

**PA Criteria List  
Federal Plan 2026**

## ACTEMRA

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### **Affected Drugs:**

Actemra  
Actemra ACTPen

**Covered Uses:** All FDA-approved indications not otherwise excluded: Rheumatoid Arthritis (ICD10: M06, M06.9), Giant-Cell Arteritis (Artery Inflammation in the Temple Area) (ICD10: M31.6), Polyarticular Juvenile Idiopathic Arthritis (ICD10: M08.09), Cytokine Release Syndrome (ICD10: D89.89), Systemic Juvenile Idiopathic Arthritis (ICD10: M08.2, M08.20), Systemic Sclerosis-Associated Interstitial Lung Disease (ICD10: J84.1, J84.9, M34.81)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs), B) Treatment of giant cell arteritis (GCA), C) Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD), D) Treatment of active polyarticular juvenile idiopathic arthritis (PJIA), E) Treatment of active systemic juvenile idiopathic arthritis (SJIA), or F) Treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS). 2) Document: A) For RA: i) Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, hydroxychloroquine, leflunomide), ii) Prior use of at least two formulary preferred drugs (e.g., Avsola, Enbrel, Humira, Orencia, Renflexis, Rinvoq, Xeljanz, if available), and iii) If available, prior use of at least one formulary non-preferred drug (e.g., Kevzara). B) For PJIA or SJIA: i) Therapeutic failure to methotrexate and ii) Prior use of Enbrel and Humira. C) For GCA and CRS: No additional medical information is required. D) For SSc-ILD: Prior use of mycophenolate. E) For all indications: Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## ADALIMUMAB-ADBM

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### Affected Drugs:

Adalimumab-adbm (2 Pen)  
Adalimumab-adbm (2 Syringe)  
Adalimumab-adbm(CD/UC/HS Strt)  
Adalimumab-adbm(Ps/UV Starter)

**Covered Uses:** All FDA-approved indications not otherwise excluded: Rheumatoid Arthritis (ICD10: M06, M06.9), Ulcerative Colitis (Ulcerated Colon) (ICD10: K51), Crohn's Disease (ICD10: K50, K50.9), Ankylosing Spondylitis (Rheumatic Disease causing Vertebrae Inflammation) (ICD10: M45, M45.9), Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), Plaque Psoriasis (ICD10: L40.0), Polyarticular Juvenile Idiopathic Arthritis (ICD10: M08.09), Hidradenitis Suppurativa (Hidradenitis Suppurativa) (ICD-10: L73.2), Uveitis (Inflammation of Uveal Tract of Eye) (ICD-10: H44.139)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) For rheumatoid arthritis (RA): Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active RA. B) For polyarticular juvenile idiopathic arthritis (PJIA): Reducing signs and symptoms of moderately to severely active polyarticular JIA. C) For psoriatic arthritis (PsA): Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with active PsA. D) For ankylosing spondylitis (AS): Reducing signs and symptoms in patients with active AS. E) For Crohn's disease (CD): Treatment of moderately to severely active CD. F) For ulcerative colitis (UC): Treatment of moderately to severely active UC. G) For plaque psoriasis (PsO): Treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate, H) For uveitis (UV): Treatment of non-infectious intermediate, posterior, and panuveitis. 2) Document: A) For RA: i) Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, hydroxychloroquine, leflunomide) and ii) Prior use of Humira or preferred biosimilars (i.e Amjevita, Hadlima, adalimumab-adaz, if available). B) For PJIA: i) Therapeutic failure to methotrexate and ii) Prior use of Humira or preferred biosimilars (i.e Amjevita, Hadlima, adalimumab-adaz, if available). C) For PsA: i) Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine) and ii) Prior use of Humira or preferred biosimilars (i.e Amjevita, Hadlima, adalimumab-adaz, if available). D) For AS: i) Therapeutic failure to at least one nonsteroidal anti-inflammatory drug (NSAID) (e.g., celecoxib, naproxen, sulindac, etc.) and ii) Prior use of Humira or preferred biosimilars (i.e Amjevita, Hadlima, adalimumab-adaz, if available). E) For CD: i) Therapeutic failure to at least one conventional drug

(e.g., azathioprine, budesonide, prednisone, mercaptopurine, mesalamine, methotrexate, etc.) and ii) Prior use of Humira or preferred biosimilars (i.e Amjevita, Hadlima, adalimumab-adaz, if available). F) For UC: i) Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, hydrocortisone, mercaptopurine, mesalamine, sulfasalazine, etc.) and ii) Prior use of Humira or preferred biosimilars (i.e Amjevita, Hadlima, adalimumab-adaz, if available). G) For PsO: i) At least 3% BSA is affected or crucial body areas such as the hands, feet, face, scalp or genitals, and ii) Prior use of at least one conventional drug (e.g., acitretin, cyclosporine, hydroxyurea, methotrexate, triamcinolone, etc and and iii) Prior use of Humira or preferred biosimilars (i.e Amjevita, Hadlima, adalimumab-adaz, if available). H) For hidradenitis suppurativa (HS): i) Condition is moderate to severe and ii) Prior use of Humira or preferred biosimilars (i.e Amjevita, Hadlima, adalimumab-adaz, if available). I) For uveitis: Prior use of Humira or preferred biosimilars (i.e Amjevita, Hadlima, adalimumab-adaz, if available). J) For all indications: Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy..

