



**Triple-S Advantage**

**2022**

**Prior Authorization Criteria**

## ABIRATERONE

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**Affected Drugs:**

Abiraterone Acetate

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) metastatic castration-resistant prostate cancer, b) metastatic high-risk castration-sensitive prostate cancer, 2) Prescribed in combination with prednisone.

**Age Restrictions:** 18 years or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist, 3) Urologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ACNE PRODUCTS

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**Affected Drugs:**

Adapalene-Benzoyl Peroxide

Tretinoin

**Off-Label Uses:** N/A

**Exclusion Criteria:** Esthetic purposes.

**Required Medical Information:** 1) Diagnosis: acne vulgaris.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ACTIMMUNE

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**Affected Drugs:**

Actimmune

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document one of the following: a. Chronic Granulomatous Disease OR b. Severe Malignant Osteopetrosis.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Endocrinologist, 2) Orthopedist, 3) Hematologist, 4) Oncologist, 5) Infectious Disease Specialist, 6) Rheumatologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ADEFOVIR

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**Affected Drugs:**

Adefovir Dipivoxil

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Chronic hepatitis B, 2) Document the following: a. Positive Hepatitis B surface antigen (HBsAg) test, b. serum aminotransferases levels.

**Age Restrictions:** 12 years of age or older.

**Prescription Order Restrictions:** 1) Gastroenterologist, 2) Infectologist, 3) Hepatologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ADEMPAS

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**Affected Drugs:**

Adempas

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Pregnancy, 2) Co-administration with nitrates or nitric oxide donors (such as amyl nitrite) in any form, 3) Concomitant administration with phosphodiesterase (PDE) inhibitors, including specific PDE-5 inhibitors (such as sildenafil) or nonspecific PDE inhibitors (such as theophylline), 4) Pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP).

**Required Medical Information:** 1) Diagnosis: a. Pulmonary Arterial Hypertension, WHO Group 1 OR b. Persistent/Recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH), WHO Group 4, 2) Document the following: Cardiac catheterization results. a. Mean pulmonary artery pressure greater than or equal to 25 mmHg OR b. Pulmonary capillary wedge pressure less than or equal to 15 mmHg, 3) For Persistent/Recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH), WHO Group 4: no prerequisites are required.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Pulmonologist, 2) Cardiologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## AFINITOR

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### Affected Drugs:

Afinitor  
Afinitor Disperz  
Everolimus

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. advanced breast cancer, b. locally advanced or metastatic neuroendocrine tumors of pancreatic, gastrointestinal or lung origin, c. advanced renal cell carcinoma, d. renal angiomyolipoma and TSC, e. subependymal giant cell astrocytoma and TSC OR f. TSC-associated partial-onset seizures, 2) For advanced breast cancer document the following: a. patient is postmenopausal, b. the stage of breast cancer, c. hormone receptor positive results, d. HER2 negative results, e. failure to treatment with letrozole or anastrozole, f. prescribed in combination with exemestane, 3) For locally advanced or metastatic neuroendocrine tumors: document disease is unresectable, 4) For advanced renal cell carcinoma: Document failure of treatment with sunitinib or sorafenib, 5) For renal angiomyolipoma and TSC: a. Document patient not requiring immediate surgery, 6) For subependymal Giant Cell Astrocytoma and TSC: Document the following: a. Patient is not candidate for curative surgical resection.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist, 3) Urologist, 4) Neurologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** Afinitor Disperz is indicated ONLY for the treatment of patients with subependymal giant cell astrocytoma and TSC AND TSC-associated partial-onset seizures.

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

## ALECENSA

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**Affected Drugs:**

Alecensa

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC).

**Age Restrictions:** 18 years of age and older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Pulmonologist, 3) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## ALPHA 1-PROTEINASE INHIBITOR, HUMAN 50 MG/ML

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**Affected Drugs:**

Prolastin-C

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Immunoglobulin A (IgA) deficiency with antibodies against IgA. 2) Alpha-1-proteinase-associated liver disease.

**Required Medical Information:** 1) Serum alpha1-antitrypsin (AAT) levels less than 11 mcmol/L, 2) FEV1 levels less than 80%, 3) Provide Hepatitis B immunization dates.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Specialist in metabolic or genetic disorders, 2) Pulmonologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** Part D vs. Part B evaluation also applies. (\*)

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

## ALUNBRIG

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**Affected Drugs:**

Alunbrig

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist, 3) Pulmonologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ANABOLIC STEROIDS

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**Affected Drugs:**

Oxandrolone

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Known or suspected nephrosis (the nephrotic phase of nephritis). 2) Known or suspected hypercalcemia. 3) Known or suspected carcinoma of the breast in women with hypercalcemia. 4) Known or suspected carcinoma of the prostate or breast in male patients. 5) Pregnancy.

**Required Medical Information:** N/A

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ARANESP

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**Affected Drugs:**

Aranesp (Albumin Free)

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Uncontrolled hypertension, 2) Pure red cell aplasia (PRCA) that begins after treatment with Aranesp or other erythropoietin protein drugs.

**Required Medical Information:** 1) Initial prescription: a. Hgb is less than 10 g/dL, b. CBC, c. Total iron binding capacity, d. Iron levels, e. Ferritin levels, f. Vitamin B12 level, g. Folate level, h. Serum creatinine, i. BUN. 2) For reauthorizations: a. Patient who received erythropoietin in previous month: an increase in Hgb of at least 1g/dL after at least 12 weeks of therapy, b. Documentation of adequate iron stores. Adequate iron stores: serum ferritin is at least 100 mg/mL or transferrin saturation is at least 20%.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Nephrologist 2) Hematologist 3) Oncologist.

**Coverage Duration:** 12 weeks.

**Other Criteria:** 1) Part D vs. Part B evaluation also applies. (\*)

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

## ARCALYST

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**Affected Drugs:**

Arcalyst

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Patient has a diagnosis of cryopyrin-associated periodic syndromes (CAPS), including familial cold auto-inflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS), B) Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg, or C) Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence, 2) Provide annually, negative tuberculosis (TB) skin test results. For positive latent TB, patient must have completed or receiving treatment for Latent Tuberculosis Infection prior to initiating Arcalyst. 3) For pediatric patients: actual body weight (weight-based dosing).

**Age Restrictions:** 1) For CAPS, including FCAS and MWS, and RP: 12 years of age and older, 2) For DIRA: Adults and pediatric patients weighing at least 10 kg.

**Prescription Order Restrictions:** 1) Rheumatologist, 2) Immunologist 3) Geneticist, 4) Dermatologist, and 5) Cardiologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## AYVAKIT

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**Affected Drugs:**

Ayvakit

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Unresectable or metastatic gastrointestinal stromal tumor (GIST), or B) Treatment of advanced systemic mastocytosis (AdvSM), including patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL). 2) For GIST, document: Platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) For GIST: Hematologist/Oncologist. 2) For AdvSM (ASM, SMAHN, MCL): A) Allergist, B) Hematologist/Oncologist, or C) Immunologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## BALVERSA

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**Affected Drugs:**

Balversa

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: locally advanced or metastatic urothelial carcinoma, 2) Document susceptible FGFR3 or FGFR2 genetic alterations as detected by an FDA-approved test, 3) Document patient progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Urologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## BENLYSTA

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**Affected Drugs:**

Benlysta

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Systemic Lupus Erythematosus (SLE), b) Active lupus nephritis. 2) For SLE: Positive autoantibody test (anti-nuclear antibody [ANA]). 3) For lupus nephritis: Prescribed in combination with standard therapy.

**Age Restrictions:** 5 years of age or older.

**Prescription Order Restrictions:** 1) Nephrologist, or 2) Rheumatologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** Part D vs. Part B evaluation also applies. (\*)

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



## BOSULIF

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**Affected Drugs:**

Bosulif

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Philadelphia positive chronic myelogenous leukemia, 2) For chronic, accelerated, or blast phase Ph+ CML, document the following: a. positive results for Philadelphia chromosome, b. disease phase, c. resistance/ intolerance to prior therapy, 3) For newly-diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML): a. positive results for Philadelphia chromosome.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## BRAFTOVI

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**Affected Drugs:**

Braftovi

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Unresectable or metastatic melanoma, b) metastatic colorectal cancer (CRC) 2) For unresectable or metastatic melanoma: a) Positive BRAF V600E or V600K mutation test, b) Binimetinib in combination with encorafenib, 3) For metastatic colorectal cancer (CRC): a) BRAF V600E mutation test, b) used in combination with cetuximab, c) documented prior therapy.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Dermatologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## BRUKINSA

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**Affected Drugs:**

Brukina

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of Mantle Cell Lymphoma (MCL) in patients who have received at least one prior therapy, B) Treatment of Waldenstrom's macroglobulinemia (WM), or C) Treatment of relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen (e.g., obinutuzumab, ofatumumab, rituximab, etc.).

**Age Restrictions:** 18 years of age and older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** 1) For MCL and MZL: Validate that prior treatment regimen is in full compliance with the most up to date NCCN guidelines recommendations.

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

## CABOMETYX

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**Affected Drugs:**

Cabometyx

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Documented diagnosis: a) Advanced Renal Cell Carcinoma (RCC), b) Hepatocellular carcinoma (HCC), 2) For RCC: i) Prescribed as monotherapy or ii) Prescribed in combination with nivolumab as first-line treatment, 3) For HCC: document patient has been previously treated with sorafenib.

**Age Restrictions:** 18 years of age and older.

**Prescription Order Restrictions:** 1) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## CALQUENCE

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**Affected Drugs:**

Calquence

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. Mantle Cell Lymphoma (MCL), b. Chronic Lymphocytic Leukemia (CLL), OR c. Small Lymphocytic Lymphoma (SLL), 2) For MCL: Document one or more prior treatments.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## CAPRELSA

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**Affected Drugs:**

Caprelsa

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Patients with congenital Long QT syndrome, 2) Patients with hypocalcemia, hypokalemia, and hypomagnesemia.

**Required Medical Information:** 1) Diagnosis: locally advanced or metastatic medullary thyroid cancer, 2) Document: a. disease is unresectable and b. CMP results.

**Age Restrictions:** 18 years or older.

**Prescription Order Restrictions:** 1) Hematologist/Oncologist, 2) Endocrinologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** For hypocalcemia (normal values are 4.5 to 5.5 mEq/L), hypokalemia (normal values are 3.5 to 5.3 mEq/L), hypomagnesemia (normal values are 1.5 to 2.5 mEq/L).

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

## CARBAGLU

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**Affected Drugs:**

Carbaglu

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Adjunctive therapy for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS), b) Maintenance therapy for the treatment of chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS), c) Adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA). 2) Plasma ammonia levels (Normal range 10 to 80 mcg/dL)

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Geneticist, 2) Physician experienced in metabolic disorder.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## CAYSTON

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**Affected Drugs:**

Cayston

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis of cystic fibrosis with pseudomonas aeruginosa in the lungs, 2) Culture results, 3) FEV1 must be more than 25% or less than 75% predicted.

**Age Restrictions:** 7 years of age and older.

**Prescription Order Restrictions:** 1) Pulmonologist, 2) Infectious Disease Specialist.

**Coverage Duration:** 6 months.

**Other Criteria:** The recommended dose of Cayston for both adults and pediatric patients 7 years of age and older is one single-use vial (75 mg of aztreonam) reconstituted with 1 ml of sterile diluent administered 3 times a day for a 28-day course (followed by 28 days off Cayston therapy).

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



## CHANTIX

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**Affected Drugs:**

Chantix

Chantix Continuing Month Pak

Chantix Starting Month Pak

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document: intended use as part of smoking cessation treatment, 2) For renewals, provide medical justification that indicates: a) patient did not successfully stop smoking during prior therapy for reasons other than intolerability of adverse events, OR b) patient relapsed after treatment.

**Age Restrictions:** 17 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 6 months.

**Other Criteria:** N/A

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

## COMETRIQ

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**Affected Drugs:**

Cometriq 100 mg Daily Dose

Cometriq 140 mg Daily Dose

Cometriq 60 mg Daily Dose

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Metastatic medullary thyroid cancer.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## COPIKTRA

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**Affected Drugs:**

Copiktra

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) relapsed follicular lymphoma (FL), b) chronic lymphocytic leukemia (CLL), or c) small lymphocytic lymphoma (SLL), 2) Received 2 or more prior systemic therapies.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## CORLANOR

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### **Affected Drugs:**

Corlanor

### **Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Heart rate is maintained exclusively by a pacemaker, 2) Severe hypotension (blood pressure less than 90/50 mmHg), 3) Severe hepatic impairment (Child-Pugh class C), 4) In combination with strong cytochrome CYP3A4 inhibitors.

**Required Medical Information:** 1) Diagnosis of: a) symptomatic chronic heart failure (NYHA class II-IV), b) stable symptomatic heart failure due to dilated cardiomyopathy, 2) For adults with symptomatic chronic heart failure: a) Documentation is provided that the member has normal sinus rhythm, b) Resting heart beat equal to or greater than 70 beats or more per minute, c) Left ventricular ejection fraction (LVEF) equal to or less than 35%, d) Patient is on maximally tolerated doses of beta-blockers (e.g., carvedilol, metoprolol succinate, bisoprolol) or has a contraindication to beta-blockers.

**Age Restrictions:** 6 months of age or older.

**Prescription Order Restrictions:** 1) Cardiologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## COTELLIC

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**Affected Drugs:**

Cotellic

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Patients with wild-type BRAF melanoma.

**Required Medical Information:** 1) Diagnosis: Unresectable or metastatic melanoma, 2) Positive BRAF V600E or V600K mutation test, 3) Cotellic will be used in combination with vemurafenib, 4) Liver Function Test: No more than 3 times the upper limit of normal.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** 1) The safety of COTELLIC has not been established in patients with a baseline LVEF that is either below institutional lower limit of normal (LLN) or below 50%.

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

## CRESEMBA

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**Affected Drugs:**

Cresemba

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Coadministration with strong CYP3A4 inhibitors, such as ketoconazole or high-dose ritonavir, 2) Coadministration with strong CYP3A4 inducers, such as rifampin, carbamazepine, or long acting barbiturates.

**Required Medical Information:** 1) Diagnosis: Invasive aspergillosis or mucormycosis, 2) Liver Function Test: No more than 3 times the upper limit of normal.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Infectologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## CYSTAGON

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**Affected Drugs:**

Cystagon

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: nephropathic cystinosis.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Nephrologist, 2) Pediatric nephrologist, 3) Geneticist, 4) Specialist in metabolic or genetic disorders.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## CYSTARAN

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**Affected Drugs:**

Cystaran

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Corneal cystine crystal accumulation in patients with cystinosis.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Ophthalmologist, 2) Specialist in metabolic or genetic disorders.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## DALFAMPRIDINE

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**Affected Drugs:**

Dalfampridine ER

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) History of seizures, 2) Moderate or severe renal impairment (CrCl less than 50ml/min).

**Required Medical Information:** 1) Diagnosis: Multiple Sclerosis, 2) Creatinine Clearance more than 50ml/min.

**Age Restrictions:** 18 years or older.

**Prescription Order Restrictions:** Neurologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## DAURISMO

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**Affected Drugs:**

Daurismo

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Newly-diagnosed acute myeloid leukemia (AML), 2) Must be used in combination with low-dose cytarabine, 3) For patients 75 years of age or older: No additional information is required. For patients less than 75 years old: documentation of comorbidities that preclude use of intensive induction chemotherapy must be provided.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## DEFERASIROX

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### **Affected Drugs:**

Deferasirox

Deferasirox Granules

### **Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Creatinine Clearance (CRCL) less than 40 mL/min, 2) Severe hepatic impairment, 3) Platelet count less than 50,000/mcL, 4) Patient with poor performance status and high-risk myelodysplastic syndrome (MDS) or advanced malignancies.

