CRITERIA**

N/A

## **XELJANZ**

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### **MEDICATION(S)**

XELJANZ, XELJANZ XR

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Must not be used in combination with, other JAK inhibitors (e.g. Olumiant), biologic disease-modifying antirheumatic drug (DMARDs) (such as but not limited to, TNF agents, anti-CD20 monoclonal antibodies, IL-1R antagonists, selective co-stimulation modulators) or potent immunosuppressants such as azathioprine and cyclosporine.

### **REQUIRED MEDICAL INFORMATION**

For RA, patient has had TF/C/I to: Humira(adalimumab) AND Enbrel(etanercept). For PsA, patient has had TF/C/I to: Humira(adalimumab) AND Enbrel(etanercept). For UC, patient had an inadequate response to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as 6-mercaptopurine, azathioprine, oral aminosalicylates, or oral corticosteroids) AND has TF/C/I to Humira (adalimumab), OR for continuation of prior tofacitinib therapy. Patient is not receiving tofacitinib in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a rheumatologist, dermatologist or gastroenterologist.

### **COVERAGE DURATION**

All indications: Initial: 6 months, Reauth: 12 months

### **OTHER CRITERIA**

N/A



## **XENAZINE**

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### **MEDICATION(S)**

TETRABENAZINE

### **PA INDICATION INDICATOR**

3 - 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): Patient has stereotypies associated with tardive dyskinesia. Tourette's syndrome (Initial): Patient has tics associated with Tourette's syndrome. Failure, contraindication, or intolerance to Haldol (haloperidol).

### **AGE RESTRICTION**

Tardive dyskinesia (Initial): Age greater than or equal to 18 years.

### **PRESCRIBER RESTRICTION**

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 indications: (Initial) 3 months, (Reauth) 12 months.

### **OTHER CRITERIA**

All indications (Reauth): Documentation of clinical response and benefit from therapy.

## **XEOMIN**

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### **MEDICATION(S)**

XEOMIN 50 UNIT VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Cervical Dystonia (CD) (init): Diagnosis of CD (also known as spasmodic torticollis). Blepharospasm (initial): Diagnosis of blepharospasm. History of previous use of Botox (onabotulinumtoxinA) for the treatment of blepharospasm. Upper limb spasticity (ULS) (init): Diagnosis of upper limb spasticity.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

All indications (init, reauth): 3 months (for 1 dose)

### **OTHER CRITERIA**

All indications (reauth): Confirmed improvement in symptoms with initial Xeomin treatment. At least 3 months have elapsed since the last treatment with Xeomin



## **XERMELO**

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### **MEDICATION(S)**

XERMELO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Carcinoid syndrome diarrhea: Treatment of carcinoid syndrome diarrhea (in combination with somatostatin analog therapy) in adults with symptoms inadequately controlled by somatostatin analog therapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial and Reauth 6 months.

### **OTHER CRITERIA**

Reauth: patient is responding well to treatment.

## **XGEVA**

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### **MEDICATION(S)**

XGEVA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Bone metastasis from solid tumors (BMST): Both of the following: 1) diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer), AND 2) 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 intravenous bisphosphonate (eg, Zometa (zoledronic acid)).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

GCTB, HCM: Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

BMST, GCTB: 12 mo. HCM: 2 mo.

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **XIFAXAN**

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### **MEDICATION(S)**

XIFAXAN

### **PA INDICATION INDICATOR**

3 - 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. 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

TD: 1 month HE: 6 months. IBS-D (initial, reauth): 2 weeks.

### **OTHER CRITERIA**

IBS-D (reauth): Patient experiences IBS-D symptom recurrence AND patient has not already received 3 treatment courses of Xifaxan for IBS-D in their lifetime.

## **XIIDRA**

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### **MEDICATION(S)**

XIIDRA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Initial: Diagnosis of dry eye disease. Patient has suppressed tear production due to ocular inflammation as determined by at least one of the following diagnostic tests: Schirmer test (aqueous tear production and clearance), tear break-up time, ocular surface dye staining, tear film osmolarity, or fluorescein clearance test/tear function test. Failure, contraindication, or intolerance to Restasis at an optimal dose and frequency for at least 2 weeks

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial, reauth: 12 months

### **OTHER CRITERIA**

Reauth: Documentation of positive clinical response to Xiidra therapy (e.g., increased tear production or improvement in dry eye symptoms).

## **XOLAIR**

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### **MEDICATION(S)**

XOLAIR

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has Moderate Persistent to Severe Persistent Asthma AND has a positive skin test or in vitro reactivity to a perennial aeroallergen, AND Mbr has an FEV1 less than 80% predicted AND Mbr IgE level is equal to or greater than 30 IU/ml. Severe asthma as defined by the National Heart, Lung, and Blood Institute: Severe Persistent Asthma: symptoms throughout the day, extremely limited normal activity. Nocturnal symptoms are frequent, FEV1 or PEF is less than or equal to 60% predicted. Moderate Persistent Asthma as defined by the National Heart, Lung, and Blood Institute: Daily symptoms, daily use of inhaled short- acting beta2-agonist, somewhat limited activity, Nocturnal symptoms occur greater than 1 time per week, FEV1 or PEF is greater than 60% and less than 80% predicted, FEV1/FVC is reduced 5 percent or exacerbations requiring oral systemic corticosteroids use for more than or equal to 2 times per year, Treatment of chronic idiopathic urticaria in adults and adolescents 12 years and older who remain symptomatic despite H1 antihistamine treatment.