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## ADCIRCA

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**Affected Drugs:**

Adcirca  
Tadalafil (PAH)

**Covered Uses:** All FDA-approved indications not otherwise excluded: Pulmonary Arterial Hypertension (I27.0)

**Exclusion Criteria:** 1) Concomitant use of nitrate therapy on a regular or intermittent basis, 2) Concomitant use of Guanylate Cyclase stimulators (such as Adempas)

**Required Medical Information:** 1) Diagnosis: Pulmonary Arterial Hypertension, WHO Group 1.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## ADEMPAS

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### **Affected Drugs:**

Adempas

**Covered Uses:** All FDA-approved indications not otherwise excluded: Pulmonary Arterial Hypertension (I27.0), Thromboembolic Pulmonary Hypertension (I26.99, I27.2, I27.21)

**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) Concomitant use of other soluble guanylate cyclase (sGC) stimulators. 5) 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 (for first prescription): a. Cardiac catheterization results. 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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## ADIPEX-P/PHENTERMINE

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### **Affected Drugs:**

Phentermine HCl

**Covered Uses:** All FDA-approved indications not otherwise excluded: Exogenous Obesity (Obesity due to Overeating) (ICD10: E66.0, E66.9)

**Exclusion Criteria:** 1) History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension, etc.). 2) During or within 14 days following the administration of monoamine oxidase inhibitors. 3) Hyperthyroidism. 4) Glaucoma. 5) Agitated states. 6) History of drug abuse. 7) Pregnancy. 8) Nursing.

**Required Medical Information:** 1) Diagnosis: As a short-term adjunct (a few weeks) in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity. 2) Document: Body mass index (BMI) greater than or equal to 30 kg/m<sup>2</sup>, or greater than or equal to 27 kg/m<sup>2</sup> in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). 3) For renewals: At least a 5% reduction in baseline body weight (actual BMI or weight and height).

**Age Restrictions:** 16 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 3 months

**Other Criteria:** For FEHB renewals: Validate patient is currently enrolled in obesity management program.

## AFINITOR

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### Affected Drugs:

Afinitor  
Afinitor Disperz  
Everolimus

**Covered Uses:** All FDA-approved indications not otherwise excluded: Advanced Renal Cell Carcinoma (ICD10: C64, C64.9), Angiomyolipoma of Kidney (ICD10: D30.0, D30.00), Subependymal Giant Cell Astrocytoma (ICD10: D43.2), Pancreatic Neuroendocrine Carcinoma (ICD10: C25.4), Hormone Receptor-Positive, HER2 Negative Breast Cancer (ICD10: C50, C50.0, C50.01, C50.011, C50.012, C50.019, C50.02, C50.021, C50.022, C50.029, C50.1, C50.11, C50.111, C50.112, C50.119, C50.12, C50.121, C50.122, C50.129, C50.2, C50.21, C50.211, C50.212, C50.219, C50.22, C50.221, C50.222, C50.229, C50.3, C50.31, C50.311, C50.312, C50.319, C50.32, C50.321, C50.322, C50.329, C50.4, C50.41, C50.411, C50.412, C50.419, C50.42, C50.421, C50.422, C50.429, C50.5, C50.51, C50.511, C50.512, C50.519, C50.52, C50.521, C50.522, C50.529, C50.6, C50.61, C50.611, C50.612, C50.619, C50.62, C50.621, C50.622, C50.629, C50.8, C50.81, C50.811, C50.812, C50.819, C50.82, C50.821, C50.822, C50.829, C50.9, C50.91, C50.911, C50.912, C50.919, C50.92, C50.921, C50.922, C50.929), Malignant Pulmonary Neuroendocrine Tumor (ICD10: D3A.8), Malignant Gastrointestinal Neuroendocrine Tumor (ICD10: C7A.8), Partial Seizure (ICD10: R56.9)

**Exclusion Criteria:** Hypersensitivity to other rapamycin derivatives (e.g., sirolimus).

**Required Medical Information:** 1) Diagnosis: a) Advanced breast cancer, b) Locally advanced or metastatic neuroendocrine tumors (NET) of pancreatic (PNET), gastrointestinal (GI) or lung origin, c) Advanced renal cell carcinoma (RCC), d) Tuberous Sclerosis Complex (TSC)-Associated Renal Angiomyolipoma, e) TSC-Associated Subependymal Giant Cell Astrocytoma (SEGA), or f) TSC-Associated Partial-Onset Seizures. 2) Document: a) For advanced breast cancer: i) Patient is postmenopausal, ii) Stage of breast cancer, iii) Hormone receptor (HR) positive results, iv) Human epidermal growth factor receptor (HER2) negative results, v) Therapeutic failure, contraindication or intolerance to letrozole or anastrozole, vi) Prescribed in combination with exemestane, b) For locally advanced or metastatic NET: Disease is unresectable, c) For advanced RCC: Therapeutic failure, contraindication or intolerance with sunitinib or sorafenib, d) For TSC-renal angiomyolipoma: i) Patient is not requiring immediate surgery, e) For TSC-SEGA: Patient is not a candidate for curative surgical resection, or f) For TSC-Associated Partial-Onset Seizures: Current main treatment for the management of partial-onset seizures.

**Age Restrictions:** 1) For TSC-SEGA: 1 year of age or older, 2) For TSC-associated partial-onset seizures: 2 years of age or older, or 3) For all other indications: 18 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** 1) Afinitor Disperz is only indicated for the treatment of patients with Tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA) and Tuberous Sclerosis Complex (TSC)-Associated Partial-Onset Seizures. 2) Validate that treatment regimen is in full compliance with the most up to date NCCN guidelines recommendations.