**Required Medical Information:** 1) Diagnosis: a) chronic iron overload due to blood transfusions, b) chronic iron overload in patients with non-transfusion-dependent thalassemia (NTDT) syndromes, 2) Creatinine clearance greater than 40 ml/min, 3) Document lack of severe hepatic impairment, 4) Bilirubin test as evidence that bilirubin level was measured before initiation of treatment, 5) Platelets more than 50, 000/mcL.

**Age Restrictions:** 1) For chronic iron overload due to blood transfusions: 2 years and older, 2) For chronic iron overload with NTDT: 10 years of age and older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## DROXIDOPA

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**Affected Drugs:**

Droxidopa

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Orthostatic dizziness, lightheadedness, or the feeling that you are about to black out in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Cardiologist, 2) Neurologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## EMGALITY

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**Affected Drugs:**

Emgality

Emgality (300 MG Dose)

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Preventive Treatment of Migraine, or B) Treatment of Episodic Cluster Headache. 2) Document: A) Therapeutic failure, contraindication or intolerance to 2 or more preventive treatments (e.g. divalproex, propranolol, topiramate, etc.) AND B) For Preventive Treatment of Migraine indication only: 4 or more migraine days per month.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Internist, 2) Neurologist, 3) Headache Specialist, 4) Pain Specialist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ENBREL

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**Affected Drugs:**

Enbrel

Enbrel Mini

Enbrel SureClick

**Off-Label Uses:** N/A**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis, 2) For Rheumatoid Arthritis and Polyarticular Juvenile Idiopathic Arthritis (PJIA) document: disease is moderate to severe, 3) For Plaque Psoriasis (PSO) document: 5% BSA or crucial body areas such as the hands, feet, face, or genitals, 4) For Ankylosing Spondylitis: Inadequate response to at least 2 NSAIDs, 5) Latent tuberculosis test result. If positive must be on treatment. Tuberculosis result must have a date of less than 12 months prior to request, 6) Psoriatic Arthritis: no additional medical information is required.

**Age Restrictions:** 1) PJIA: 2 years of age or older, 2) PSO: 4 years of age or older, 3) For all other indications: 18 years of age or older.

**Prescription Order Restrictions:** 1) Dermatologist, 2) Rheumatologist.

**Coverage Duration:** End of Contract Year.

**Other Criteria:** N/A

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

## ENTECAVIR

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**Affected Drugs:**

Baraclude  
Entecavir

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: chronic hepatitis B virus infection, 2) Document the following: a. Hepatitis B surface antigen (HBsAg), b. Liver Function Test: No more than 3 times the upper limit of normal.

**Age Restrictions:** 2 years of age or older.

**Prescription Order Restrictions:** 1) Gastroenterologist, 2) Infectologist, 3) Hepatologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ENTRESTO

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**Affected Drugs:**

Entresto

**Off-Label Uses:** N/A

**Exclusion Criteria:** History of angioedema related to previous ACE inhibitor or ARB therapy.

**Required Medical Information:** 1) Diagnosis: A) To reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure, or B) for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction.

**Age Restrictions:** 1 year of age or older.

**Prescription Order Restrictions:** 1) Cardiologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** If currently on an ACE inhibitor or ARB, Entresto will replace them.

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



## EPIDIOLEX

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**Affected Drugs:**

Epidiolex

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Hypersensitivity to cannabidiol or any of the ingredients in Epidiolex.

**Required Medical Information:** 1) Diagnosis: Seizures associated with Lennox-Gastaut syndrome, Dravet syndrome or Tuberous Sclerosis Complex. 2) Document: Patient's actual body weight (weight-based dosing).

**Age Restrictions:** 1 year of age or older.

**Prescription Order Restrictions:** Neurologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## EPO

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**Affected Drugs:**

Procrit  
Retacrit

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Uncontrolled hypertension.

**Required Medical Information:** 1) Document the following: a. anemia diagnosis OR b. reduction of allogeneic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery, 2) For treatment of anemia document the cause: a. CKD, b. zidovudine in HIV-affected patients, OR c. myelosuppressive chemotherapy, 3) For anemia diagnosis initial prescription: a. Hgb is less than 10 g/dL, 4) For anemia associated to zidovudine in HIV Patients: a. Concomitant use of Zidovudine at a maximum dose of 4200 mg/week, 5) For reduction of allogeneic red blood cell transfusions in patients undergoing elective noncardiac, nonvascular surgery document: a. Hgb levels must be greater than 10 and less than or equal to 13 g/dL AND b. patient is at high risk for perioperative blood loss AND c. type of surgery, 6) For renewals: a. Patient who received erythropoietin in previous month: an increase in Hgb of at least 1 g/dL after at least 12 weeks of therapy, b. Documentation of adequate iron stores. Adequate iron stores: serum ferritin is at least 100 ng/mL or transferrin saturation is at least 20%.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 weeks.

**Other Criteria:** 1) Part D vs. Part B evaluation also applies. (\*)

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

## ERIVEDGE

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**Affected Drugs:**

Erivedge

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Pregnancy.

**Required Medical Information:** 1) Diagnosis: a. Metastatic Basal Cell Carcinoma (BCC) OR, b. Locally advanced BCC that has recurred following surgery or the patient is not a candidate for radiation or surgery. 2) Document the following: a. patient has recurred following surgery OR b. patient is not a candidate for radiation or surgery, 3) Negative pregnancy affirmation.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist, 3) Dermatologist

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ERLEADA

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**Affected Drugs:**

Erleada

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) metastatic castration-sensitive prostate cancer, b) non-metastatic, castration-resistant prostate cancer (NM-CRPC). 2) Document: Patient is receiving a gonadotropin-releasing hormone (GnRH) analog concurrently or had a bilateral orchiectomy.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Urologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ERLOTINIB

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**Affected Drugs:**

Erlotinib HCl

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Patients on platinum-based chemotherapy.

**Required Medical Information:** 1) Diagnosis: a. metastatic or locally advanced non-small cell lung cancer (NSCLC) OR b. locally advanced or metastatic pancreatic cancer, 2) Metastatic or locally advanced NSCLC: a. For first line treatment document: results for EGFR exon 19 deletions or exon 21 L858R substitution mutations, b. For previously treated patients document: failure to at least one prior chemotherapy regimen, c. For maintenance treatment document: a. completion of four cycles of platinum-based first-line chemotherapy without disease progression AND b. erlotinib is being used as monotherapy, 3) For metastatic pancreatic cancer document: a. disease is unresectable AND b. prescribed in combination with gemcitabine.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ESBRIET

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**Affected Drugs:**

Esbriet

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis of Idiopathic Pulmonary Fibrosis.

**Age Restrictions:** 18 years or older.

**Prescription Order Restrictions:** 1) Pulmonologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## EXKIVITY\*

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**Affected Drugs:**

Exkivity

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations. 2) Document: A) Evidence of confirmed epidermal growth factor receptor (EGFR) exon 20 insertion mutation, and B) Therapeutic failure with platinum-based chemotherapy (e.g., carboplatin, cisplatin, etc.).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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\* Pending CMS review

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

## FARYDAK

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**Affected Drugs:**

Farydak

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: multiple myeloma, 2) Document the following: a. prescribed in combination with bortezomib and dexamethasone, b. patient has received at least 2 prior regimens, including Bortezomib and an immunomodulatory agent (e.g. thalomid and pomalidomide).

**Age Restrictions:** 18 years or older.

**Prescription Order Restrictions:** 1) Oncologist 2) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** Therapy will be discontinued after a lifetime total of 16 cycles of treatment.

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



## FASENRA

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**Affected Drugs:**

Fasenra Pen

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Severe asthma with an eosinophilic phenotype, 2) Blood eosinophilic count greater than or equal to 150 cells/mcL (within previous 6 weeks), 3) Evidence of at least 3 consecutive months of therapy with high-dose of inhaled corticosteroids (ICS) in combination with other controller medications (eg. Long acting beta agonist (LABAs), Leukotriene receptor antagonist (LTRAs) with oral corticosteroids (OCS) use.

**Age Restrictions:** 12 years or older.

**Prescription Order Restrictions:** 1) Pulmonologist, 2) Immunologist, 3) Allergist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## FENTANYL PATCH

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### **Affected Drugs:**

FentaNYL

### **Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Patients who are not opioid tolerant (Patients are considered opioid tolerant if they have been taking at least 60 mg of oral morphine per day, 25 mcg of transdermal fentanyl/hr, 30 mg of oral oxycodone daily, 8 mg of oral hydromorphone daily, 25 mg oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer), 2) Patients with acute or intermittent pain, postoperative pain and/ or mild pain, 3) Patients who do not require continuous opioid analgesia.

**Required Medical Information:** 1) Document ALL of the following: a) Diagnosis: Pain, chronic (Severe), in opioid-tolerant patients AND b) previous failure or intolerability to non-opioid analgesics and immediate release opioids.

**Age Restrictions:** 2 years or older.

**Prescription Order Restrictions:** 1) Pain specialist, 2) Hematologist, 3) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## FERRIPROX

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**Affected Drugs:**

Deferiprone

Ferriprox

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Transfusional iron overload due to thalassemia syndromes, or B) Transfusional iron overload due to with sickle cell disease or other anemias, 2) Document the following: a. Absolute neutrophil count (ANC), b. CBC with differential, AND c. failure to current chelation therapy.

**Age Restrictions:** 8 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## FOTIVDA

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**Affected Drugs:**

Fotivda

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of relapsed or refractory advanced renal cell carcinoma (RCC). 2) Document: Prior use of two or more prior systemic therapies (e.g., axitinib, lenvatinib + everolimus, pazopanib, sorafenib, sunitinib, etc.).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist/Oncologist, or 2) Nephrologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## GATTEX

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**Affected Drugs:**

Gattex

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Short Bowel Syndrome (SBS) in adults who are dependent on parenteral support. 2) Laboratories: a. Liver Function test: ALT and AST (No more than 3 times the upper limit of normal), b. Bilirubin, c. Amylase and Lipase.

**Age Restrictions:** 1 year of age or older.

**Prescription Order Restrictions:** 1) Gastroenterologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## GAVRETO

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**Affected Drugs:**

Gavreto

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Treatment of RET Fusion-Positive Non-Small Cell Lung Cancer (NSCLC), b) RET-mutant medullary thyroid cancer (MTC), or c) RET fusion-positive thyroid cancer, 2) For RET Fusion-Positive NSCLC, document: a) Disease is metastatic, b) Disease is RET fusion-positive detected by FDA-approved test, 3) For RET-mutant MTC, document: a) Disease is advanced or metastatic, b) Require systemic therapy, c) Disease is RET-mutant-positive detected by FDA-approved test, 4) For RET fusion-positive thyroid cancer, document: a) Disease is advanced or metastatic, b) require systemic therapy, c) radioactive iodine-refractory (if radioactive iodine is appropriate), d) Disease is RET fusion-positive detected by FDA-approved test.

**Age Restrictions:** 12 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## GEMTESA

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**Affected Drugs:**

Gemtesa

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency. 2) Document: A) Treatment failure, intolerance, or contraindication to an antimuscarinic agent (e.g., oxybutynin, trospium, or tolterodine, etc.) OR B) Intolerance to mirabegron due to presence of cardiovascular comorbidities (e.g., hypertension, coronary artery disease, peripheral artery disease, cerebrovascular disease, arrhythmias and valvular heart disease, etc.).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## GILOTRIF

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**Affected Drugs:**

Gilotrif

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. metastatic non-small cell lung cancer OR b. metastatic, squamous non-small cell lung cancer, 2) For metastatic non-small cell lung cancer: document results of non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test, 3) For metastatic, squamous non-small cell lung cancer: document use of previous platinum-based chemotherapy.

**Age Restrictions:** 18 years or older.

**Prescription Order Restrictions:** 1) Pulmonologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## GROWTH HORMONE

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### **Affected Drugs:**

Genotropin  
Genotropin MiniQuick  
Humatrope  
Norditropin FlexPro  
Nutropin AQ NuSpin 10  
Nutropin AQ NuSpin 20  
Nutropin AQ NuSpin 5  
Serostim

### **Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Active malignancy, active proliferative or severe non-proliferative diabetic retinopathy, acute critical illness, 2) Closed epiphyses for pediatric patients, 3) Prader-Willi syndrome, in patients who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment, sudden death has been reported, 4) Underlying intracranial tumor, evidence of progression or recurrence, 5) Post kidney transplant, 6) Respiratory insufficiency.

**Required Medical Information:** 1) Total or partial deficiency of endogenous growth hormone evidenced by 1 or more of the following indicators: a. Minimum of 2 or more abnormal growth hormone provocative tests, secretion of the Growth Hormone is less than 10ng/ml, b. Delayed bone age of 2 or more years (2 standard deviations below the mean for chronological age), c. Slowed growth rate demonstrated by deviation from normal growth curves (growth rate below 7cm per year for children 3 years old and younger and less than 4-5cm per year for children from 3 years old until puberty), 2) For HIV-wasting: a. Current antiretroviral therapy, 3) For adult GHD (meets one of the following): a. Failed to stim tests with peak below 5 g/L, b. 3 or more PTH deficiency, c. Child onset GHD with no mutations embryopathic lesions or irreversible structural lesions/damage, low pre-treatment IGF-1 and failed 1 stim test (peak below 5 g/L) prior to starting GH treatment.

### **Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Endocrinologist, 2) Infectious Disease Specialist, 3) Nephrologist.

**Coverage Duration:** HIV-wasting: 12 weeks. All other indications: End of contract year.

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

**Other Criteria:** 1) For renewal of PWS only: body composition has improved, 2) Renewal for adult GHD: IGF-1 levels will be evaluated to confirm appropriateness of continued tx, 3) Renewal for HIV-wasting: BMI has improved or stabilized.

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

## HETLIOZ

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**Affected Drugs:**

Hetlitz

Hetlitz LQ

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Non 24-Hour Sleep-Wake Disorder (Non-24), b) Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS).

**Age Restrictions:** 1) For Hetlitz: 16 years of age or older. 2) For Hetlitz LQ: 3 to 15 years of age.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## HIGH RISK MEDICATIONS

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### **Affected Drugs:**

Benzotropine Mesylate  
Butalbital-APAP-Caffeine  
Cyclobenzaprine HCl  
Cyproheptadine HCl  
Dicyclomine HCl  
Digox  
Digoxin  
Duavee  
Estradiol  
Estradiol-Norethindrone Acet  
GuanFACINE HCl  
HydrOXYzine HCl  
Indomethacin  
Methyldopa  
Norpace CR  
Premarin  
Promethazine HCl  
Scopolamine  
Zolpidem Tartrate  
Zolpidem Tartrate ER

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Provider acknowledgement that medication is a HRM in the elderly and that the patient has failed and/or tried at least one non-high risk alternative.

**Age Restrictions:** PA applies to patients 65 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 1) For Cyclobenzaprine only: 21 days, renewals: 21 days. 2) All other drugs: End of contract year.

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

**Other Criteria:** For Cyclobenzaprine, Dicyclomine, Digoxin and Scopolamine Transdermal: only provider attestation of risks and benefits of therapy is required.

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

## HIGH RISK MEDICATIONS 2

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**Affected Drugs:**

PARoxetine HCl

PARoxetine HCl ER

Paxil

PHENobarbital

Trihexyphenidyl HCl

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Provider acknowledgement that medication is a HRM in the elderly and that the patient has failed and/or tried at least one non-high risk alternative.

**Age Restrictions:** PA applies to patients 65 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** For Phenobarbital: only provider attestation of risks and benefits of therapy is required.

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

## HUMAN PAPILLOMAVIRUS (HPV) VACCINE

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**Affected Drugs:**

Gardasil 9

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** N/A

**Age Restrictions:** 9 to 45 years of age.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 6 to 12 months, following the schedule, see Other Criteria.