### **AGE RESTRICTION**

Patient is 12 years of age or older for urticaria and 6 years of age or older for moderate to severe persistent asthma

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

For moderate to severe persistent asthma, Mbr symptoms are inadequately controlled after a minimum of 3 months with combination controller therapy (medium to high doses of inhaled corticosteroids plus long acting beta-2 agonists or Leukotriene modifiers), or cannot tolerate these medications. Continued treatment beyond 12 months is allowed when treatment has resulted in clinical improvement as documented by one or more of the following: Decreased utilization of rescue medications OR Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids) OR Increase in percent predicted FEV1 from pretreatment baseline OR Reduction in reported asthma-related symptoms, such as, but not limited to, wheezing, shortness of breath, coughing, fatigue, sleep disturbance, or asthmatic symptoms upon awakening. For chronic idiopathic urticaria, individual is refractory to prior treatment of ONE potent antihistamine at maximal FDA approved dosage.

## **XOSPATA**

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### **MEDICATION(S)**

XOSPATA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Acute myeloid leukemia, relapsed or refractory. Treatment of relapsed or refractory acute myeloid leukemia (AML) in adult patients with an FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an approved test.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

FMS-like tyrosine kinase 3 (FLT3) mutation

## **XPOVIO**

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### **MEDICATION(S)**

XPOVIO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Multiple myeloma, relapsed or refractory: Treatment of relapsed or refractory multiple myeloma (in combination with dexamethasone) in adults who have received 4 or more prior therapies and whose disease is refractory to 2 or more proteasome inhibitors, 2 or more immunomodulatory agents, and an anti-CD38 monoclonal antibody. Diffuse large B-cell lymphoma, relapsed or refractory: Treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, in adults after at least 2 lines of systemic therapy.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist/hematologist.

### **COVERAGE DURATION**

Authorization: 12 months.

### **OTHER CRITERIA**

N/A



## **XTANDI**

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### **MEDICATION(S)**

XTANDI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Prostate Cancer: Treatment of castration-resistant prostate cancer (CRPC). Treatment of metastatic castration-sensitive prostate cancer.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed or in consultation with an oncologist or urologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **XYREM**

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### **MEDICATION(S)**

XYREM

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are present, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are absent, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present, AND trial and failure, contraindication, or intolerance to one of the following: 1) amphetamine-based stimulant (eg, amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

All uses (initial, reauth): 12 months

### **OTHER CRITERIA**

Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with Xyrem therapy, OR documentation demonstrating a reduction in symptoms of

excessive daytime sleepiness associated with Xyrem therapy. Narcolepsy Type 2 (reauth):  
Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy.

## **YERVOY**

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### **MEDICATION(S)**

YERVOY 50 MG/10 ML VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Unresectable or metastatic melanoma: Diagnosis of unresectable, metastatic melanoma. Cutaneous melanoma: Diagnosis of cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm. Patient has undergone resection, including total lymphadenectomy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **YONSA**

---

### **MEDICATION(S)**

YONSA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Females who are or may become pregnant

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of covered use

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

## **ZALTRAP**

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### **MEDICATION(S)**

ZALTRAP 100 MG/4 ML VIAL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Colon and/or rectal cancer: Diagnosis of metastatic colon and/or rectal cancer. Ziv-aflibercept is being used in combination with 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI) regimen. Patient has disease that is resistant to or has progressed following an oxaliplatin-containing regimen [e.g., 5-fluorouracil, leucovorin, and oxaliplatin (FOLFOX)].

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **ZARXIO**

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### **MEDICATION(S)**

ZARXIO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm<sup>3</sup>), AND 2) patients with a history of FN during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) Patient is receiving National Cancer Institutes Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm<sup>3</sup>), AND 2) patients with FN at high risk for infection-associated complications.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by hematologist/oncologist except HIVN: Prescribed by hematologist/oncologist or infectious disease specialist

### **COVERAGE DURATION**

BMSCT, AML, CFN, secondary prophylaxis of FN, NDDC:3mo or duration of tx. HIVN:6mo. Tx of FN, ARS:1 mo.

### **OTHER CRITERIA**

N/A





## **ZAVESCA**

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### **MEDICATION(S)**

MIGLUSTAT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease. Patient is unable to receive enzyme replacement therapy due to one of the following conditions: allergy or hypersensitivity to enzyme replacement therapy, poor venous access, unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Gaucher disease: 12 months

### **OTHER CRITERIA**

N/A

## **ZEJULA**

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### **MEDICATION(S)**

ZEJULA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Ovarian, fallopian tube, or primary peritoneal cancer: First-line maintenance treatment of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in adults who are in a complete or partial response to first-line platinum-based chemotherapy. Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in adults who are in a complete or partial response to platinum-based chemotherapy. Treatment of advanced ovarian, fallopian tube, or primary peritoneal cancer in adults who have been treated with 3 or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency positive status, defined by either a deleterious or suspected deleterious BRCA mutation or genomic instability and progression more than 6 months after response to the last platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for niraparib.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy

## **ZELBORAF**

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### **MEDICATION(S)**

ZELBORAF

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1) Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by an FDA-approved test (eg, cobas 4600 BRAFV600 Mutation Test) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 2) Erdheim-Chester disease (ECD): Diagnosis of ECD with a BRAF V600 mutation

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **ZEPZELCA**

---

### **MEDICATION(S)**

ZEPZELCA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Dx: metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

### **AGE RESTRICTION**

Patient must be 18 years of age or older.