## AJOVY

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**Affected Drugs:**

Ajovy

**Covered Uses:** All FDA-approved indications not otherwise excluded: Migraine (G43, G43.9)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Preventive treatment of migraine. 2) Document: a) 4 or more migraine days per month, and b) Therapeutic failure, contraindication or intolerance to 2 or more preventive treatments (e.g., divalproex, propranolol, topiramate, etc.).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## AKYNZEO

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**Affected Drugs:**

Akynzeo

**Covered Uses:** All approved FDA indication not otherwise excluded: Cancer Chemotherapy-Induced Nausea and Vomiting (R11.2, T45.1X5A, T45.1X5D, T45.1X5S)

**Exclusion Criteria:**1) Pregnancy

**Required Medical Information:**1) Diagnosis: Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, 2) Document: a) Prescribed in combination with dexamethasone, b) Chemotherapy regimen (including highly emetogenic drug)

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** Once per chemotherapy cycle

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## ALECENSA

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**Affected Drugs:**

Alecensa

**Covered Uses:** All FDA-approved indications not otherwise excluded: Malignant Neoplasm of Lung (ICD10: C34, C34.9, C34.90)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) or B) as adjuvant treatment following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations, 2) FDA approved tests (to validate ALK protein expression or rearrangements): FoundationOne CDx (Foundation Medicine, Inc.), Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.)

## ALPHA 1-PROTEINASE INHIBITOR

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**Affected Drugs:**

Aralast NP  
Glassia

**Covered Uses:** All approved FDA indication not otherwise excluded: Alpha 1-Antitrypsin Deficiency (E88.01)

**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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## ALUNBRIG

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**Affected Drugs:**

Alunbrig

**Covered Uses:** All FDA-approved indications not otherwise excluded: Non-Small-Cell Lung Carcinoma (ICD10: C34, C34.9, C34.90)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Anaplastic Lymphoma Kinase (ALK)-Positive Metastatic Non-Small Cell Lung Cancer (NSCLC). 2) Document: Disease is kinase (ALK)-positive and metastatic.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## AMITIZA/LUBIPROSTONE

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### **Affected Drugs:**

Amitiza

Lubiprostone

**Covered Uses:** All FDA-approved indications not otherwise excluded: Constipation associated with Irritable Bowel Syndrome (ICD10: K58, K58.1, K58.9, K59.0, K59.00), Chronic Idiopathic Constipation (ICD10: K59.0, K59.00, K59.04), Opioid-Induced Constipation (ICD10: F11, F11.99, K59.03, T40.605A, T40.605D)

**Exclusion Criteria:** Known or suspected mechanical gastrointestinal obstruction.

**Required Medical Information:** 1) Diagnosis: a. chronic idiopathic constipation, b. opioid-induced constipation OR c. irritable bowel syndrome with constipation.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Chronic Idiopathic Constipation and Opioid induced constipation: 24 mcg capsules twice daily, 2) Irritable bowel syndrome with constipation: 8mcg capsules twice daily.

## AMPYRA

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**Affected Drugs:**

Ampyra  
Dalfampridine ER

**Covered Uses:** All approved FDA indication not otherwise exclude: Multiple Sclerosis (G35)

**Exclusion Criteria:** 1) History of Seizures, 2) Moderate to severe renal impairment (CrCL 50ml/min or less)

**Required Medical Information:** 1) Diagnosis: To Improve Walking in a Patient with Multiple Sclerosis (MS), 2) Document: Creatinine clearance (CrCl) or actual body weight and serum creatinine (sCr).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** If CrCl (mL/min) is not provided it can be calculated using the Cockcroft and Gault equation:  $CrCl = \{(140 - \text{age}) \times \text{weight}\} / (\text{Scr} \times 72)$  (x 0.85 for females), weight in kg

## APRETUDE

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### **Affected Drugs:**

Apretude

**Covered Uses:** All FDA-approved indications not otherwise excluded: Human Immunodeficiency Virus (HIV) Disease (B20), Pre-Exposure Prophylaxis of HIV (HIV Infection Risk Reduction Before Potential Exposure) (ICD10: Z20.6, Z41.9)

**Exclusion Criteria:** Individuals with unknown or positive HIV-1 status.

**Required Medical Information:** 1) Diagnosis: HIV-1 pre-exposure prophylaxis (PrEP). 2) Document: A) Negative HIV-1 status test (result lecture date must be less than 30 days), B) Patient is at risk of acquiring HIV-1 infection, and C) Patient's actual body weight.

**Age Restrictions:** Adults and adolescents weighing at least 35 kg

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) At risk individuals include: has partner(s) known to be HIV-1 infected, or engages in sexual activity within a high prevalence area or social network and has additional risk factors for HIV-1 acquisition, such as: inconsistent or no condom use, diagnosis of sexually transmitted infections, exchange of sex for commodities (such as money, food, shelter, or drugs), use of illicit drugs or alcohol dependence, incarceration, or partner(s) of unknown HIV-1 status with any of the factors listed above.

## APTIVUS

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**Affected Drugs:**

Aptivus

**Covered Uses:** All FDA-approved indications not otherwise excluded: Human Immunodeficiency Virus Disease (B20)

**Exclusion Criteria:** Do not use APTIVUS/ritonavir in treatment-naive patients, B. Patients with moderate or severe (Child-Pugh Class B or C) hepatic impairment

**Required Medical Information:** 1) Documentation of HIV-1 strains resistant to more than one protease inhibitor, 2) Documentation of concurrent use with ritonavir, 3) For pediatric patients only document actual body weight.