**Other Criteria:** 1) Following the schedule: a) For ages 9 through 14 years: 0, 6 to 12 months OR 0, 2, and 6 months, b) For ages 15 through 45 years: 0, 2, and 6 months.

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

## HUMIRA

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### **Affected Drugs:**

Humira

Humira Pediatric Crohn's Start

Humira Pen

Humira Pen-CD/UC/HS Starter

Humira Pen-Pediatric UC Start

Humira Pen-Ps/UV/Adol HS Start

Humira Pen-Psor/Uveit Starter

### **Off-Label Uses:** N/A

### **Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. Rheumatoid Arthritis, b. Psoriatic Arthritis, c. Ankylosing Spondylitis, d. Juvenile Idiopathic Arthritis, e. Chron's Disease, f. Ulcerative Colitis, g. Plaque Psoriasis, h. Hidradenitis Suppurativa, OR Uveitis 2) Latent tuberculosis test result. If positive must be on treatment. Tuberculosis result must have a date of less than 12 months prior to request, 3) For Crohn's Disease document: a. Inadequate response to at least 2 of the following: Corticosteroids, Sulfasalazine, Azathioprine Mesalamine, 6-mercaptopurine, or Methotrexate, 4) For Pediatric Crohn's disease document: Inadequate response to at least 2 of the following: Corticosteroids, Azathioprine, 6-mercaptopurine, or Methotrexate, 5) For Plaque Psoriasis: 5% BSA or crucial body areas such as hands, feet, genitals, head, 6) For Ankylosing Spondylitis: Inadequate response to at least 2 NSAIDs, 7) For Ulcerative Colitis document: inadequate response to at least 2 of the following: Corticosteroids, Azathioprine, or 6-mercaptopurine. 8) For Hidradenitis Suppurativa, Juvenile Idiopathic Arthritis, Uveitis, and Psoriatic Arthritis: no additional medical information is required.

**Age Restrictions:** 1) For Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Adult Crohn's disease, and Plaque Psoriasis: 18 years of age or older. 2) For Juvenile Idiopathic Arthritis: 2 years of age or older. 3) For Pediatric Crohn's disease: 6 years of age or older. 4) For Hidradenitis Suppurativa: 12 years of age or older. 5) For Uveitis: 2 years of age or older. 6) For Ulcerative Colitis: 5 years of age or older.

**Prescription Order Restrictions:** 1) Rheumatologist, 2) Gastroenterologist, 3) Dermatologist, 4) Ophthalmologist.

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



**Coverage Duration:** End of Contract Year.

**Other Criteria:** N/A

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

## IBRANCE

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**Affected Drugs:**

Ibrance

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Documented diagnosis: Hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative advanced or metastatic breast cancer, 2) If used in combination with an aromatase inhibitor (i.e. letrozole, exemestane, anastrozole), document if patient is post-menopausal women or in men, 3) If used in combination with fulvestrant, document disease progression following endocrine therapy.

**Age Restrictions:** 18 years or older.

**Prescription Order Restrictions:** 1) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ICATIBANT

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**Affected Drugs:**

Icatibant Acetate

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Hereditary angioedema.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ICLUSIG

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**Affected Drugs:**

Iclusig

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. T3151-positive chronic myeloid leukemia (CML), b. T3151-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL), c. chronic myeloid leukemia, OR Ph+ALL, d. chronic phase (CP) chronic myeloid leukemia (CML), 2) For T3151-positive CML document the following: a. disease phase, b. positive results for T3151 mutation, 3) For T3151 positive Ph+ ALL document the following: a. positive results for T3151 mutation, b. positive results for Philadelphia chromosome, 4) For chronic myeloid leukemia document the following: a. disease phase, b. document intolerance or contraindication to other tyrosine kinase inhibitor therapy, 5) For Ph+ ALL document the following: a. positive results for Philadelphia chromosome, b. document intolerance or contraindication to other tyrosine kinase inhibitor therapy, 6) For CP-CML document the following: resistance or intolerance to at least two prior kinase inhibitors, 7) For renewals: document response to treatment.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist 2) Hematologist.

**Coverage Duration:** 1) Initial: 3 months, 2) Renewals: end of contract year.

**Other Criteria:** N/A

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

## IDHIFA

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**Affected Drugs:**

IDHIFA

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis of relapsed or refractory acute myeloid leukemia (AML). 2) Documented isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## IMATINIB

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**Affected Drugs:**

Imatinib Mesylate

**Off-Label Uses:** N/A**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. Philadelphia positive chronic myeloid leukemia (Ph+CML), b. Philadelphia positive acute lymphoblastic leukemia (Ph+ALL), c. myelodysplastic/myeloproliferative disease, d. aggressive systemic mastocytosis, e. hypereosinophilic syndrome and/or chronic eosinophilic leukemia, f. dermatofibrosarcoma protuberans (DFSP), OR g. gastrointestinal stromal tumors (GIST), 2) For adults with Ph+ALL document: disease relapse, 3) For pediatric Ph+ALL document: a. newly diagnosed AND b. prescribed in combination with chemotherapy, 4) For DFSP document: disease is unresectable, recurrent and/or metastatic, 5) For GIST document: a. CD117 positive results, AND b. one of the following: 1. disease is unresectable and/or metastatic, 2. Use of Imatinib for adjuvant therapy following resection, OR 3. GIST is resectable and Imatinib will be used to improve surgical morbidity by reducing tumor size preoperatively.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist, 3) Allergist, 4) Immunologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## IMBRUVICA

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**Affected Drugs:**

Imbruvica

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. mantle cell lymphoma (MCL), b. chronic lymphocytic leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) with or without 17p deletion, c. Waldenstrom's macroglobulinemia (WM), d. marginal zone lymphoma OR e) chronic graft versus host disease (cGVHD). 2) For MCL: document prior treatment. 3) For marginal zone lymphoma: document prior use of anti-CD20 therapy. 4) For cGVHD: document failure of one or more lines of systemic therapy. 5) For CLL/SLL: can be administered as a single agent, in combination with rituximab or obinutuzumab, or in combination with bendamustine and rituximab. 6) For WM: may be used in combination with rituximab or as a single agent.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematology, 3) Transplant Specialist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## IMMUNESUPPRESANTS

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**Affected Drugs:**

Azasan  
AzaTHIOprine  
CycloSPORINE  
CycloSPORINE Modified  
Everolimus  
Mycophenolate Mofetil  
Mycophenolate Sodium  
Prograf  
Rapamune  
SandIMMUNE  
Sirolimus  
Tacrolimus  
Zortress

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** 1) Part D vs. Part B evaluation also applies. (\*)

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



## INCRELEX

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**Affected Drugs:**

Increlex

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Epiphyseal closure, active malignancy, or concurrent use with GH therapy. 2) Patient has secondary causes of IGF-1 deficiency (e.g. hypothyroidism, malignancy, chronic systemic disease, skeletal disorders, malnutrition, celiac disease).

**Required Medical Information:** 1) Diagnosis: a. growth failure with severe primary IGFD OR b. growth hormone gene deletion with neutralizing antibodies to GH, 2) For growth failure with severe primary IGFD, document the following: a. Height standard deviation score, b. Growth hormone levels, c.IGF-1 standard deviation score.

**Age Restrictions:** 2 years of age or older.

**Prescription Order Restrictions:** 1) Endocrinologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## INJECTABLE MULTIPLE SCLEROSIS

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**Affected Drugs:**

Avonex Pen  
Avonex Prefilled  
Betaseron  
Copaxone  
Glatiramer Acetate

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Multiple Sclerosis (MS).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Neurologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## INJECTABLE TESTOSTERONE

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**Affected Drugs:**

Testosterone Cypionate

Testosterone Enanthate

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Males with carcinoma of the breast, 2) Males with known or suspected carcinoma of the prostate gland.

**Required Medical Information:** 1) Diagnosis, 2) For hypogonadism: a) For new starts only: Patient has a confirmed low testosterone level (i.e. morning total testosterone less than 300 ng/dL, morning free testosterone less than 9 ng/dL) or absence of endogenous testosterone, b) For renewals: patient has a total testosterone level of less than 450 ng/dL.

**Age Restrictions:** 12 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## INLYTA

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**Affected Drugs:**

Inlyta

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: advanced renal cell carcinoma (RCC), 2) Document: A) Prescribed in combination with avelumab for first-line treatment, B) Prescribed in combination with pembrolizumab for first-line treatment, or C) Prescribed as a single agent after failure of one prior systemic therapy. Examples of prior systemic therapies for RCC include regimens containing pazopanib, sorafenib, sunitinib, and cytokines (interferon alpha or interleukin-2).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist, 3) Urologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## INQOVI

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**Affected Drugs:**

Inqovi

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Myelodysplastic Syndrome (MDS), including previously treated and untreated, de novo and secondary MDS. 2) Document: A) French-American-British subtype (must include one of the following: refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia). B) International Prognostic Scoring System group (must be intermediate-1, intermediate-2, or high-risk).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## INREBIC

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**Affected Drugs:**

Inrebic

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document if the patient has intermediate or high-risk myelofibrosis (MF): a. Intermediate and high-risk MF patients include anyone over the age of 65 or who have or have had any of the following: anemia, constitutional symptoms, elevated white blood cell or blast counts or platelet counts less than  $100 \times 10^9/L$ , b. To continue therapy beyond 6 months, document spleen size reduction or symptom improvement since initiation of therapy with Inrebic (35% or more reduction in spleen volume on MRI or CT), 2) Document baseline values for: a) thiamine (vitamin B1), b) complete blood count with platelets, c) creatinine and BUN, d) hepatic panel, e) amylase and lipase.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 1) Initial evaluation: 6 months. 2) Renewals: End of contract year.

**Other Criteria:** N/A

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

## IRESSA

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**Affected Drugs:**

Iressa

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Documented Diagnosis of metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Pulmonologist, 3) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## IVIG

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**Affected Drugs:**

Gammagard  
Gammagard S/D Less IgA  
Gammaplex  
Gamunex-C

**Off-Label Uses:** N/A

**Exclusion Criteria:** IgA deficiency with antibodies to IgA and a history of hypersensitivity, history of anaphylaxis or severe systemic reaction to human immune globulin or product components. For Carimune, history of anaphylaxis or severe systemic reaction to human immune globulin or product components.

**Required Medical Information:** 1) Diagnosis, 2) Document at least one prior systemic therapy, 3) CBC with diff, 4) BMP.

**Age Restrictions:** N/A**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** Part D vs. Part B evaluation also applies. (\*)

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



## JAKAFI

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### **Affected Drugs:**

Jakafi

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document if the patient has intermediate or high-risk myelofibrosis (MF): a. Intermediate and high-risk MF patients include anyone over the age of 65 or who have or have had any of the following: anemia, constitutional symptoms, elevated white blood cell or blast counts or platelet counts less than  $100 \times 10^9/L$ , b. To continue therapy beyond 6 months, document spleen size reduction or symptom improvement since initiation of therapy with Jakafi (50% reduction from pretreatment baseline in palpable spleen length, or a 35% reduction in spleen volume on MRI or CT), 2) Document if the patient has polycythemia vera (PV): a. If patient had an inadequate response to or are intolerant to hydroxyurea, 3) Document if patient has steroid-refractory acute graft-versus-host disease (GVHD), 4) CBC.

**Age Restrictions:** 1) For MF and PV: 18 years of age or older, 2) For GVHD: 12 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 1) For MF: Initial: 6 months, renewals: End of Contract Year, 2) For PV and GVHD: End of contract year.

**Other Criteria:** N/A

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

## JUXTAPID

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**Affected Drugs:**

Juxtapid

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Pregnancy, 2) Concomitant use with strong or moderate CYP3A4 inhibitors, 3) Moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests.

**Required Medical Information:** 1) Diagnosis: homozygous familial hypercholesterolemia, 2) Document the following: a. Liver Function Test: No more than 3 times the upper limit of normal, b. Bilirubin levels: a. 0.2 to 0.8mg/dL, c. Negative pregnancy affirmation, 3) For untreated LDL-C provide values above 500mg/dL for diagnosis of HoFH, 4) Prior use of Statins or Ezetimibe for at least 90 days in the past 12 months OR adverse effects or intolerance to Statins or Ezetimibe.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Cardiologist, 2) Geneticist, 3) Endocrinologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** 1) Patient must start at an initial dose of 5mg.

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

## KALYDECO

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**Affected Drugs:**

Kalydeco

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Patients homozygous for the F508del mutation in the CFTR gene.

**Required Medical Information:** 1) Diagnosis of Cystic Fibrosis (CF), 2) Document patient has one mutation in the CFTR gene that is responsive to ivacaftor 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 bi-directional sequencing when recommended by the mutation test instructions for use. 3) Baseline FEV1 levels results, 4) Liver Function Test: No more than 3 times the upper limit of normal.

**Age Restrictions:** 4 months and older.

**Prescription Order Restrictions:** 1) Pulmonologist.

**Coverage Duration:** Initial: 3 months, renewals: end of contract year.

**Other Criteria:** 1) For Renewals document the following: a) Improvement of FEV1 Levels, 2) Decreased number of pulmonary exacerbations.

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

## KESIMPTA

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**Affected Drugs:**

Kesimpta

**Off-Label Uses:** N/A

**Exclusion Criteria:** Active Hepatitis B infection.

**Required Medical Information:** 1) Diagnosis: Treatment of Relapsing Forms of Multiple Sclerosis (MS), Including Clinically Isolated Syndrome, Relapsing-Remitting Disease, and Active Secondary Progressive Disease. 2) Document (only for first prescription): Hepatitis B virus screening test result [surface antigen (HBsAg) and anti HBV tests, must be negative].

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Neurologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## KISQALI

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**Affected Drugs:**

Kisqali 200 Dose

Kisqali 400 Dose

Kisqali 600 Dose

Kisqali Femara 200 Dose

Kisqali Femara 400 Dose

Kisqali Femara 600 Dose

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document diagnosis for advance or metastatic breast cancer, 2) If used in combination with an aromatase inhibitors (e.g., anastrozole, exemestane, letrozole), document: a) used as initial endocrine based therapy, b) patient is pre/perimenopausal or postmenopausal, 3) If used in combination with fulvestrant, document: a) used as initial endocrine based therapy or disease progression following endocrine therapy, b) patient is postmenopausal, 4) Bio-markers test result evidencing: a) Human epidermal growth factor receptor 2 (HER2)-negative, b) Positive hormone receptor (HR), 5) For post-menopausal women only, document intolerance or contraindication to least one of the following: a) Ibrance or b) Verzenio.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** 1) For Kisqali Femara Co-Pack, concurrent use of aromatase inhibitors (e.g. anastrozole, exemestane, letrozole) is not required.

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

## KORLYM

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**Affected Drugs:**

Korlym

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Pregnancy, 2) Use of simvastatin or lovastatin and CYP3A substrates with narrow therapeutic range, 3) Concurrent long-term corticosteroid use, 4) Women with history of unexplained vaginal bleeding, 5) Women with endometrial hyperplasia with atypia or endometrial carcinoma.

**Required Medical Information:** 1) Diagnosis: Hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed pituitary surgery or are not candidates for pituitary surgery, 2) Negative pregnancy affirmation.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## KOSELUGO

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**Affected Drugs:**

Koselugo

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Neurofibromatosis Type 1 (NF1), 2) Document: a) Patient has symptomatic and inoperable plexiform neurofibromas (PN), and b) Patient's body surface area (BSA) or actual body weight and height.

**Age Restrictions:** Pediatric patients 2 years of age or older.

**Prescription Order Restrictions:** 1) Geneticist, 2) Neurologist, 3) Neurosurgeon, 4) Oncologist, 5) Ophthalmologist, or 6) Orthopedic Surgeon.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## KUVAN

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**Affected Drugs:**

Kuvan

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: hyperphenylalaninemia due to tetrahydrobiopterin-(BH4)-responsive PKU, 2) For renewal: doctor must document a decrease in phenylalanine levels.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Geneticist, 2) Physician specialized in metabolic or genetic disorders.