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial and Reauth: 6 months.

### **OTHER CRITERIA**

N/A

## **ZOKINVY**

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### **MEDICATION(S)**

ZOKINVY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has a body surface area (BSA) of 0.39 m<sup>2</sup> and above. Patient has a diagnosis of one of the following: 1. Hutchinson-Gilford progeria syndrome (HGPS) AND patient has had a confirmatory mutational analysis with a G608G mutation in the lamin A gene (LMNA gene) (e.g., c.1824C greater than T) OR 2. Processing-deficient progeroid laminopathies AND Heterozygous LMNA mutation with progerin-like protein accumulation (e.g., pathogenic variant in either the exon 11 splice junction or intron 11 of LMNA gene) OR Homozygous or compound heterozygous ZMPSTE24 mutations.

### **AGE RESTRICTION**

Patient is 12 months of age or older

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with a hematologist or oncologist.

### **COVERAGE DURATION**

Initial and Reauth: 6 months.

### **OTHER CRITERIA**

N/A

## **ZOLEDRONIC ACID 5MG/100ML**

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### **MEDICATION(S)**

ZOLEDRONIC ACID 5 MG/100 ML

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For Paget's disease of bone in men and women, treatment is indicated with elevations in serum alkaline phosphatase of two times or higher than the upper limit of the age-specific normal reference range, or those who are symptomatic, or those at risk for complications from their disease.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

## **ZOLINZA**

---

### **MEDICATION(S)**

ZOLINZA

### **PA INDICATION INDICATOR**

3 - 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 RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist/oncologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **ZORBTIVE**

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### **MEDICATION(S)**

ZORBTIVE

### **PA INDICATION INDICATOR**

3 - 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 Zorbative.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a gastroenterologist.

### **COVERAGE DURATION**

SBS: 4 weeks.

### **OTHER CRITERIA**

N/A



## **ZORTRESS**

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### **MEDICATION(S)**

EVEROLIMUS 0.25 MG TABLET, EVEROLIMUS 0.5 MG TABLET, EVEROLIMUS 0.75 MG TABLET, ZORTRESS 1 MG TABLET

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Prevention of kidney transplant organ rejection: The medication is being used for prevention of kidney transplant organ rejection. Patient is at low-to-moderate immunologic risk. Patient is prescribed concurrent therapy with reduced doses of cyclosporine AND corticosteroids. Prevention of liver transplant organ rejection: The medication is being used for prevention of liver transplant organ rejection. Thirty (30) or more days have passed since the transplant procedure. Patient is prescribed concurrent therapy with reduced doses of tacrolimus and corticosteroids.

### **AGE RESTRICTION**

All indications: 18 years of age or older

### **PRESCRIBER RESTRICTION**

All indications: Prescriber is experienced in immunosuppressive therapy and management of transplant patients.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Subject to Part B vs. Part D review. Approve for continuation of prior therapy.

## **ZYDELIG**

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### **MEDICATION(S)**

ZYDELIG

### **PA INDICATION INDICATOR**

3 - 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]). Follicular Lymphoma (FL): Diagnosis of FL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]). Small lymphocytic lymphoma (SLL): Diagnosis of SLL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

All uses: Prescribed by or in consultation with an oncologist/hematologist.

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.



## **ZYKADIA**

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### **MEDICATION(S)**

ZYKADIA

### **PA INDICATION INDICATOR**

3 - 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 an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility. Trial and failure or intolerance to Xalkori (crizotinib).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy.

## **ZYNLONTA**

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### **MEDICATION(S)**

ZYNLONTA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient diagnosis is relapsed or refractory large B-cell lymphoma AND patient has had 2 or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Must be prescribed by or in consultation with an oncologist.

### **COVERAGE DURATION**

Initial: 6mths. Reauth: 6 months

### **OTHER CRITERIA**

Reauth Criteria: Patient must continue to meet the above criteria AND Disease response with treatment.

## **ZYTIGA**

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### **MEDICATION(S)**

ABIRATERONE ACETATE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Prostate Cancer: Diagnosis of metastatic, castration-resistant (chemical or surgical) prostate cancer AND used in combination with prednisone. Diagnosis of metastatic, high-risk castration-sensitive prostate cancer AND used in combination with prednisone.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prostate Cancer: Prescribed by or in consultation with an oncologist or urologist

### **COVERAGE DURATION**

Prostate Cancer: 12 months

### **OTHER CRITERIA**

Approve for continuation of prior therapy