**Age Restrictions:** 18 years of and older and pediatric patients weighing 36 kg or greater

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## ARCALYST

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### **Affected Drugs:**

Arcalyst

**Covered Uses:** All FDA-approved indications not otherwise excluded: Familial Cold Autoinflammatory Syndrome (ICD10: L50.2, M04.2), Muckle-Wells Syndrome (ICD10: M04.2), Deficiency of Interleukin-1 Receptor Antagonist (ICD10: D84.8, D84.81, D84.89, M04.8)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment 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 annual negative tuberculosis (TB) skin test results. For positive latent TB, patient must have completed or receiving treatment for latent tuberculosis infection. 3) For pediatric patients: actual body weight (weight-based dosing).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## ATOMOXETINE

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### **Affected Drugs:**

Atomoxetine  
Strattera

**Covered Uses:** All FDA-approved indications not otherwise excluded: Attention Deficit Hyperactivity Disorder (F90, F90.8, F90.9)

**Exclusion Criteria:** Concomitant use of Monoamine oxidase inhibitors (MAOI's) or use within 14 days of MAOI discontinuation 2) Pheochromocytoma or history of pheochromocytoma 3) Narrow Angle Glaucoma. 4) Severe cardiac or vascular disorders in which the condition would be expected to deteriorate with clinically important increases in blood pressure (e.g., 15 to 20 mm Hg) or heart rate (e.g., 20 bpm).

**Required Medical Information:** 1) Diagnosis: a. attention deficit disorder, b. attention deficit hyperactive disorder, 2) Document patient presents at least one of the following: a. Evidence of ongoing symptoms due to ADHD that cause significant impairment in academic, or occupational functioning. b. Anxiety, tension or marked agitation, c. Previous stimulant use in the past 90 days, d) Contraindication to stimulants, e) History of substance abuse, f) History of tics/Tourette's Syndrome

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** The criteria only apply to patients 18 years or older.

## AUBAGIO

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### **Affected Drugs:**

Aubagio

Teriflunomide

**Covered Uses:** All approved FDA indication not otherwise excluded: Relapsing, Remitting Multiple Sclerosis (ICD10: G35), Secondary Progressive Multiple Sclerosis (ICD10: G35), Clinically Isolated Syndrome (First Clinical Episode Suggestive of Multiple Sclerosis) (ICD10: G37.8)

**Exclusion Criteria:** 1) Severe Hepatic Impairment, 2) Pregnancy, and 3) Current leflunomide treatment

**Required Medical Information:** 1) Diagnosis: Treatment of Relapsing Forms of Multiple Sclerosis (MS), To Include Clinically Isolated Syndrome, Relapsing-Remitting Disease, and Active Secondary Progressive Disease. 2) Document: Liver function test results [transaminase (ALT and AST) and bilirubin levels, results must be lower than two times the normal limit based on laboratory test reference range]. 3) In naïve patients first treatment of choice is a generic therapeutic alternative (e.g., dimethyl fumarate, glatiramer acetate). In order to consider any other agent, patients must have documented previous use and therapeutic failure, intolerance or contraindication to at least one generic therapeutic alternative.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## **BANZEL**

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**Affected Drugs:**

Banzel  
Rufinamide

**Covered Uses:** All approved FDA indication not otherwise excluded: Lennox-Gastaut Syndrome (G40.81)

**Exclusion Criteria:** Patients with Familial Short QT syndrome

**Required Medical Information:** 1) Diagnosis: Lennox-Gastaut Syndrome., 2) For pediatric patients document: Actual body weight (weight-based dosing)

**Age Restrictions:** 1 years old or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## **BENLYSTA**

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### **Affected Drugs:**

Benlysta

**Covered Uses:** All FDA-approved indications not otherwise excluded: Systemic Lupus Erythematosus (M32, M32.9), Lupus Nephritis (ICD10: M32.14, M32.15)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Active systemic lupus erythematosus (SLE), or B) Active lupus nephritis. 2) Document: A) For SLE: i) Positive autoantibody test (anti-double-stranded DNA [anti-dsDNA]), ii) Prescribed in combination with standard therapy (e.g., corticosteroids, antimalarials, NSAIDs, immunosuppressors, etc.), iii) For pediatric patients: Actual body weight (weight-based dosing). B) For lupus nephritis: Prescribed in combination with standard therapy (e.g., cyclophosphamide, methylprednisolone sodium succinate, mycophenolate mofetil, tacrolimus).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate if intravenous infusion drugs are covered under the Pharmacy benefit. Normally these drugs are not covered under the Pharmacy benefit, validate coverage.

## BLOOD COMPONENT

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### Affected Drugs:

Advate	Adynovate
Afstyla	Aldurazyme
Alphanate	Alphanate/VWF Complex/Human
AlphaNine SD	Alprolix
BeneFIX	Coagadex
Eloctate	Epoprostenol Sodium
Feiba	Flolan
Hemlibra	Hemofil M
Humate-P	Idelvion
Ixinity	Jivi
Koate	Koate-DVI
Kogenate FS	Kovaltry
Mononine	Novoeight
NovoSeven RT	Nuwiq
Obizur	Profilnine
Rebinyn	Recombinate
Rixubis	Veletri
Wilate	Xyntha
Xyntha Solofuse	

**Covered Uses:** All FDA-approved indications not otherwise excluded: Congenital Hemophilia A (ICD10: D66), Von Willebrand Disease (ICD10: D68.0), Hemophilia B (ICD10: D67), Hereditary Factor X Deficiency (Inherited Deficiency in Blood Coagulation Factor X) (ICD10: D68.2), Factor XIII Deficiency Disease (ICD10: D68.2), Hemorrhaging in Factor XIII Deficiency (Bleeding in Factor XIII Deficiency) (ICD10: D68.2), Acute Hemorrhage (ICD10: R58), Coumarin-Induced Anticoagulation (ICD10: Z79.01), Factor VIII Deficiency (Deficiency in Blood Coagulation Factor VIII) (ICD10: D68.4) [For drug specific information refer to package insert], Hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or Hemophilia B (congenital factor IX deficiency) without IX inhibitors (ICD-10: D50-D89, D65-D69, D66, D67).