**Coverage Duration:** Initial: 3 months, renewals: end of contract year.

**Other Criteria:** N/A

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



## LAPATINIB

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**Affected Drugs:**

Lapatinib Ditosylate

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Advanced or metastatic breast cancer, 2) Document positive results for HER2, 3) For patients with advanced or metastatic breast cancer document the following: a prescribed in combination with capecitabine. AND b. prior therapy with an anthracycline, a taxane, and trastuzumab. 4) For postmenopausal patients with hormone receptor positive metastatic breast cancer for whom hormonal therapy is indicated: prescribed in combination with letrozole.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## LENVIMA

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### **Affected Drugs:**

Lenvima (10 MG Daily Dose)  
Lenvima (12 MG Daily Dose)  
Lenvima (14 MG Daily Dose)  
Lenvima (18 MG Daily Dose)  
Lenvima (20 MG Daily Dose)  
Lenvima (24 MG Daily Dose)  
Lenvima (4 MG Daily Dose)  
Lenvima (8 MG Daily Dose)

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) differentiated thyroid cancer (DTC), b) renal cell cancer (RCC), c) hepatocellular carcinoma (HCC) or d) advanced endometrial carcinoma, 2) For DTC: document the tumor is locally recurrent or metastatic, progressive, failure or unresponsive to radioactive iodine treatment, 3) For RCC: a) Document the patient has advanced RCC and has used one prior-angiogenic therapy (for example: Sutent, Inlyta, Nexavar or Votrient) and prescribed in combination with everolimus, or b) Prescribed in combination with pembrolizumab for the first line treatment of advanced RCC. 4) For HCC: document disease is unresectable, 5) For advanced endometrial carcinoma: a) must be used in combination with pembrolizumab, b) advanced endometrial carcinoma is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), c) documented disease progression following prior systemic therapy and that patient is not candidate for curative surgery or radiation.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## LEUKINE

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**Affected Drugs:**

Leukine

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Hypersensitivity to yeast-derived products. 2) Use of Leukine within 24 hours preceding or following chemotherapy or radiotherapy. 3) Use of Leukine for prophylaxis of FN. 4) When Leukine is used for treatment of acute FN: patient received prophylactic Neulasta during the current chemotherapy cycle. 5) When Leukine is used for acute myelogenous leukemia (AML): excessive leukemic myeloid blasts (greater than or equal to 10%) in the bone marrow or peripheral blood.

**Required Medical Information:** 1) Diagnosis, 2) CBC with differential, 3) Complete Metabolic Panel (CMP), 4) Body weight.

**Age Restrictions:** N/A**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** Part D vs. Part B evaluation also applies. (\*)

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

## LIDOCAINE PATCH

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**Affected Drugs:**

Lidocaine

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: pain associated with post-herpetic neuralgia.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## LINEZOLID

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### **Affected Drugs:**

Linezolid

### **Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Carcinoid syndrome (unless monitored for signs/symptoms of serotonin syndrome), 2) Concomitant use of MAOIs (e.g. phenelzine, isocarboxazid) or use within 2 weeks of taking an MAOI, 3) Concomitant use of serotonin reuptake inhibitors, tricyclic antidepressants, triptans, meperidine, or buspirone (unless monitored for signs/symptoms of serotonin syndrome), 4) Concomitant use of sympathomimetic agents (e.g. pseudoephedrine), vasopressor agents (e.g. epinephrine, norepinephrine), or dopaminergic agents (e.g. dopamine) (unless monitored for potential blood pressure increases), 5) Uncontrolled hypertension (unless monitored for potential blood pressure increases), 6) Pheochromocytoma (unless monitored for potential blood pressure increases), 7) Thyrotoxicosis (unless monitored for potential blood pressure increases).

**Required Medical Information:** 1) Diagnosis: a. nosocomial pneumonia, b. community-acquired pneumonia, c. skin infection, OR d. Vancomycin-resistant *Enterococcus faecium* infection, 2) Culture results.

### **Age Restrictions:** N/A

### **Prescription Order Restrictions:** N/A

### **Coverage Duration:** 31 days.

### **Other Criteria:** N/A

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

## LONSURF

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**Affected Drugs:**

Lonsurf

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) metastatic colorectal cancer or b) metastatic gastric or gastroesophageal junction adenocarcinoma. 2) For metastatic colorectal cancer: Documentation of previously treated with: a) fluoropyrimidine-, oxaliplatin-, and b) irinotecan-containing chemotherapy, and c) anti-VEGF therapy, and d) if RAS wild type, anti-EGFR therapy, 3) For metastatic gastric or gastroesophageal junction adenocarcinoma: Documentation of previously treated with: a) at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and b) if appropriate, HER2/neu-targeted therapy.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## LORBRENA

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**Affected Drugs:**

Lorbrena

**Off-Label Uses:** N/A

**Exclusion Criteria:** Concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. Johns wort, or long-acting barbiturates).

**Required Medical Information:** 1) Diagnosis: Treatment of metastatic non-small cell lung cancer (NSCLC), 2) Document: Tumors are anaplastic lymphoma kinase (ALK)-positive.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Pulmonologist, 3) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## LUMAKRAS

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**Affected Drugs:**

Lumakras

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC). 2) Document: A) Evidence of KRAS G12C mutation, and B) Prior use of at least one systemic therapy (e.g., atezolizumab, bevacizumab, carboplatin, cisplatin, nivolumab, paclitaxel, pemetrexed, etc.).

**Age Restrictions:** 18 years of age and older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## LUPKYNIS

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**Affected Drugs:**

Lupkynis

**Off-Label Uses:** N/A

**Exclusion Criteria:** Patients concomitantly using strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin).

**Required Medical Information:** 1) Diagnosis: Treatment of active lupus nephritis (LN). 2) Document: Prescribed in combination with background immunosuppressive therapy regimen (mycophenolate mofetil and corticosteroid).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Nephrologist, or 2) Rheumatologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## LYNPARZA

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### **Affected Drugs:**

Lynparza

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) advanced ovarian cancer, b) advance or recurrent epithelial ovarian cancer, c) advanced or recurrent fallopian tube cancer, d) advanced or recurrent primary peritoneal cancer, e) metastatic breast cancer, f) metastatic pancreatic adenocarcinoma, OR g) metastatic castration-resistant prostate cancer (mCRPC). 2) For advance ovarian cancer document the following: a. gBRCA mutation or suspected, b. prior treatment with at least three chemotherapy regimens. 3) For advanced or recurrent epithelial ovarian cancer, fallopian tube cancer, OR primary peritoneal cancer document: a) prior treatment with a platinum containing regimen. 4) For advanced epithelial ovarian cancer, fallopian tube cancer, OR primary peritoneal cancer, if cancer is associated with homologous recombination deficiency (HRD)-positive status: used in combination with bevacizumab. 5) For metastatic breast cancer document the following: a) gBRCA mutation or suspected, b) Bio-markers test result evidencing: i) Human epidermal growth factor receptor 2 (HER2)-negative, ii) Positive hormone receptor (HR). 6) If human epidermal growth factor receptor 2 (HER2)-negative: document previous chemotherapy treatment. 7) If hormone receptor (HR)-positive breast cancer: patient should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. 8) For metastatic pancreatic adenocarcinoma document the following: a) deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), b) disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. 9) For metastatic castration-resistant prostate cancer (mCRPC) document the following: a) deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation, and b) disease has progressed following prior treatment with enzalutamide or abiraterone.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist, 3) Gastroenterologist, 4) Urologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** Homologous recombination deficiency (HRD)-positive status is defined by either: a) a deleterious or suspected deleterious BRCA mutation, and/or b) genomic instability.

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

## MAVYRET

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### **Affected Drugs:**

Mavyret

### **Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Patients with severe hepatic impairment (Child-Pugh C), 2) Coadministration with atazanavir and rifampin.

**Required Medical Information:** 1) Documented diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6. 2) Documentation of hepatic fibrosis status by one of the following: a. Clinical evidence stating the cirrhosis status as attested by the prescribing physician, b. Liver biopsy METAVIR score, or alternative scoring equivalent, c. Radiological imaging of the liver, d. Transient elastography (FibroScan) score, e. FibroTest (FibroSure) score, f. APRI score. 3) Indicate if patient is naive or experienced, if experienced document prior use of PEG-IFN, RBV, HCV protease or polymerase inhibitors.

**Age Restrictions:** 3 years of age or older.

**Prescription Order Restrictions:** 1) Hepatologist, 2) Gastroenterologist or, 3) Infectious Disease Specialist.

**Coverage Duration:** 8 to 16 weeks based on HCVs and patients characteristics, see Other Criteria.

**Other Criteria:** Duration for genotypes 1, 2, 3, 4, 5 and 6 during 8 - 16 weeks according to the clinical scenario assessed by the pharmacist in full compliance with the updated HCV guidelines recommendations at the time.

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

## MAYZENT

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**Affected Drugs:**

Mayzent

Mayzent Starter Pack

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Patients with a CYP2C9 3/3 genotype, 2) Patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure, 3) Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker.

**Required Medical Information:** 1) Diagnosis: Multiple Sclerosis (MS), 2) Document patient has been tested for CYP2C9 variants to determine CYP2C9 genotype.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Neurologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## MEGESTROL 1

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**Affected Drugs:**

Megestrol Acetate Suspension

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Cachexia or an unexplained, significant weight loss in patients with a diagnosis of acquired immunodeficiency syndrome (AIDS). 2) If patient is 65 years of age or older, document provider acknowledgement that medication is a HRM in the elderly and that the patient has failed and/or tried at least one non-high risk alternative.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## MEGESTROL 2

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**Affected Drugs:**

Megestrol Acetate Tablet

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Palliative treatment of advanced carcinoma of the breast or endometrium (i.e., recurrent, inoperable, or metastatic disease). 2) If patient is 65 years of age or older, document provider acknowledgement that medication is a HRM in the elderly.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## MEKINIST

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**Affected Drugs:**

Mekinist

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. melanoma with involvement of lymph node(s), b. unresectable or metastatic melanoma, c. metastatic non-small cell lung cancer OR d. locally advanced or metastatic anaplastic thyroid cancer (ATC), 2) For melanoma with involvement of lymph node(s), document the following: a. positive results for BRAF V600E or V600K mutations, b. complete resection, c. must be used in combination with dabrafenib, 3) For unresectable or metastatic melanoma, document the following: a. positive results for BRAF V600E or V600K mutations, b. indicated as a single agent or in combination with dabrafenib, 4) For metastatic non-small cell lung cancer document the following: a. positive results for BRAF V600E mutations AND b. must be used in combination with dabrafenib, 5) For locally advanced or metastatic anaplastic thyroid cancer (ATC), document the following: a. positive results for BRAF V600E mutation, b. no satisfactory locoregional treatment option, AND c. must be used in combination with dabrafenib.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## MEKTOVI

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**Affected Drugs:**

Mektovi

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Unresectable or metastatic melanoma, 2) Positive BRAF V600E or V600K mutation test, 3) Encorafenib in combination with Binimetinib.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Dermatologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## MEPERIDINE

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**Affected Drugs:**

Meperidine HCl

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: moderate to severe pain OR 2) document procedure.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** For procedures: One month. For any other purposes: 3 months.

**Other Criteria:** N/A

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

## MODAFINIL

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**Affected Drugs:**

Modafinil

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: excessive sleepiness associated with a. narcolepsy, b. obstructive sleep apnea OR c. shift work disorder, 2) For obstructive sleep apnea: a. Current therapies for sleep apnea.

**Age Restrictions:** 17 years of age and older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## NAMENDA

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**Affected Drugs:**

Memantine HCl

Memantine HCl ER

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of moderate to severe dementia of the Alzheimer's type, 2) Prior use of memantine immediate release, 3) For oral suspension: documented swallowing disorder or an inability to swallow tablets.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## NATPARA

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**Affected Drugs:**

Natpara

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, patients with hereditary disorders predisposing to osteosarcoma or patients with a history of prior external beam or implant radiation therapy involving the skeleton), 2) Patients with hypoparathyroidism caused by calcium-sensing receptor mutations, 3) Patients with acute post-surgical hypoparathyroidism.

**Required Medical Information:** 1) Diagnosis: hypocalcemia in patients with hypoparathyroidism, 2) Serum calcium (albumin-corrected): Level must be above 7.5 mg.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Endocrinologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## NERLYNX

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**Affected Drugs:**

Nerlynx

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) HER2-positive early-stage breast cancer, or b) advanced or metastatic HER2-positive breast cancer. 2) Document: a) For HER2-positive early-stage breast cancer: treatment with trastuzumab-based therapy, or b) for advanced or metastatic HER2-positive breast cancer: i) prescribed in combination with capecitabine, and ii) prior treatment with two or more anti-HER2 based regimens, and c) for all diagnosis: positive results for HER2.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## NEUPOGEN / NEULASTA

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**Affected Drugs:**

Neulasta

Neupogen

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) For Neupogen: Hypersensitivity to E. coli-derived proteins, 2) For Neulasta: not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

**Required Medical Information:** 1) For Neupogen document: a. cancer patients receiving chemotherapy OR b. cancer patients undergoing bone marrow transplantation OR c. patients undergoing leukapheresis OR d. severe chronic neutropenia OR e. exposure to myelosuppressive doses of radiation, 2) For Neulasta document: a. cancer patient receiving chemotherapy OR b. exposure to myelosuppressive doses of radiation, 3) Document the following lab results: a. Platelet counts AND b. CBC with differential.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist, 3) Infectious Disease Specialist.

**Coverage Duration:** 3 months.

**Other Criteria:** Part D vs. Part B evaluation also applies. (\*)

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

## NEXAVAR

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**Affected Drugs:**

NexAVAR

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Combination with carboplatin and paclitaxel in patients with squamous cell lung cancer.

**Required Medical Information:** 1) Diagnosis: a. hepatocellular carcinoma (HCC), b. renal cell carcinoma (RCC), OR c. locally recurrent or metastatic differentiated thyroid carcinoma (DTC), 2) For HCC: document disease is unresectable, 3) For RCC document one of the following: a. Disease relapse, b. Stage IV and medically or surgically unresectable disease, c. Progression despite cytokine therapy, 4) For locally recurrent or metastatic DTC document: failure /unresponsive to radioactive iodine treatment.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Nephrologist, 3) Gastroenterologist, 4) Hepatologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## NINLARO

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**Affected Drugs:**

Ninlaro

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Multiple Myeloma, 2) Document if patient has received at least one prior therapy, 3) Use in combination with lenalidomide and dexamethasone must be documented.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** Indicated on days 1, 8 and 15 of a 28-day cycle.

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



## NITYR

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**Affected Drugs:**

Nityr

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document the following: a. patient has a diagnosis of hereditary tyrosinemia type 1.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Physician specializing in metabolic or genetic disorders, 2) Geneticist, 3) Gastroenterologist, 4) Hematologist, 5) Nephrologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## NOXAFIL

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### **Affected Drugs:**

Noxafil

Posaconazole

### **Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Concomitant use with HMG-CoA reductase inhibitors primarily metabolized by CYP3A4 (eg, atorvastatin, lovastatin, and simvastatin), sirolimus, or CYP3A4 substrates that prolong the QT interval (pimozide and quinidine).

**Required Medical Information:** 1) Document: a. Treatment of invasive aspergillosis, b. Intended use for prophylaxis of invasive aspergillosis or candida infections due to being severely immunocompromised OR c. Diagnosis of oropharyngeal candidiasis, 2) For prophylaxis of invasive aspergillosis and candida infections: Document patient is at high risk to develop these infections such as one of the following: a. HCST (Hemopoietic stem cell transplantation), b. GVHD (graft-versus-host disease), OR c. Patients with hematologic malignancies with prolonged neutropenia from chemotherapy, 3) For oropharyngeal candidiasis, document failure or intolerant to itraconazole and/or fluconazole, 4) Liver Function Test: No more than 3 times the upper limit of normal.