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis (for drug specific information refer to package insert). 2) Document: A) Type of hemophilia, B) Type and severity of bleeding, C) Patient's actual body weight, and D) Factor deficiency level.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** One-time approval. Duration according to the specific clinical scenario assessed by the pharmacist in full compliance with up-to-date bleeding disorders clinical guidelines and FDA recommendations.

**Other Criteria:** 1) For dosage and administration information refer to package insert, 2) Routine prophylaxis to reduce the frequency of bleeding episodes is an FDA approved indication, but is usually not covered under the Pharmacy benefit, validate coverage.

## BOSULIF

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### **Affected Drugs:**

Bosulif

**Covered Uses:** All FDA-approved indications not otherwise excluded: Philadelphia Chromosome + Chronic Myelocytic Leukemia (ICD10: C92.1, C92.10)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Philadelphia positive chronic myelogenous leukemia (Ph+ CML), 2) ) For chronic, accelerated, or blast phase Ph+ CML, 2) Document the following: a. positive results for Philadelphia chromosome, b. disease phase, c. resistance/ intolerance to prior therapy, 3) For newly-diagnosed 3) For patients with chronic phase Ph+ CML Ph+ chronic myelogenous leukemia (CML): a. positive results for Philadelphia chromosome. a) patient is newly-diagnosed OR b) resistant or intolerant to prior therapy (i.e imatinib, dasatinib, nilotinib), 4) For patients with accelerated, or blast phase Ph+ CML: a) documented resistance or intolerance to prior therapy (i.e imatinib, dasatinib, nilotinib).

**Age Restrictions:** 1) For accelerated, blast phase Ph+ CML with resistance or intolerance to prior therapy: 18 years of age or older, 2) For chronic phase Ph+ CML newly diagnosed or with resistance or intolerance to prior therapy: 1 year of age and older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## **BRAFTOVI**

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### **Affected Drugs:**

Braftovi

**Covered Uses:** All FDA-approved indications not otherwise excluded: Malignant Melanoma (Melanoma), Malignant Neoplasm of Colon (Cancer of the Colon) C18, C18.0, C18.1, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9, Malignant Neoplasm of Rectum (Cancer of the Rectum) C20, C21.8, Non-Small-Cell Lung Carcinoma (Non-Small-Cell Lung Cancer) (ICD-10: C34, C34.9, C34.90)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Unresectable or metastatic melanoma, b) metastatic colorectal cancer (CRC), or c) metastatic non-small cell lung cancer (NSCLC), 2) For unresectable or metastatic melanoma: a) Positive BRAF V600E or V600K mutation test, b) use in combination with binimetinib, 3) For metastatic colorectal cancer (CRC): a) BRAF V600E mutation test, b) document it will be used with cetuximab or cetuximab and mFOLFOX6 c) if used with cetuximab only: documented prior therapy, 4) For NSCLC: a) BRAF V600E mutation test, b) prescribed in combination with binimetinib.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## **BUDESONIDE ER**

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### **Affected Drugs:**

Budesonide  
Budesonide ER  
Entocort EC  
Uceris

**Covered Uses:** All FDA-approved indications not otherwise excluded: Crohns Disease (ICD10: K50, K50.9), Ulcerative Colitis (Ulcerated Colon) (ICD10: K51)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) For Uceris (budesonide ER tablet): induction of remission in patients with active, mild to moderate ulcerative colitis (UC), b) For Entocort (budesonide ER capsule): i) Treatment of mild to moderate active Crohns disease (CD) involving the ileum and/or the ascending colon, or ii) Maintenance of clinical remission of mild to moderate Crohns disease involving the ileum and/or the ascending colon. 2) Document: a) For UC (tablet formulation): disease is active, and severity is mild to moderate, b) For CD (capsule formulation): i) Therapeutic failure, contraindication or intolerance with mesalamine and/or sulfasalazine

**Age Restrictions:** 1) For tablet formulation (induction of remission): 18 years of age or older, or 2) For capsule formulation: a) Induction of remission: 8 years of age or older, or b) Maintenance of remission: 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 1) For active disease (induction of remission): 8 weeks, or 2) For maintenance (only for capsule formulation): 3 months

**Other Criteria:** For recurring episodes a repeat 8-week course may be given

## CABOMETYX

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### **Affected Drugs:**

Cabometyx

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hepatic Carcinoma (Liver Carcinoma) (ICD10: C22, C22.0, C22.8, C22.9), Renal Cell Carcinoma (Kidney Cell Carcinoma) (ICD10: C64, C64.1, C64.2, C64.9), Differentiated Thyroid Carcinoma (ICD10: C73), Pancreatic Neuroendocrine Tumor (Pancreatic Islet Cell Tumor) (ICD10: D3A.8)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Advanced Renal Cell Carcinoma (RCC), B) Hepatocellular carcinoma (HCC), C) Treatment of locally advanced or metastatic differentiated thyroid cancer (DTC), D) Locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors (pNET), E) Locally advanced or metastatic, well-differentiated extra-pancreatic neuroendocrine tumors (epNET). 2) Document: A) For RCC: i) Prescribed as monotherapy OR ii) Prescribed in combination with nivolumab as first-line treatment, B) For HCC: i) patient has been previously treated with sorafenib, C) For DTC: i) Patient has progressed following prior VEGFR-targeted therapy [e.g., Lenvima (Lenvatinib), Nexavar (sorafenib), etc.] and is radioactive iodine-refractory or ineligible, D) For pNET AND epNET: i) patient has been previously treated (e.g. everolimus, sunitinib) and the condition is unresectable.

**Age Restrictions:** 1) For DTC, pNET, and epNET: 12 years of age or older. 2) For all other indications: 18 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## CALQUENCE

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**Affected Drugs:**

Calquence

**Covered Uses:** All FDA-approved indications not otherwise excluded: Mantle Cell Lymphoma (ICD10: C83.1, C83.10), Chronic Lymphocytic Leukemia (ICD10: C91.1), Small Lymphocytic Lymphoma (ICD10: C85.8, C85.80 C91.1)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) For the treatment of untreated Mantle Cell Lymphoma (MCL) who are ineligible for autologous hematopoietic stem cell transplantation (HSCT), B) For the treatment of MCL who have received at least one prior therapy, C) For the treatment of Chronic Lymphocytic Leukemia (CLL), OR D) For the treatment of Small Lymphocytic Lymphoma (SLL). 2) Document: A) For untreated MCL who are ineligible for autologous hematopoietic stem cell transplantation (HSCT): i) use in combination with bendamustine and rituximab, B) For MCL who have received at least one prior therapy: i) Document one or more prior treatments.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## CAPECITABINE/XELODA

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**Affected Drugs:**

Capecitabine  
Xeloda

**Covered Uses:** All FDA-approved indications not otherwise excluded: Metastatic Malignant Neoplasm of Breast (C79.81), Malignant Neoplasm of Colon (C18, C18.9), Malignant Neoplasm of Rectum (C20, C21.8)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Adjuvant Colon Cancer (Dukes C Colon Cancer), b) Metastatic Colorectal Cancer, c) Metastatic Breast Cancer, 2) For metastatic breast cancer: a) When given in combination with Docetaxel must have failed prior Anthracycline-containing therapy, b) As monotherapy validate resistance or therapeutic failure to both Paclitaxel and Anthracycline-containing regimen.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## CAPRELSA

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**Affected Drugs:**

Caprelsa

**Covered Uses:** All FDA-approved indications not otherwise excluded: Medullary Thyroid Carcinoma (ICD10: C73)

**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 of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## CERDELGA

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**Affected Drugs:**

Cerdelga

**Covered Uses:** All FDA-approved indications not otherwise excluded: Gaucher Disease Type 1 (E75.22)

**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 and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## CEREZYME

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**Affected Drugs:**

Cerezyme

**Covered Uses:** All FDA-approved indications not otherwise excluded: Gaucher's Disease (E75.22)

**Exclusion Criteria:**1) Type 2 or 3 Gaucher disease

**Required Medical Information:**1) Diagnosis: type 1 Gaucher disease

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## CHOLBAM

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**Affected Drugs:**

Cholbam

**Covered Uses:** All approved FDA indication not otherwise excluded: Peroxisomal Disorder (E71.5, E71.50, E71.51, E71.518), Bile Acid Synthesis Disorder (E78.70, E78.79)

**Exclusion Criteria:** N/A

**Required Medical Information:**1) Liver Function Test

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## **CIALIS (BPH)**

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### **Affected Drugs:**

Cialis  
Tadalafil

**Covered Uses:** All FDA-approved indications not otherwise excluded: Benign Prostatic Hypertrophy (ICD10: N40)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Benign prostatic hyperplasia (BPH), b) Benign prostatic hyperplasia (BPH) with Erectile dysfunction (ED)

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## CIBINQO

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**Affected Drugs:**

Cibinqo

**Covered Uses:** All FDA-approved indications not otherwise excluded: Atopic Dermatitis (ICD10: L20, L20.9)

**Exclusion Criteria:** Antiplatelet therapies (e.g., clopidogrel, ticagrelor, Prasugrel, dipyridamole, etc.) except for low-dose aspirin (less than or similar to 81 mg daily), during the first 3 months of treatment.

**Required Medical Information:** 1) Diagnosis: Treatment of refractory, moderate-to-severe atopic dermatitis (AD). 2) Document: A) Disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. And B) Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

**Affected Drugs:**

Cimzia  
Cimzia (2 Syringe)  
Cimzia-Starter

**Covered Uses:** All approved FDA indication not otherwise excluded: Rheumatoid Arthritis (ICD10: M06, M06.9), Crohn's Disease (ICD10: K50, K50.9), Ankylosing Spondylitis (Rheumatic Disease causing Vertebrae Inflammation) (ICD10: M45, M45.9), Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), Plaque Psoriasis (ICD10: L40.0), Non-radiographic Axial Spondyloarthritis (M46.80, M46.87, M46.88)