**Age Restrictions:** 1) For prophylaxis: 2 years of age or older, or 2) For treatment: 13 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## NUEDEXTA

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**Affected Drugs:**

Nuedexta

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Concomitantly taking other drugs containing quinidine, quinine, mefloquine, monoamine oxidase inhibitors (MAOIs), or drugs that both prolong QT interval and are metabolized by CYP2D6. 2) Patient has a prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, or heart failure. 3) Patient has complete atrioventricular (AV) block without implanted pacemaker or is at high risk of complete AV block.

**Required Medical Information:** 1) Documented Diagnosis of neurological disease associated with Pseudobulbar affect.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## NUPLAZID

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**Affected Drugs:**

Nuplazid

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis of hallucinations and delusions associated with Parkinson's disease psychosis.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Neurologist, 2) Psychiatrist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## NURTEC

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**Affected Drugs:**

Nurtec

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Acute treatment of migraine with or without aura OR B) Preventive treatment of episodic migraine. 2) Document: A) For Acute treatment of migraine with or without aura: i) Therapeutic failure, contraindication or intolerance to at least two triptans (e.g., rizatriptan, sumatriptan, etc.), and ii) Number of migraine episodes in the last 30 days, B) For the Preventive treatment of episodic migraine: i) Therapeutic failure, contraindication or intolerance to at least two preventive treatments.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Internist, 2) Neurologist, 3) Headache Specialist, 4) Pain Specialist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## OCREVUS\*

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**Affected Drugs:**

Ocrevus

**Off-Label Uses:** N/A

**Exclusion Criteria:** Active hepatitis B virus infection.

**Required Medical Information:** 1. Documentation of relapsing forms of Multiple Sclerosis (MS): a. Relapse-Relapsing MS (RRMS). 2. Documentation of Progressive forms of MS: a. Primary Progressive MS (PPMS). 3. Hepatitis B virus screening before the first dose.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Neurologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** Part D vs. Part B evaluation also applies.(\*)

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\* Pending CMS review

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

## OCTREOTIDE

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**Affected Drugs:**

Octreotide Acetate

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. acromegaly, b. diarrhea and/or flushing episodes associated with metastatic carcinoid tumor OR c. diarrhea associated with VIP-secreting tumors, 2) For acromegaly document: inadequate response/unable to tolerate surgery, pituitary irradiation, and bromocriptine at maximally tolerated doses.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** Part D vs. Part B evaluation also applies. (\*)

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

## ODOMZO

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**Affected Drugs:**

Odomzo

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Pregnancy.

**Required Medical Information:** 1) Documented diagnosis of locally advanced BCC that has recurred following surgery or the patient is not a candidate for radiation or surgery, 2) Negative pregnancy affirmation.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Hematologist/Oncologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## OFEV

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**Affected Drugs:**

Ofev

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Idiopathic pulmonary fibrosis, b) Systemic sclerosis-associated interstitial lung disease (SSc-ILD) or c) Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Pulmonologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ONUREG

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**Affected Drugs:**

Onureg

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Acute Myeloid Leukemia (AML). 2) Document: A) Patient achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy [e.g., cytarabine, daunorubicin, idarubicin (Idamycin PFS), midostaurin (Rydapt), gemtuzumab ozogamicin (Mylotarg), cladribine (Cladribine Novaplus)], or B) Patient is not able to complete intensive curative therapy.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## OPSUMIT

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**Affected Drugs:**

Opsumit

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Pregnancy.

**Required Medical Information:** 1) Diagnosis of Pulmonary Arterial Hypertension, WHO Group 1, 2) Cardiac catheterization results: a. Mean pulmonary artery pressure (greater than or equal to 25mmHg) OR b. Pulmonary capillary wedge pressure (less than or equal to 15mmHg), 3) Acute vasodilator testing result (required for patients with Idiopathic Pulmonary Arterial Hypertension ONLY).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Pulmonologist, 2) Cardiologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ORAL LONG ACTING OPIOIDS

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### Affected Drugs:

Morphine Sulfate ER  
OxyCODONE HCl ER

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) In patient with acute or severe bronchial asthma, 2) In any patient who has or is suspected of having a paralytic ileus, 3) For Oxycodone ER and Morphine ER 100 mg and 200 mg: Patients who are not opioid tolerant. (Patients are considered opioid tolerant if they have been taking at least 60 mg of oral morphine per day, 25 mcg of transdermal fentanyl/hr, 30 mg of oral oxycodone daily, 8 mg of oral hydromorphone daily, 25 mg oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer), 4) Patients with acute or intermittent pain, postoperative pain and/ or mild pain, 5) Patients who do not require continuous opioid analgesia.

**Required Medical Information:** 1) Document ALL of the following: a) Diagnosis: Pain, chronic (Severe), b) previous failure or intolerability to non-opioid analgesics and immediate release opioids, AND c) For Oxycodone ER and Morphine ER equal or greater than 60 mg: For opioid-tolerant patients only, as documented by prescriber.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Pain specialist, 2) Hematologist, 3) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ORAL MULTIPLE SCLEROSIS

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**Affected Drugs:**

Dimethyl Fumarate

Dimethyl Fumarate Starter Pack

Gilenya

**Off-Label Uses:** N/A

**Exclusion Criteria:** For Gilenya only: 1) Patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure, 2) History or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless patient has a functioning pacemaker, 3) Baseline QTc interval greater or equal to 500 ms, 4) Treatment with Class Ia or Class III anti-arrhythmic drugs.

**Required Medical Information:** 1) Diagnosis: Multiple Sclerosis.

**Age Restrictions:** 18 years of age or older, For Gilenya only: 10 years of age or older.

**Prescription Order Restrictions:** 1) Neurologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ORENCIA

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**Affected Drugs:**

Orencia

Orencia ClickJect

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Concomitant use of biologic rheumatoid arthritis therapy. 2) Tumor necrosis factor (TNF) antagonists, live vaccines, or use of live vaccines within 3 months of discontinuation of abatacept is not recommended.

**Required Medical Information:** 1) Diagnosis: a. Adult Rheumatoid Arthritis, b. Juvenile Idiopathic Arthritis OR c. Psoriatic Arthritis, 2) Latent tuberculosis test result. If positive must be on treatment. Tuberculosis result must have a date of less than 12 months prior to request.

**Age Restrictions:** 2 years of age or older.

**Prescription Order Restrictions:** 1) Rheumatologist.

**Coverage Duration:** End of Contract Year.

**Other Criteria:** N/A

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

## ORFADIN

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**Affected Drugs:**

Nitisinone  
Orfadin

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document the following: a. patient has a diagnosis of hereditary tyrosinemia type 1.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Physician specializing in metabolic or genetic disorders, 2) Geneticist, 3) Gastroenterologist, 4) Hematologist, 5) Nephrologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ORGOVYX

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**Affected Drugs:**

Orgovyx

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: For the treatment of advanced prostate cancer.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Urologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## ORKAMBI

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**Affected Drugs:**

Orkambi

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis of Cystic Fibrosis (CF) in patients with F508del, 2) Baseline FEV1 levels results, 3) Liver Function Test: No more than 3 times the upper limit of normal.

**Age Restrictions:** 2 years and older.

**Prescription Order Restrictions:** Pulmonologist.

**Coverage Duration:** Initial: 3 months, renewals: End of contract year.

**Other Criteria:** 1) For Renewals document the following: a) Improvement of FEV1 Levels, OR b) Decreased number of pulmonary exacerbations.

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

## PANRETIN\*

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**Affected Drugs:**

Panretin

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Dermatologist, 2) Infectologist, or 3) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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\* Pending CMS review

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

## PARICALCITOL

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**Affected Drugs:**

Paricalcitol

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Hypercalcemia, 2) Vitamin D toxicity.

**Required Medical Information:** 1) Document the following: a. intended use for prevention and treatment secondary hyperparathyroidism AND. patient has chronic kidney disease (CKD) stage 3, 4, or 5, 2) Provide with the prescription the laboratory results for the following test (the test should be done within 30 days of the prescription, except intact parathyroid hormone (iPTH) which is valid for 90 days): 1. Serum Phosphorous: a. For CKD Stage 3 and 4 levels should be 2.7-4.6 mg/dL b. For CKD Stage 5 levels should be 3.5-5.5mg/dL, 2. Plasmatic IPTH: a. For CKD Stage 3 levels should be greater than 70 pg/mL, b. For CKD Stage 4 levels should be greater than 110 pg/mL, c. For CKD Stage 5 levels should be greater than 300pg/mL, 3. CMP.

**Age Restrictions:** 10 years or older.

**Prescription Order Restrictions:** 1) Endocrinologist, 2) Nephrologist, 3) Oncologist, 4) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## PCSK9 INHIBITORS

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### **Affected Drugs:**

Praluent

Repatha

Repatha Pushtronex System

Repatha SureClick

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Primary Hyperlipidemia, B) Heterozygous Familial Hypercholesterolemia (HeFH), C) Homozygous Familial Hypercholesterolemia (HoFH), or D) Clinical Atherosclerotic Cardiovascular Disease (ASCVD). 2) Document: A) For the first prescription: i) Baseline LDL-C Level greater than 70 mg/dL (lipid panel results), and ii) One of the following: a) Patient has completed a continuous trial of 12-weeks (84 days) of one high or moderate intensity statin at the patients maximally tolerated dose, or b) Therapeutic failure, adverse effects, or intolerance to at least 2 high intensity statins (e.g. atorvastatin equal to or greater than 40 mg, rosuvastatin equal to or greater than 20 mg) or 2 moderate intensity statin in combination with ezetimibe. B) For renewals: Clinical response with LDL-C lowering evidence (lipid panel results).

**Age Restrictions:** 1) For Praluent: 18 years of age or older, 2) For Repatha: 13 years of age or older.

**Prescription Order Restrictions:** 1) Cardiologist, 2) Endocrinologist, 3) Internist, 4) Lipidologist, or 5) Vascular Surgeon.

**Coverage Duration:** 1) For the first prescription: 6 months, or 2) For renewals: End of contract year.

**Other Criteria:** Clinical Atherosclerotic cardiovascular disease (ASCVD) can be considered as: acute coronary syndromes (ACS), stroke, myocardial infarction, transient ischemic attack, stable or unstable angina, peripheral arterial disease, coronary or arterial revascularization, or myocardial revascularization procedures (CABG or PCI).

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

## PEGASYS

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**Affected Drugs:**

Pegasys

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Hepatic decompensation (Child-Pugh score greater than 6 [class B or C]) in cirrhotic patients before treatment, 2) Autoimmune hepatitis.

**Required Medical Information:** 1) Diagnosis: a. Chronic Hepatitis C (CHC) OR b. Chronic Hepatitis B (CHB), 2) Creatinine Clearance (CRCL), 3) For Chronic HCV: a. HCV genotype, 4) For Hepatitis B: a. Hepatitis B surface antigen (HBsAg).

**Age Restrictions:** 1) For CHC: 5 years of age or older, 2) For CHB: 3 years of age or older.

**Prescription Order Restrictions:** 1) Gastroenterologist, 2) Infectologist, 3) Hepatologist.

**Coverage Duration:** 12 to 24wks for HCV genotypes 1, 2, 3, 4, 5 & 6 depending on updated HCV guidelines. 48wks for HBV.

**Other Criteria:** N/A

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

## PEMAZYRE

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**Affected Drugs:**

Pemazyre

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Cholangiocarcinoma, 2) Document: a) Fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, b) Previously used therapies, c) Disease is unresectable and locally advanced or metastatic.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## PIQRAY

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**Affected Drugs:**

Piqray (200 MG Daily Dose)

Piqray (250 MG Daily Dose)

Piqray (300 MG Daily Dose)

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Advanced or metastatic breast cancer, 2) Document patient is postmenopausal or men, 3) Bio-markers test result evidencing: a) Human epidermal growth factor receptor 2 (HER2)-negative, b) Positive hormone receptor (HR), 4) The patient has PIK3CA-mutated breast cancer as detected by a FDA approved test, 5) The patient has progressed on or after at least one prior endocrine-based regimen, 6) Used in combination with fulvestrant.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## PLEGRIDY

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**Affected Drugs:**

Plegridy

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Multiple Sclerosis, 2) Liver Function Test: No more than 3 times the upper limit of normal.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Neurologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## POMALYST

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**Affected Drugs:**

Pomalyst

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Pregnancy.

**Required Medical Information:** 1) Diagnosis: a) multiple myeloma or b) Kaposi sarcoma (KS), 2) For multiple myeloma document the following: a. prescribed in combination with dexamethasone, AND b. prior treatment with at least 2 therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of last therapy, 3) For Kaposi sarcoma (KS) document: a) patient is HIV-negative or b) patient has AIDS-related KS and failed highly active antiretroviral therapy (HAART), 4) Negative pregnancy affirmation.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## PRETOMANID

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### **Affected Drugs:**

Pretomanid

### **Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Drug-sensitive (DS) tuberculosis, 2) Latent infection due to *Mycobacterium tuberculosis*, 3) Extra-pulmonary infection due to *Mycobacterium tuberculosis*, 4) MDR-TB that is not treatment-intolerant or nonresponsive to standard therapy (e.g. isoniazid, rifampin, ethambutol, pyrazinamide).

**Required Medical Information:** 1) Diagnosis: a) Treatment of pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (T B): in combination with bedaquiline and linezolid, 2) Document: a) Concurrent use of: i) Bedaquiline, AND ii) Linezolid, AND b) Latent tuberculosis test result.

**Age Restrictions:** 18 years of age and older.

**Prescription Order Restrictions:** 1) Infectologist, 2) Internist.

**Coverage Duration:** 26 weeks.

**Other Criteria:** 1) Co-administration of strong or moderate CYP3A4 inducers (i.e. rifampin or efavirenz) is not recommended. 2) Physician should monitor: a) Liver function test results (within normal limits WNL): i) alanine aminotransferase (ALT), ii) aspartate aminotransferase (AST), iii) alkaline phosphatase (ALP), AND iv) bilirubin (TBil), AND d) Complete blood count (CBC) results (WNL).

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

## PREVYMIS

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**Affected Drugs:**

Prevymis

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Receiving pimozide or ergot alkaloids, 2) Receiving cyclosporine co-administered with pitavastatin or simvastatin

**Required Medical Information:** 1) Diagnosis: For prophylaxis of cytomegalovirus (CMV) infection and disease 2) Post hematopoietic stem cell transplant (HSCT) within the last 28 days. 3) CMV sero-positive recipient [R+]

**Age Restrictions:** 18 years of age or older

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist, 3) Infectious Disease Specialist

**Coverage Duration:** 100 days

**Other Criteria:** N/A

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

## PROMACTA

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**Affected Drugs:**

Promacta

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. Thrombocytopenia with Chronic Idiopathic Thrombocytopenia (ITP), b. Thrombocytopenia with Hepatitis C infection, OR c. Severe Aplastic Anemia, 2) For Chronic ITP document the following: a. Previous corticosteroids use, b. Previous Immunoglobulin use, OR c. Splenectomy, 3) For Thrombocytopenia with Chronic Hepatitis C: Evidence that the patient is on or will initiate interferon-based therapy, 4) For Severe Aplastic Anemia: a) in combination with standard immunosuppressive therapy for first-line treatment or b) document failure to immunosuppressive therapy.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Hematologist, 2) Hepatologist, 3) Infectious disease specialist, 4) Gastroenterologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## **QINLOCK**

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**Affected Drugs:**

Qinlock

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Advanced Gastrointestinal Stromal Tumor (GIST). 2) Document: Patient has received prior treatment with 3 or more kinase inhibitors (e.g. bosutinib, pazopanib, sunitinib, etc.), including imatinib.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## RAVICTI

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**Affected Drugs:**

Ravicti

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis of Urea cycle disorders (UCDs).