**Exclusion Criteria:**1) Concurrent use with another biological response modifier

**Required Medical Information:**1) Diagnosis: A) Reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in patients with moderately to severely active disease who have had an inadequate response to conventional therapy. B) Treatment of moderately to severely active rheumatoid arthritis (RA). C) Treatment of active psoriatic arthritis (PsA). D) Treatment of active ankylosing spondylitis (AS). E) Treatment of active non-radiographic axial spondyloarthritis (nr-AxSpA) with objective signs of inflammation. F) Treatment of moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy 2) Document: A) For CD: i) Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, prednisone, mercaptopurine, mesalamine, methotrexate, etc.), ii) Prior use of at least two formulary preferred drugs (e.g., Avsola, Humira, Renflexis, Stelara, if available) and iii) If available, prior use of at least one formulary non-preferred drug (e.g., Entyvio). B) For RA: i) Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, hydroxychloroquine, leflunomide), ii) Prior use of at least two formulary preferred drugs (e.g., Avsola, Enbrel, Humira, Orencia, Renflexis, Rinvoq, Xeljanz, if available), and iii) If available, prior use of at least one formulary non-preferred drug (e.g., Kevzara). C) For PsA: i) Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine) and ii) Prior use of at least two formulary preferred drugs (e.g., Avsola, Enbrel, Humira, Orencia, Renflexis, Stelara, Taltz, Xeljanz, if available). D) For AS: i) Therapeutic failure to at least one nonsteroidal anti-inflammatory drug (NSAID) (e.g., celecoxib, naproxen, sulindac, etc.), ii) Prior use of at least two formulary preferred drugs (e.g., Avsola, Enbrel, Humira, Renflexis, Taltz, if available), and iii) If available, prior use of at least one formulary non-preferred drug (e.g., Cosentyx). E) For nr-AxSpA: Therapeutic failure to at least one NSAIDs (e.g., diclofenac, ibuprofen, naproxen, etc.). F) For PsO: i) At least 3% BSA is affected or crucial body areas such as the hands, feet, face, scalp or genitals, ii) Prior use of at least one conventional drug (e.g., acitretin, cyclosporine, hydroxyurea, methotrexate, triamcinolone, etc.), and iii) Prior use of at least two formulary preferred drugs (e.g., Avsola, Enbrel, Humira, Renflexis, Skyrizi, Stelara, Taltz, if available). G) For all indications: Only for biologic therapy-naïve patients: Physician's

certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## COMETRIQ

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**Affected Drugs:**

Cometriq (100 MG Daily Dose)

Cometriq (140 MG Daily Dose)

Cometriq (60 MG Daily Dose)

**Covered Uses:** All FDA-approved indications not otherwise excluded: Medullary Thyroid Carcinoma (ICD10: C73)

**Exclusion Criteria:** N/A

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

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## CONTRAVE

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**Affected Drugs:**

Contrave

**Covered Uses:** All FDA-approved indications not otherwise excluded: Obesity (ICD10: E66, E66.9)

**Exclusion Criteria:** 1) Uncontrolled hypertension. 2) Seizure disorders, anorexia nervosa or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs. 3) Use of other bupropion-containing products. 4) Chronic opioid use. 5) During or within 14 days of taking monoamine oxidase inhibitors (MAOI).

**Required Medical Information:** 1) Diagnosis: As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management. 2) Document: Body mass index (BMI) greater than or equal to 30 kg/m<sup>2</sup>, or greater than or equal to 27 kg/m<sup>2</sup> in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). 3) For renewals: At least a 5% reduction in baseline body weight (actual BMI or weight and height).

**Age Restrictions:** 18 years or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 3 months

**Other Criteria:** For FEHB renewals: Validate patient is currently enrolled in obesity management program.

## **CYSTADANE**

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**Affected Drugs:**

Betaine  
Cystadane

**Covered Uses:** All approved FDA indication not otherwise excluded: Homocystinuria (E72.11)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Cystathionine beta-synthase (CBS) deficiency, b) 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency, c) Cobalamin cofactor metabolism (cbl) defect.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## CYSTAGON

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**Affected Drugs:**

Cystagon

**Covered Uses:** All approved FDA indication not otherwise excluded: Nephropathic Cystinosis (ICD10: E72.04)

**Exclusion Criteria:** N/A

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

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## DARAPRIM

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**Affected Drugs:**

Daraprim  
Pyrimethamine

**Covered Uses:** All approved FDA indication not otherwise excluded: Toxoplasmosis (ICD10: B58, B58.9)

**Exclusion Criteria:** Megaloblastic anemia due to folate deficiency

**Required Medical Information:** 1) Diagnosis: Treatment of Toxoplasmosis. 2) Document: Prescribed in combination with a sulfonamide (e.g., sulfadiazine).

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 1) Treatment of toxoplasmosis: up to 5 weeks, 2) Treatment of acute malaria: a) Starting dose for 2 days, b) Maintenance dose: for up to 10 weeks, 3) For early recrudescence and late relapse of malaria: up to 10 weeks

**Other Criteria:** 1) Daraprim is available through a restricted specialty pharmacy program called Daraprim Direct. For more information refer to <http://www.daraprimdirect.com/>, 2) Note: Chemoprophylaxis of malaria due to susceptible strains of plasmodia. According to literature, resistance to pyrimethamine is prevalent worldwide thus it is not suitable as a prophylactic agent for travelers to most areas. Consider using recommended alternatives included in the WHO Malaria Guideline or CDC recommendations, 3) Refer to the insert product information for dosage and administration.

## DESCOVY

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### **Affected Drugs:**

Descovy

**Covered Uses:** All FDA-approved indications not otherwise excluded: Human Immunodeficiency Virus (HIV) Disease (B20), Pre-Exposure Prophylaxis of HIV (HIV Infection Risk Reduction Before Potential Exposure) (ICD10: Z20.6, Z41.9)

**Exclusion Criteria:** For PrEP: Contraindicated in individuals with unknown or positive HIV-1 status.

**Required Medical Information:** 1) Diagnosis: A) Treatment of HIV-1 infection, or B) HIV-1 pre-exposure prophylaxis (PrEP). 2) Document: A) For HIV-1 infection: No other medical information is required. B) For PrEP: i) Negative HIV-1 status test (result lecture date must be less than 30 days), ii) Patient is at risk of acquiring HIV-1 infection, and iii) Patient's actual body weight.