**Age Restrictions:** 2 months of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## REBLOZYL\*

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**Affected Drugs:**

Reblozyl

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Treatment of anemia in patients with beta thalassemia who require regular red blood cell (RBC) transfusions, 2) Document: a) Patient requires regular RBC transfusions, b) Complete blood count (CBC) results (Hemoglobin - Hgb level must be 11 g/dL), AND c) Patient's body weight.

**Age Restrictions:** 18 years of age and older.

**Prescription Order Restrictions:** 1) Hematologist.

**Coverage Duration:** 9 weeks.

**Other Criteria:** 1) Part D vs. Part B evaluation also applies, 2) Discontinue REBLOZYL if a patient does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose level or if unacceptable toxicity occurs at any time.(\*).

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\* Pending CMS review

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

## RELISTOR

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**Affected Drugs:**

Relistor

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Known or suspected mechanical gastrointestinal obstruction.

**Required Medical Information:** 1) Diagnosis: Opioid-induced constipation (OIC), 2) Patient demonstrated an inadequate treatment response or intolerance or contraindication to a drug regimen of polyethylene glycol 3350 (PEG 3350), 3) Document patients opioid regimen for chronic pain management, 4) Creatinine Clearance.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## RESTASIS

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**Affected Drugs:**

Restasis

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document: Keratoconjunctivitis sicca, 2) Failure to conventional Lubricant or corticosteroids.

**Age Restrictions:** 16 years of age or older.

**Prescription Order Restrictions:** 1) Ophthalmologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## RETEVMO

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**Affected Drugs:**

Retevmo

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of RET Fusion-Positive Non-Small Cell Lung Cancer (NSCLC), B) Treatment of RET-Mutant Medullary Thyroid Cancer (MTC), or C) Treatment of RET Fusion-Positive Thyroid Cancer. 2) Document: A) For RET Fusion-Positive NSCLC: i) Disease is metastatic, and ii) Disease is RET fusion-positive (in tumor specimens or plasma). B) For RET-Mutant Medullary Thyroid Cancer: i) Disease is advanced or metastatic, ii) Disease is RET-mutant (in tumor specimens or plasma), and iii) Requires systemic therapy. C) For RET Fusion-Positive Thyroid Cancer: i) Disease is advanced or metastatic, ii) Disease is RET fusion-positive (in tumor specimens or plasma), iii) Requires systemic therapy, and iv) Disease is radioactive iodine-refractory (if radioactive iodine is appropriate). D) For all indications: Patient's actual body weight (weight-based dosing).

**Age Restrictions:** 1) For NSCLC: 18 years of age or older, or 2) For MTC and Thyroid Cancer: 12 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## REVLIMID

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**Affected Drugs:**

Revlimid

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Pregnancy, 2) Chronic Lymphocytic Leukemia.

**Required Medical Information:** 1) Diagnosis: a. multiple myeloma (MM), b. transfusion-dependent anemia due to myelodysplastic syndrome, c. mantle cell lymphoma (MCL), d. MM, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT), e. follicular lymphoma (FL), OR f. marginal zone lymphoma (MZL), 2) For MM: Prescribed in combination with dexamethasone, 3) For transfusion dependent anemia due to myelodysplastic syndromes: Document 5q deletion, 4) For MCL: document the following: a. disease progression or relapse, b. prior use of at least 2 therapies, including Bortezomib, 5) For FL and MZL: a) patient has been previously treated, b) prescribed in combination with a rituximab product, 6) Negative pregnancy affirmation.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## REZUROCK

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**Affected Drugs:**

Rezurock

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of chronic graft-versus-host disease (chronic GVHD). 2) Document: Failure of at least two prior lines of systemic therapy (e.g., prednisone, methotrexate, cyclosporine, tacrolimus, mycophenolate, Imbruvica (ibrutinib), Jakafi (ruxolitinib), etc.).

**Age Restrictions:** 12 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist/Oncologist, 2) Transplant Specialist.

**Coverage Duration:** End of contract year.

**Other Criteria:** Part D vs. Part B evaluation also applies. (\*)

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

## RIBAVIRIN

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**Affected Drugs:**

Ribavirin

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Women who are pregnant or men whose female are pregnant. 2) Hemoglobinopathy, hemoglobin less than 8.5 g/dL. 3) Coadministration with didanosine in HIV coinfecting patients. 4) Renal impairment (CRCL less than 50 mL/min) for Ribavirin only.

**Required Medical Information:** 1) Diagnosis: Chronic hepatitis C, 2) Document the following: a. Hgb levels, b. CRCL, c. Negative pregnancy affirmation.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Gastroenterologist, 2) Infectious Disease specialist, 3) Hepatologist.

**Coverage Duration:** Initial 12 weeks, for renewal: End of contract year.

**Other Criteria:** For Hepatitis C: Ribavirin should always be prescribed in combination with other agents.

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

## RILUZOLE

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**Affected Drugs:**

Riluzole

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: amyotrophic lateral sclerosis (ALS).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Neurologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## RINVOQ

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**Affected Drugs:**

Rinvoq

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Patients currently on other Janus Kinase (JAK) inhibitors, biologic disease-modifying anti-rheumatic drugs (DMARDs), or potent immunosuppressants such as azathioprine and cyclosporine.

**Required Medical Information:** 1) Diagnosis: Moderate or severe active rheumatoid arthritis (RA). 2) Document: a) previous use/intolerance of at least 1 or more DMARDs and/or methotrexate, b) latent tuberculosis test result. If positive must be on treatment. Tuberculosis result must have a date of less than 12 months prior to request.

**Age Restrictions:** 18 years of age and older.

**Prescription Order Restrictions:** 1) Rheumatologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ROZLYTREK

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**Affected Drugs:**

Rozlytrek

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Adult with ROS1-positive metastatic non-small cell lung cancer (NSCLC), b) adult and pediatric patients 12 years of age and older with metastatic solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, 2) Document: a) Patient has progressed following treatment or have no satisfactory alternative therapy, b) Surgical resection is likely to result in severe morbidity.

**Age Restrictions:** 12 years of age and older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## RUBRACA

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**Affected Drugs:**

Rubraca

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis of recurrent OR deleterious BRCA mutation-associated: a) epithelial ovarian cancer, b) fallopian tube cancer, c) primary peritoneal cancer, or d) metastatic castration-resistant prostate cancer (mCRPC), 2) If deleterious BRCA mutation-associated cancer: Document prior treatment with at least 2 chemotherapies, 3) If recurrent cancer: Document prior treatment with a platinum containing regimen, 4) If mCRPC: Document patient has been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Urologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## RYDAPT

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**Affected Drugs:**

Rydapt

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Newly diagnosed acute myeloid leukemia (AML), b) Aggressive systemic mastocytosis (ASM), c) Systemic mastocytosis with associated hematological neoplasm (SM-AHN), d) Mast cell leukemia (MCL), 2) For AML: a) FLT3 mutation-positive AML detected by FDA-approved test, b) Concurrent therapy with cytarabine and daunorubicin for standard induction, c) Concurrent therapy with cytarabine for consolidation.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## SCSEMBLIX\*

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**Affected Drugs:**

Scemblix

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), or B) 2) Document: A) For Ph+ CML-CP: Previously treated with two or more tyrosine kinase inhibitors (TKIs) [e.g., Bosulif (bosutinib), Iclusig (ponatinib), Sprycel (dasatinib), Tassigna (nilotinib), etc.]. B) For Ph+ CML-CP T315I: Confirmed T315I mutation.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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\* Pending CMS review

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

## SIGNIFOR

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**Affected Drugs:**

Signifor

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document the following: a. For Signifor: a. Diagnosis of Cushing disease AND b. pituitary surgery is not an option or has not been curative, 2) Prior to starting treatment document: a. Liver Function Test: No more than 3 times the upper limit of normal, b. Fasting Plasma Glucose (FPG), c. HA1C Results, d. ECG, e. Serum Magnesium, f. Serum Potassium.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Endocrinologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** Part D vs. Part B evaluation also applies. (\*)

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

## SILDENAFIL

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**Affected Drugs:**

Sildenafil Citrate

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Concomitant use of nitrate therapy on a regular or intermittent basis, 2) Concomitant use of Adempas.

**Required Medical Information:** 1) Diagnosis of Pulmonary Arterial Hypertension, WHO Group 1, 2) Cardiac catheterization results: a. Mean pulmonary artery pressure (more than or equal to 25 mmHg), OR b. Pulmonary capillary wedge pressure (less than or equal to 15 mmHg), 3) Acute vasodilator testing result (required for patients with Idiopathic Pulmonary Arterial Hypertension ONLY).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Pulmonologist, 2) Cardiologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## SIMVASTATIN

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**Affected Drugs:**

Simvastatin

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document: a. For new Starts: Prior use and/or failure to at least one statin in the last 12 months, b. For renewals: Prior use of simvastatin 80mg in the last 12 months.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## SIRTURO

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**Affected Drugs:**

Sirturo

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document of the following: a. pulmonary multi-drug resistant tuberculosis (MDR-TB) AND b. no other effective treatments available for the patient AND c. prescribed in combination with at least 3 other anti-mycobacterial drugs for MDR-TB.

**Age Restrictions:** 5 years of age or older weighting at least 15 kg.

**Prescription Order Restrictions:** 1) Infectious Disease specialist, 2) Pulmonologist.

**Coverage Duration:** 24 weeks.

**Other Criteria:** N/A

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

## SIVEXTRO

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**Affected Drugs:**

Sivextro

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: acute bacterial skin and/or skin structure infections, 2) Culture results.

**Age Restrictions:** 12 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 6 days.

**Other Criteria:** N/A

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



## SKYRIZI

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**Affected Drugs:**

Skyrizi

Skyrizi 150 MG Dose

Skyrizi Pen

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Documented diagnosis: Moderate to severe plaque psoriasis: at least 5% BSA or crucial body areas such as the hands, feet, face, or genitals. 2) Latent tuberculosis test result. If positive must be on treatment. Tuberculosis result must have a date of less than 12 months prior to request.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Dermatologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## SOFOSBUVIR-VELPATASVIR

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**Affected Drugs:**

Sofosbuvir-Velpatasvir

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Documented diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6, 2) Documentation of hepatic fibrosis status by one of the following: a. Clinical evidence stating the cirrhosis status as attested by the prescribing physician, b. Liver biopsy METAVIR score, or alternative scoring equivalent, c. Radiological imaging of the liver, d. Transient elastography (FibroScan) score, e. FibroTest (FibroSure) score, f. APRI score, 3) Indicate if patient is naive or experienced, if experienced document prior use of PEG-IFN, RBV, HCV protease or polymerase inhibitors.

**Age Restrictions:** 3 years of age and older.

**Prescription Order Restrictions:** 1) Hepatologist, 2) Gastroenterologist or 3) Infectious Disease Specialist.

**Coverage Duration:** 12 weeks.

**Other Criteria:** Duration for genotypes 1, 2, 3, 4, 5 and 6 during 12 weeks, with or without ribavirin, according to the clinical scenario assessed by the pharmacist in full compliance with the updated HCV guidelines recommendations at the time.

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

## SODIUM PHENYLBUTYRATE

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**Affected Drugs:**

Sodium Phenylbutyrate

**Off-Label Uses:** N/A

**Exclusion Criteria:** Management of acute hyperammonemia.

**Required Medical Information:** 1) Diagnosis, 2) Results of plasma ammonia levels.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## SOMAVERT

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**Affected Drugs:**

Somavert

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Patient meets the following criteria for initiation of therapy: a. Clinical evidence of acromegaly, b. Pre-treatment high IGF-1 level for age/gender, c. Patient has had an inadequate or partial response to octreotide or lanreotide OR patient is intolerant to or has a contraindication to octreotide or lanreotide, and d. Patient has had an inadequate or partial response to surgery and/or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy, e. Liver Function Tests: No more than 3 times the upper limit of normal, 2) For continuation of therapy: a. IGF-1 level decreased or normalized.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Endocrinologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** Part D vs. Part B evaluation also applies. (\*)

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

## SPRYCEL

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**Affected Drugs:**

Sprycel

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) or b. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL), 2) For newly diagnosed Ph+ CML: document patient is in chronic phase, 3) For previously treated Ph+ CML document: resistance or intolerance to prior therapy including imatinib, 4) For Ph+ALL document: resistance or intolerance to prior therapy.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## STELARA

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**Affected Drugs:**

Stelara

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Negative Tuberculosis test, if positive must be on treatment, 2) Moderate to severe plaque psoriasis (PSO): a) at least 5% BSA or crucial body areas such as the hands, feet, face, or genitals, b) Document prior use of two first-line drugs: Humira, Skyrizi or Taltz, 3) Psoriatic arthritis: a) Document prior use of two first-line drugs: Humira, Enbrel, Xeljanz or Taltz, 4) Moderately to severely active Crohn disease in adult patients who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but who have never failed treatment with a tumor necrosis factor (TNF) blocker, or in patients who failed or were intolerant to treatment with 1 or more TNF blockers: a) Document prior use of one first-line drugs: Humira, 5) Moderately to severely active ulcerative colitis (UC): document prior use of Humira and Xeljanz.

**Age Restrictions:** 1) For PSO: 6 years of age or older, 2) For all other indications: 18 years of age or older

**Prescription Order Restrictions:** 1) Dermatologist, 2) Rheumatologist, 3) Gastroenterologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## STIVARGA

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**Affected Drugs:**

Stivarga

**Off-Label Uses:** N/A

**Exclusion Criteria:** Hepatic impairment, severe (Child-Pugh Class C).

**Required Medical Information:** 1) Diagnosis: a. metastatic colorectal cancer, b. locally advanced or metastatic gastrointestinal stromal tumor, OR c. Hepatocellular carcinoma (HCC), 2) For gastrointestinal stromal tumor document: a. disease is unresectable AND b. prior treatment with imatinib and sunitinib, 3) For metastatic colorectal cancer document: a. prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy, and anti-VEGF therapy, and if KRAS wild type, an anti-EGFR therapy, 4) Liver function test as evidence that ALT and AST levels were measured before initiation of treatment, 5) For hepatocellular carcinoma document: previous treatment with sorafenib.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## SUTENT

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**Affected Drugs:**

SUNItinib Malate

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. gastrointestinal stromal tumor (GIST), b. advanced renal cell carcinoma, c. locally advanced or metastatic pancreatic neuroendocrine tumors (pNET) OR d. high risk of recurrent renal cell carcinoma (RCC), 2) For GIST document: a. failure to or intolerance to imatinib, 3) For pNET document: tumor is unresectable, 4) For patients at high risk of recurrent RCC document: a) document nephrectomy, b) will be used as adjuvant treatment.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist, 3) Gastroenterologist, 4) Nephrologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## SYMDEKO

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**Affected Drugs:**

Symdeko

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis of Cystic Fibrosis (CF) in patients who are homozygous for the F508del mutation or who have at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor, 2) Baseline FEV1 level results, 3) Liver Function Test: No more than 3 times the upper limit of normal.

**Age Restrictions:** 6 years of age or older.

**Prescription Order Restrictions:** 1) Pulmonologist.

**Coverage Duration:** Initial: 3 months, renewals: end of contract year.

**Other Criteria:** N/A

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

## TABRECTA

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**Affected Drugs:**

Tabrecta

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Non-Small Cell Lung Cancer (NSCLC).  
2) Document: A) Disease is metastatic, and B) Tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TADALAFIL (PAH)

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**Affected Drugs:**

Tadalafil (PAH)

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Concomitant organic nitrates, 2) Concomitant Guanylate Cyclase (GC) Stimulators.

**Required Medical Information:** 1) Diagnosis of Pulmonary Arterial Hypertension, WHO Group 1, 2) Cardiac catheterization results: a. Mean pulmonary artery pressure (greater than or equal to 25mmHg) OR b. Pulmonary capillary wedge pressure (less than or equal to 15mmHg), 3) Acute vasodilator testing result (required for patients with Idiopathic Pulmonary Arterial Hypertension ONLY).

**Age Restrictions:** 18 years of age and older.

**Prescription Order Restrictions:** 1) Pulmonologist, 2) Cardiologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TAFINLAR

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**Affected Drugs:**

Tafinlar

**Off-Label Uses:** N/A**Exclusion Criteria:** 1) Wild-type BRAF melanoma.

**Required Medical Information:** 1) Diagnosis: a. melanoma with involvement of lymph node(s), b. unresectable or metastatic melanoma, c. metastatic non-small cell lung cancer OR d. locally advanced or metastatic anaplastic thyroid cancer (ATC), 2) For melanoma with involvement of lymph node(s), document the following: a. positive results for BRAF V600E or V600K mutations, b. complete resection, c. must be used in combination with trametinib, 3) For unresectable or metastatic melanoma, document the following: a. positive results for BRAF V600E or V600K mutations, b. If BRAF V600K mutation is positive: prescribed in combination with trametinib, OR c. If BRAF V600E mutation is positive: indicated as a single agent or in combination with trametinib, 4) For metastatic non-small cell lung cancer document the following: a. positive results for BRAF V600E mutations AND b. must be used in combination with trametinib, 5) For locally advanced or metastatic anaplastic thyroid cancer (ATC), document the following: a. positive results for BRAF V600E mutation, b. no satisfactory locoregional treatment option, AND c. must be used in combination with trametinib.

**Age Restrictions:** 18 years of age or older.**Prescription Order Restrictions:** 1) Oncologist.**Coverage Duration:** End of contract year.**Other Criteria:** N/A

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

## TAGRISSO

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**Affected Drugs:**

Tagrisso

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Pregnancy.

**Required Medical Information:** 1) Diagnosis: Non-small cell lung cancer (NSCLC), 2) Document the following: a) Positive EGFR T790M mutation test OR b) for first line treatment or as adjuvant therapy after tumor resection, document results for EGFR exon 19 deletions or exon 21 L858R substitution mutations.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Oncologist, 2) Pulmonologist, 3) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TALTZ

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**Affected Drugs:**

Taltz

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of Moderate to Severe Plaque Psoriasis (PsO), B) Treatment of Active Psoriatic Arthritis (PsA), C) Treatment of Ankylosing Spondylitis (AS), or D) Treatment of Active Non-Radiographic Axial Spondyloarthritis (nr-AxSpA) with objective signs of inflammation. 2) Document: A) For PsO: At least 5% of BSA or crucial body areas such as the hands, feet, face, or genitals, B) For PsA: No other medical information or prior use of other medications is required, C) For AS: Inadequate response to at least 2 NSAIDs, D) For nr-AxSpA: Inadequate response to at least 2 NSAIDs, E) For all indications: Latent tuberculosis test result. If positive must be on treatment. Tuberculosis result must have a date of less than 12 months prior to request.

**Age Restrictions:** 1) For PsO: 6 years of age or older, 2) For all other indications: 18 years of age or older

**Prescription Order Restrictions:** 1) Dermatologist, 2) Rheumatologist

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TALZENNA

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**Affected Drugs:**

Talzenna

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis of deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TARGRETIN

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**Affected Drugs:**

Targretin

**Off-Label Uses:** N/A

**Exclusion Criteria:** Pregnancy.

**Required Medical Information:** 1) Diagnosis: a) Cutaneous T-cell Lymphoma (Stage IA and IB), 2) Document: a) refractory or persistent disease after previous therapy, OR b) intolerance to previous therapies.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Dermatologist, 2) Hematologist, or 3) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## TASIGNA

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**Affected Drugs:**

Tasigna

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Uncorrected hypokalemia or hypomagnesemia, 2) long QT syndrome.

**Required Medical Information:** 1) Diagnosis: Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML), 2) For previously treated Ph+ CML adults patients, document: a) resistance or intolerance to prior therapy including imatinib, b) document patient is in chronic phase (CP) or accelerated phase (AP), 3) For newly diagnosed Ph+ CML: document patient is in chronic phase, 4) For previously treated Ph+ CML pediatric patients, document: a) patient is resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy, b) document patient is in chronic phase (CP).

**Age Restrictions:** 1 year of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TAZORAC

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**Affected Drugs:**

Tazarotene

Tazorac

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Pregnancy, 2) Esthetics purposes.

**Required Medical Information:** 1) Diagnosis: a. acne vulgaris OR b. plaque psoriasis, 2) Negative pregnancy affirmation.

**Age Restrictions:** 12 years of age or older.

**Prescription Order Restrictions:** 1) Dermatologist, 2) Rheumatologist, 3) Pediatrician.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TAZVERIK

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**Affected Drugs:**

Tazverik

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Treatment of metastatic or locally advanced epithelioid sarcoma, b) relapsed or refractory follicular lymphoma. 2) For the treatment of metastatic or locally advanced epithelioid sarcoma document: a) Patient is not eligible for complete resection. 3) For the treatment of relapsed or refractory follicular lymphoma document: a) tumor is positive for an EZH2 mutation as detected by an FDA-approved test and patient has received at least 2 prior systemic therapies, OR b) patient has no satisfactory alternative treatment options.

**Age Restrictions:** 16 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, or 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TERIPARATIDE

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**Affected Drugs:**

Forteo

Teriparatide (Recombinant)

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. postmenopausal women with osteoporosis (high risk of fracture), b. men with primary or hypogonadal osteoporosis, OR c. osteoporosis associated with sustained systemic glucocorticoid therapy, 2) Document the following: A. previous osteoporosis therapy: a. failure/intolerance to bisphosphonates, b. patient is at increased risk of fracture, c. multiple risk factors for fracture, OR B. history of osteoporotic fracture.

**Age Restrictions:** 18 years or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** Use of teriparatide for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture.

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

## TEPMETKO

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**Affected Drugs:**

Tepmetko

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of metastatic non-small cell lung cancer (NSCLC). 2) Document: Tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## THALOMID

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**Affected Drugs:**

Thalomid

**Off-Label Uses:** N/A

**Exclusion Criteria:** Pregnancy.

**Required Medical Information:** 1) Diagnosis: a. multiple myeloma OR b. erythema nodosum leprosum (ENL), 2) For multiple myeloma: prescribed in combination with dexamethasone, 3) Negative pregnancy affirmation.

**Age Restrictions:** 12 years of age or older.

**Prescription Order Restrictions:** 1) Dermatologist, 2) Hematologist, 3) Oncologist, 4) Infectious disease specialist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## THERAPY FOR GAUCHER DISEASE

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**Affected Drugs:**

Miglustat

**Off-Label Uses:** N/A

**Exclusion Criteria:** Gaucher disease type 2 or 3.

**Required Medical Information:** 1) Diagnosis: type 1 Gaucher disease, 2) Document the following: a. enzyme replacement is not a therapeutic option for the patient, b. CBC with platelets.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TIBSOVO

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**Affected Drugs:**

Tibsovo

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Relapsed or refractory acute myeloid leukemia (RR-AML), b) Newly-diagnosed acute myeloid leukemia (AML), or c) Locally advanced or metastatic cholangiocarcinoma who have been previously treated. 2) FDA-approved test results positive for IDH1 mutation. 3) For newly-diagnosed AML: a) For patients 75 years of age or older: No additional information is required. For patients less than 75 years old: documentation of comorbidities that preclude use of intensive induction chemotherapy must be provided.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## TIRF

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**Affected Drugs:**

Fentanyl Citrate  
Lazanda

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Patients who are not opioid tolerant. (Patients are considered opioid tolerant if they have been taking at least 60 mg of oral morphine per day, 25 mcg of transdermal fentanyl/hr, 30 mg of oral oxycodone daily, 8 mg of oral hydromorphone daily, 25 mg oral oxymorphone daily or an equianalgesic dose of another opioid for a week or longer), 2) Management of acute or postoperative pain, including headache/migraine and dental pain.

**Required Medical Information:** 1) Document ALL of the following: a. medical justification that indicates use for the management of breakthrough pain in cancer patient who is already receiving and is tolerant to opioid therapy AND b. previous failure to one or more short acting opioid analgesic (For example: Morphine or Tramadol) OR to one or more long acting opioid analgesic (For example: Morphine ER or Oxycodone ER).

**Age Restrictions:** 18 years of age and older.

**Prescription Order Restrictions:** 1) Oncologist 2) Pain specialist.

**Coverage Duration:** 6 months.

**Other Criteria:** N/A

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

## TOPICAL TESTOSTERONES

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**Affected Drugs:**

Testosterone

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Carcinoma of the breast or known or suspected prostate cancer, 2) late onset hypogonadism.

**Required Medical Information:** 1) Diagnosis: a. primary hypogonadism OR b. hypogonadotropic hypogonadism, 2) Before the start of testosterone therapy patient had (or patient currently has) a confirmed low testosterone level (i.e. morning total testosterone less than 300 ng/dL, morning free testosterone less than 9 ng/dL) or absence of endogenous testosterone.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TRACLEER

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**Affected Drugs:**

Bosentan

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Pregnancy, 2) Use with Cyclosporine A, 3) Use with Glyburide.

**Required Medical Information:** 1) Diagnosis of Pulmonary Arterial Hypertension, WHO Group 1, 2) Cardiac catheterization results: a. Mean pulmonary artery pressure (greater than or equal to 25mmHg) OR b. Pulmonary capillary wedge pressure (less than or equal to 15mmHg), 3) Acute vasodilator testing result (required for patients with Idiopathic Pulmonary Arterial Hypertension ONLY).

**Age Restrictions:** 3 years of age or older.

**Prescription Order Restrictions:** 1) Cardiologist, 2) Pulmonologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TRUSELTIQ\*

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### **Affected Drugs:**

Truseltiq (100MG Daily Dose)

Truseltiq (125MG Daily Dose)

Truseltiq (50MG Daily Dose)

Truseltiq (75MG Daily Dose)

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement. 2) Document: A) Evidence of FGFR2 fusion or other rearrangement, and B) Prior therapy (e.g., combination of chemotherapy agents that might include gemcitabine, paclitaxel, oxaliplatin, cisplatin, fluorouracil, capecitabine, and/or epirubicin).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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\* Pending CMS review

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

## TUKYSA

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**Affected Drugs:**

Tukysa

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of HER2-Positive Breast Cancer, 2) Document: A) Disease is advanced and unresectable or metastatic (including brain metastases), B) HER2-positive status, C) Patient has received one or more prior anti-HER2-based regimen in the metastatic setting, and D) Prescribed in combination with trastuzumab and capecitabine.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TURALIO

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**Affected Drugs:**

Turalio

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Symptomatic tenosynovial giant cell tumor (TGCT), 2) Document severe morbidity or functional limitations and not amenable to improvement with surgery, 3) Liver function test: ALT and AST, no more than 3 times the upper limit of normal.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## TYMLOS

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**Affected Drugs:**

Tymlos

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis of postmenopausal women with osteoporosis at high risk for fracture, 2) Documented multiple risk factors for fracture AND failure or intolerance to other available osteoporosis therapy, OR history of osteoporotic fracture.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** Therapy will be discontinued after a lifetime total of 24 months of treatment.

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

## UKONIQ

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**Affected Drugs:**

Ukoniq

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of relapsed or refractory marginal zone lymphoma (MZL), or B) Treatment of relapsed or refractory follicular lymphoma (FL). 2) Document: A) For MZL: Prior use of at least one anti-CD20-based regimen (e.g., obinutuzumab, ofatumumab, rituximab, etc.). B) For FL: Prior use of at least three prior lines of systemic therapy (e.g., bendamustine, cyclophosphamide, doxorubicin, rituximab, etc.).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## UPTRAVI

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**Affected Drugs:**

Uptravi

**Off-Label Uses:** N/A

**Exclusion Criteria:** Concomitant use with strong CYP2C8 inhibitors (e.g., gemfibrozil).

**Required Medical Information:** 1) Diagnosis: pulmonary arterial hypertension (PAH, WHO Group I), 2) Must meet the following requirements: 1. The patient has tried two oral therapies for PAH from two of the three following different categories (either alone or in combination) each for at least 60 days: a. one phosphodiesterase type 5 (PDE5) inhibitor (e.g., Sildenafil), b. One endothelin receptor antagonist (ERA) (e.g. Opsumit), c. Adempas OR 2. The patient is receiving, or has received in the past, one prostacyclin therapy for PAH (e.g., Ventavis)

**Age Restrictions:** 18 years of age and older.

**Prescription Order Restrictions:** 1) Cardiologist, 2) Pulmonologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## VENCLEXTA

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**Affected Drugs:**

Venclexta

Venclexta Starting Pack

**Off-Label Uses:** N/A

**Exclusion Criteria:** Concomitant use of strong inhibitors of CYP3A4 during initiation and ramp-up phase (first 5 weeks of treatment).

**Required Medical Information:** 1) Diagnosis: a) Chronic Lymphocytic Leukemia (CLL), b) Small Lymphocytic Lymphoma (SLL), OR c) Newly-diagnosed acute myeloid leukemia (AML), 2) For CLL or SLL: a) Used in combination with rituximab, obinutuzumab or alone, 3) For newly-diagnosed AML: a) In combination with azacitidine or decitabine or low-dose cytarabine, b) For patients 75 years of age or older: No additional information is required. For patients less than 75 years old: documentation of comorbidities that preclude use of intensive induction chemotherapy must be provided.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## VENTAVIS

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**Affected Drugs:**

Ventavis

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis of Pulmonary Arterial Hypertension, WHO Group 1, 2) Cardiac catheterization results: a. Mean pulmonary artery pressure (greater than or equal to 25 mmHg) AND b. Pulmonary capillary wedge pressure (less than or equal to 15 mmHg), 3) Acute vasodilator testing result (required for patients with Idiopathic Pulmonary Arterial Hypertension ONLY).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Pulmonologist, 2) Cardiologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## VERQUVO

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**Affected Drugs:**

Verquvo

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators. 2) Pregnancy.

**Required Medical Information:** 1) Diagnosis: To reduce the risk of cardiovascular death and heart failure (HF) hospitalization. 2) Document: A) Symptomatic chronic heart failure (HF), B) Ejection fraction (must be less than 45%), and C) Patient was hospitalized for heart failure or required outpatient IV diuretics.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Cardiologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## VERZENIO

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**Affected Drugs:**

Verzenio

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document diagnosis for advance or metastatic breast cancer, 2) If used in combination with fulvestrant, document disease progression following endocrine therapy, 3) If used as monotherapy, document disease progression following endocrine therapy and prior chemotherapy in metastatic setting, 4) As initial endocrine based therapy, used in combination with an aromatase inhibitor (i.e. letrozole, exemestane, anastrozole), 5) Bio-markers test result evidencing: a) Human epidermal growth factor receptor 2 (HER2)-negative, b) Positive hormone receptor (HR)

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## VIBERZI

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### **Affected Drugs:**

Viberzi

### **Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Known or suspected biliary duct obstruction, or Sphincter of Oddi disease or dysfunction, 2) A history of pancreatitis, or structural diseases of the pancreas, including known or suspected pancreatic duct obstruction, 3) Severe hepatic impairment (Child-Pugh Class C), 4) A history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical GI obstruction, 5) Patients without gallbladder.

**Required Medical Information:** 1) Documented diagnosis of Irritable Bowel Syndrome with Diarrhea, 2) Gallbladder status (if patient have gallbladder or it has been removed).

**Age Restrictions:** 18 years of age and older.

**Prescription Order Restrictions:** 1) Gastroenterologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## VITRAKVI

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**Affected Drugs:**

Vitakvi

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Solid tumor, 2) Document all of the followings: a) neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, b) metastatic or where surgical resection is likely to result in severe morbidity, AND c) have no satisfactory alternative treatments or that have progressed following treatment.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** 1) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## VIZIMPRO

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**Affected Drugs:**

Vizimpro

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. metastatic or locally advanced non-small cell lung cancer (NSCLC), 2) Metastatic or locally advanced NSCLC: a. For first line treatment document: results for EGFR exon 19 deletions or exon 21 L858R substitution mutations.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Pulmonologist, 3) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## VORICONAZOLE

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**Affected Drugs:**

Voriconazole

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Concomitant use of carbamazepine, CYP3A4 substrates (eg. pimozide or quinidine), long-acting barbiturates, rifabutin, rifampin, ritonavir in high doses (400 mg every 12 hours), efavirenz in high doses (400 mg q 24h or higher), or sirolimus.

**Required Medical Information:** 1) Diagnosis: a. invasive aspergillosis, b. candidemia, c. candidiasis, OR d. serious infections caused by *Scedosporium apiospermum* and *Fusarium*, 2) Document the following: a. culture results, b. Liver Function Test: No more than 3 times the upper limit of normal, 3) For candidemia document: a. patient is non-neutropenic, and b. CBC.

**Age Restrictions:** 2 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## VOTRIENT

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**Affected Drugs:**

Votrient

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Adipocytic soft tissue sarcoma, 2) Gastrointestinal stromal tumors.

**Required Medical Information:** 1) Diagnosis: a. advanced renal cell carcinoma or b. advanced soft tissue sarcoma, 2) For advanced soft tissue sarcoma document: prior chemotherapy.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Nephrologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## WELIREG\*

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**Affected Drugs:**

Welireg

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of von Hippel-Lindau (VHL) disease not requiring immediate surgery. 2) For initial evaluation document: A) Confirmed Von Hippel-Lindau disease by germline VHL alteration. B) Patient requires therapy for one of the following conditions: associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET).

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Hematologist/Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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\* Pending CMS review

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

## XALKORI

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**Affected Drugs:**

Xalkori

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Metastatic non-small cell lung cancer (NSCLC), or B) Relapsed or refractory systemic anaplastic large cell lymphoma (ALCL). 2) Document: A) For NSCLC: Positive results for anaplastic lymphoma kinase (ALK) or ROS-1 mutation, or B) For ALCL: i) Positive result for ALK and ii) Patient's body surface area (BSA) or actual body weight and height (BSA-based dosing).

**Age Restrictions:** 1 year of age and older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Pulmonologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## XATMEP

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**Affected Drugs:**

Xatmep

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) For pJIA: Pregnancy.

**Required Medical Information:** 1) Diagnosis: a) Acute lymphoblastic leukemia (ALL), b) Active polyarticular juvenile idiopathic arthritis (pJIA), 2) For ALL: Document combination chemotherapy maintenance regimen, 3) For pJIA: a) Patient has had an inadequate therapeutic response to, OR is intolerant to, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs), b) Negative pregnancy affirmation.

**Age Restrictions:** 18 years and younger.

**Prescription Order Restrictions:** 1) Oncologist, 2) Rheumatologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## **XCOPRI**

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### **Affected Drugs:**

Xcopri

Xcopri 250 MG Daily Dose

Xcopri 350 MG Daily Dose

**Off-Label Uses:** N/A

**Exclusion Criteria:** Familial Short QT Syndrome.

**Required Medical Information:** 1) Diagnosis: Treatment of Partial-Onset Seizures. 2) Document: Therapeutic failure, intolerance or contraindication to at least one of the following formulary alternatives: carbamazepine, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, zonisamide or topiramate.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** Neurologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## XELJANZ

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**Affected Drugs:**

Xeljanz

Xeljanz XR

**Off-Label Uses:** N/A

**Exclusion Criteria:** Patients currently on biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

**Required Medical Information:** 1) Diagnosis: a) Moderate or severe active rheumatoid arthritis, b) psoriatic arthritis, c) moderately to severely active ulcerative colitis (UC), and d) active polyarticular course juvenile idiopathic arthritis (pcJIA), 2) For moderate or severe active rheumatoid arthritis and psoriatic arthritis document: previous use/intolerance of at least 1 or more DMARDs and/or Methotrexate, 3) Latent tuberculosis test result. If positive must be on treatment. Tuberculosis result must have a date of less than 12 months prior to request.

**Age Restrictions:** 1) pcJIA: 2 years of age or older, 2) For all other indications: 18 years of age or older.

**Prescription Order Restrictions:** 1) Rheumatologist, 2) Gastroenterologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## XERMELO

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**Affected Drugs:**

Xermelo

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document diagnosis of Carcinoid Syndrome Diarrhea. 2) Inadequately controlled by somatostatin analog therapy.

**Age Restrictions:** 18 years and older

**Prescription Order Restrictions:** Hematologist/Oncologist

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## XIFAXAN

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**Affected Drugs:**

Xifaxan

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document one of any of the following Diagnosis: a) Irritable bowel syndrome with diarrhea (IBS-D), b) Hepatic encephalopathy (HE), Prophylaxis.

**Age Restrictions:** 1) For IBS-D and HE: 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 1) For IBS-D: Initial: 14 days, Renewals: 14 days 2) For HE: End of contract year.

**Other Criteria:** For IBS-D, therapy will be discontinued after a lifetime total of 42 days.

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

## XOSPATA

---

**Affected Drugs:**

Xospata

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Relapsed or refractory acute myeloid leukemia (AML), 2) FLT3 mutation-positive AML as detected by an FDA-approved test.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## XPOVIO

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### **Affected Drugs:**

Xpovio (100 MG Once Weekly)  
Xpovio (40 MG Once Weekly)  
Xpovio (40 MG Twice Weekly)  
Xpovio (60 MG Once Weekly)  
Xpovio (60 MG Twice Weekly)  
Xpovio (80 MG Once Weekly)  
Xpovio (80 MG Twice Weekly)

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Documented diagnosis: a) multiple myeloma, b) relapsed or refractory multiple myeloma, c) relapsed or refractory diffuse large B-cell lymphoma (DLBCL). 2) For multiple myeloma: a) In combination with bortezomib and dexamethasone, b) Failure to at least one prior therapy, 3) For Relapsed or refractory multiple myeloma: a) document prescription in combination with dexamethasone, b) Failure to at least 4 prior antineoplastic therapies (e.g., bortezomib, carfilzomib, ixazomib, thalidomide, lenalidomide, pomalidomide), c) In addition, the multiple myeloma must be refractory to at least 2 proteasome inhibitors (e.g., bortezomib, carfilzomib, ixazomib), plus to at least 2 immunomodulatory agents (e.g., thalidomide, lenalidomide, pomalidomide), and plus an anti-CD38 monoclonal antibody (e.g., daratumumab). 4) For DLBCL: document prior treatment with at least 2 lines of systemic therapy.

**Age Restrictions:** 18 years of age and older.

**Prescription Order Restrictions:** 1) Hematologist, 2) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## XTANDI

---

**Affected Drugs:**

Xtandi

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) castration-resistant prostate cancer, b) metastatic castration-sensitive prostate cancer, 2) Documented previous use of Zytiga for metastatic CRPC only.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist, 3) Urologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## XYREM

---

**Affected Drugs:**

Xyrem

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) If the patient is taking alcohol (ethanol), sedative/hypnotic drugs, or other CNS depressants. 2) Succinic semialdehyde dehydrogenase deficiency.

**Required Medical Information:** 1) Patient has a diagnosis of narcolepsy and experiences episodes of cataplexy OR, 2) Patient has a diagnosis of narcolepsy and experiences excessive daytime sleepiness.

**Age Restrictions:** 7 years of age and older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ZEJULA

---

**Affected Drugs:**

Zejula

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Advanced or recurrent epithelial ovarian cancer, b) Advanced or recurrent fallopian tube cancer, c) Advanced or recurrent primary peritoneal cancer, d) advanced ovarian, e) advanced fallopian tube, or f) advanced primary peritoneal cancer, 2) For a) Advanced or recurrent epithelial ovarian cancer, b) Advanced or recurrent fallopian tube cancer, c) Advanced or recurrent primary peritoneal cancer: Document prior treatment with a platinum containing regimen. 3) For d) advanced ovarian, e) fallopian tube, or f) primary peritoneal cancer: Document patient has been treated with three or more prior chemotherapy regimens and that cancer is associated with homologous recombination deficiency (HRD) positive status.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** Homologous recombination deficiency (HRD) positive status defined by either: a) a deleterious or suspected deleterious BRCA mutation, or b) genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy.

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

## ZELBORAF

---

**Affected Drugs:**

Zelboraf

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) Patients with QTc greater than 500 ms, 2) Patients with wild-type BRAF melanoma.

**Required Medical Information:** 1) Diagnosis: a) metastatic melanoma, b) Erdheim-Chester Disease, 2) Document the following: a, disease is unresectable AND b. positive results for the BRAF V600E mutations, c. ECG, d. serum electrolytes, 3) Erdheim-Chester Disease document the following: a) positive results for the BRAF V600E mutations.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ZEPOSIA

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### **Affected Drugs:**

Zeposia

Zeposia 7-Day Starter Pack

Zeposia Starter Kit

### **Off-Label Uses:** N/A

**Exclusion Criteria:** 1) In the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure. 2) Presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker. 3) Severe untreated sleep apnea. 4) Concomitant use of monoamine oxidase inhibitor.

**Required Medical Information:** 1) Diagnosis: A) Treatment of Relapsing Forms of Multiple Sclerosis (MS), including Clinically Isolated Syndrome, Relapsing-Remitting Disease, and Active Secondary Progressive Disease, or B) Treatment of moderately to severely active ulcerative colitis (UC). 2) Document: A) Only for first prescription: Electrocardiogram (ECG) result (to determine preexisting conduction abnormalities), B) For UC: Document prior use of Humira and Xeljanz.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Neurologist, or 2) Gastroenterologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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



## ZOLINZA

---

**Affected Drugs:**

Zolinza

**Off-Label Uses:** N/A

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Cutaneous T-cell lymphoma, 2) Document the following: a. disease is progressive, persistent or recurrent, b. failure/intolerance to at least two prior systemic therapies, 3) Liver Function Test: No more than 3 times the upper limit of normal.

**Age Restrictions:** 18 years or older.

**Prescription Order Restrictions:** 1) Oncologist, 2) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## ZYDELIG

---

**Affected Drugs:**

Zydelig

**Off-Label Uses:** N/A

**Exclusion Criteria:** 1) History of toxic epidermal necrolysis.

**Required Medical Information:** 1) Diagnosis: a. relapsed chronic lymphocytic leukemia (CLL), b. relapsed follicular B-cell non-Hodgkin lymphoma, or c. relapsed small lymphocytic lymphoma (SLL), 2) For CLL document: 1) prescribed in combination with rituximab AND 2) failure to at least 1 prior systemic therapy, 3) For relapsed follicular B-cell Non-Hodgkin's lymphoma OR relapsed SLL document: failure to at least 2 prior systemic therapies.

**Age Restrictions:** 18 years of age or older.

**Prescription Order Restrictions:** 1) Oncologist 2) Hematologist.

**Coverage Duration:** End of contract year.

**Other Criteria:** N/A

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

## Drugs That May Be Covered Under Medicare Part B or Part D

| Drug Name                       | Drug Name                         |
|---------------------------------|-----------------------------------|
| Abelcet IV                      | Acetylcysteine INH                |
| Acyclovir Sodium IV             | Albuterol Sulfate INH             |
| Aminosyn II IV                  | Aminosyn-PF IV                    |
| Amphotericin B IV               | Ampicillin Sodium INJ             |
| Ampicillin Sodium IV            | Ampicillin-Sulbactam Sodium IV    |
| Aprepitant Oral Cap             | Azithromycin IV                   |
| Bicillin C-R 900/300 IM         | Budesonide INH                    |
| Bumetanide INJ                  | ceFAZolin Sodium INJ              |
| cefOXitin Sodium IV             | cefTAZidime INJ                   |
| Cefuroxime Sodium INJ           | Cefuroxime Sodium IV              |
| Cinacalcet HCl Oral Tab         | Cinryze IV                        |
| Ciprofloxacin in D5W IV         | Clindamycin Phosphate INJ         |
| Clindamycin Phosphate in D5W IV | Clinimix E/Dextrose (2.75/5) IV   |
| Clinimix E/Dextrose (4.25/5) IV | Clinimix E/Dextrose (5/15) IV     |
| Clinimix E/Dextrose (5/20) IV   | Clinimix/Dextrose (4.25/10) IV    |
| Clinimix/Dextrose (4.25/5) IV   | Clinimix/Dextrose (5/15) IV       |
| Clinimix/Dextrose (5/20) IV     | Clinisol SF IV                    |
| Colistimethate Sodium (CBA) INJ | Cromolyn Sodium INH               |
| Cyclophosphamide Oral Cap       | Dextrose IV                       |
| Dextrose-NaCl IV                | Diphtheria-Tetanus Toxoids DT IM  |
| Doxy 100 IV                     | Dronabinol Oral Cap               |
| Eligard SUBQ                    | Emend Oral Susp                   |
| Engerix-B INJ                   | Eraxis IV                         |
| Erythrocin Lactobionate IV      | Fluconazole in Sodium Chloride IV |
| fluPHENAZine Decanoate INJ      | fluPHENAZine HCl INJ              |
| Gentamicin Sulfate INJ          | Granisetron HCl Oral Tab          |
| Heparin Sodium (Porcine) INJ    | Hepatamine IV                     |
| Imipenem-Cilastatin IV          | Imovax Rabies IM                  |
| Intralipid IV                   | Intron A INJ                      |
| Ipratropium Bromide INH         | Ipratropium-Albuterol INH         |
| Isolyte-S pH 7.4 IV             | KCl in Dextrose-NaCl IV           |
| Leuprolide Acetate INJ          | Linezolid IV                      |
| Lupron Depot (1-Month) IM       | Lupron Depot (3-Month) IM         |
| Lupron Depot (4-Month) IM       | Lupron Depot (6-Month) IM         |
| Magnesium Sulfate INJ           | Methotrexate Sodium INJ           |
| Methotrexate Sodium (PF) INJ    | metroNIDAZOLE in NaCl IV          |
| Moxifloxacin HCl in NaCl IV     | OLANzapine IM                     |
| Ondansetron HCl Oral Tab        | Ondansetron HCl Oral Soln         |

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

| Drug Name                         | Drug Name                       |
|-----------------------------------|---------------------------------|
| Ondansetron ODT                   | Oxacillin Sodium INJ            |
| Oxacillin Sodium IV               | Penicillin G Pot in Dextrose IV |
| Penicillin G Potassium INJ        | Penicillin G Sodium INJ         |
| Pentamidine Isethionate INH       | Pentamidine Isethionate INJ     |
| Plasma-Lyte 148 IV                | Plasma-Lyte A IV                |
| Polymyxin B Sulfate INJ           | Potassium Chloride IV           |
| Potassium Chloride in Dextrose IV | Potassium Chloride in NaCl IV   |
| Premasol IV                       | Privigen IV                     |
| Procalamine IV                    | Prolia SUBQ                     |
| Pulmozyme INH                     | RabAvert IM                     |
| Recombivax HB INJ                 | rifAMPin IV                     |
| Sivextro IV                       | Sodium Chloride IV              |
| Streptomycin Sulfate IM           | Synribo SUBQ                    |
| TDVax IM                          | Teflaro IV                      |
| Tigecycline IV                    | Tobramycin INH                  |
| Tobramycin Sulfate INJ            | TPN Electrolytes IV             |
| Travasol IV                       | TrophAmine IV                   |
| Twinrix IM                        | Vancomycin HCl IV               |
| Voriconazole IV                   | Xgeva SUBQ                      |
| Xolair SUBQ                       | Ziprasidone Mesylate IM         |

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

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