**Age Restrictions:** Adults and adolescents weighing at least 35 kg

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** At risk individuals include: has partner(s) known to be HIV-1 infected, or engages in sexual activity within a high prevalence area or social network and has additional risk factors for HIV-1 acquisition, such as: inconsistent or no condom use, diagnosis of sexually transmitted infections, exchange of sex for commodities (such as money, food, shelter, or drugs), use of illicit drugs or alcohol dependence, incarceration, or partner(s) of unknown HIV-1 status with any of the factors listed above. 2) PrEP indication does not include individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated

## DESFERAL

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**Affected Drugs:**

Deferoxamine Mesylate  
Desferal

**Covered Uses:** All FDA-approved indications not otherwise excluded: Chronic Iron Overload (E83.11, E83.119), Acute Iron Intoxication (T45.4X1A)

**Exclusion Criteria:** 1) Transfusional iron overload in patients with other chronic anemias. 2) Contraindicated in patients with severe renal disease or anuria, since the drug and the iron chelate are excreted primarily by the kidney

**Required Medical Information:** 1) Diagnosis: transfusional iron overload due to thalassemia syndromes, 2) Document the following: a. Absolute neutrophil count (ANC), b. CBC with differential, AND d. failure to current chelation therapy

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## DIAGNOSIS

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**Affected Drugs:**

Chloroquine Phosphate

Hydroxychloroquine Sulfate

Plaquenil

**Covered Uses:** All FDA-approved indications not otherwise excluded.

**Exclusion Criteria:** N/A

**Required Medical Information:** Validate diagnosis.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## DUPIXENT

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### Affected Drugs:

Dupixent

**Covered Uses:** All FDA-approved indications not otherwise excluded: Atopic Dermatitis (ICD10: L20, L20.9), Asthma (ICD10: J45, J45.9, J45.90), Moderate Persistent Asthma (ICD10: J45.4), Rhinosinusitis (Inflammation of the Sinuses and the Nose) (ICD10: J31.0, J32.9), Severe Persistent Asthma (ICD10: J45.5), Eosinophilic Esophagitis (ICD10: K20.0), Prurigo Nodularis (ICD10: L28.1), Chronic Obstructive Pulmonary Disease (J44, J44.9), Chronic Idiopathic Urticaria (Persistent Hives of Unknown Cause) (ICD10: L50.1, L50.8, L50.9)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of Moderate-to-Severe Atopic Dermatitis, B) Add-on Maintenance Treatment of Moderate-to-Severe Asthma, C) Add-on Maintenance Treatment of Inadequately Controlled Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP), D) Treatment of eosinophilic esophagitis (EoE), E) Prurigo Nodularis (PN), F) Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD), or G) Chronic Spontaneous Urticaria (CSU). 2) Document: A) For Atopic Dermatitis: i) Previous use or contraindication to topical corticosteroids (e.g., flucinolone, flucinonide, mometasone, etc.), topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus, etc.) or phosphodiesterase inhibitors [e.g., crisaborole (Eucrisa)], and ii) 10% or more of the body surface area (BSA) is affected or an eczema area and severity index (EASI) score of = 16. B) For Asthma: i) Prescribed as an add-on therapy, ii) Current asthma therapy, iii) Test result validating eosinophilic phenotype (validate blood eosinophil count greater than or equal to 150 cells/mcL within 6 weeks of request) or patient has oral corticosteroid dependent asthma [validate daily oral corticosteroid use (e.g., prednisone or methylprednisolone 7.5-60mg daily dose), or history of 1 or more asthma exacerbations that required treatment with systemic corticosteroids], and iv) Evidence of at least 3 consecutive months of therapy with high-dose of inhaled corticosteroids (ICS) in combination with other controller medications [e.g., Long acting beta agonist (LABAs), Leukotriene receptor antagonist (LTRAs) with oral corticosteroids (OCS) use]. C) For CRSwNP: Prescribed as an add-on therapy and current therapy. D) For EoE: Document inadequate response, intolerance or contraindication to high-dose PPI therapy and/or swallowed inhaled respiratory corticosteroid therapy. E) For PN: Document prior failure or contraindications to medium to high potency topical corticosteroids, F) For COPD: i) Prescribed as add-on therapy, ii) exacerbation history of at least two moderate or one severe exacerbation in the previous year despite receiving maintenance triple inhaled therapy for COPD LAMA/LABA/ICS (i.e. Breztri, Trelegy) or LABA/LAMA (i.e. Anoro, Stiolto) if ICS are contraindicated, iii) Test result validating eosinophilic phenotype (validate blood eosinophil count greater than or equal to 300 cells/mcL within 6 weeks of request), G) For CSU: Therapeutic failure to antihistamine,

leukotriene inhibitors or immunosuppressive therapies. H) For Pediatric Patients: Actual body weight (weight-based dosing).

**Age Restrictions:** 1) For Atopic Dermatitis: 6 months of age or older 2) For Asthma: 6 years of age or older, 3) For CRSwNP: 12 years and older, 4) PN and COPD: 18 years of age and older, or 5) For EoE: 1 year and older, weighing at least 15 kg, 6) For CSU: 12 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## EBGLYSS

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**Affected Drugs:**

Ebglyss

**Covered Uses:** All FDA-approved indications not otherwise excluded: Atopic Dermatitis (ICD10: L20, L20.9)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: For the treatment of moderate-to-severe atopic dermatitis. 2) Document: Previous use or contraindication to topical corticosteroids (e.g., fluocinolone, fluocinonide, mometasone, etc.), topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus, etc.) and phosphodiesterase inhibitors [e.g., crisaborole (Eucrisa), if available], and ii) 10% or more of the body surface area (BSA) is affected or an eczema area and severity index (EASI) score of = 16.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## ELELYSO

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**Affected Drugs:**

ElELYso

**Covered Uses:** All FDA-approved indications not otherwise excluded: Gaucher Disease Type 1 (E75.22)

**Exclusion Criteria:** Type 2 or 3 Gaucher disease

**Required Medical Information:**1) Diagnosis: type 1 Gaucher disease

**Age Restrictions:** 4 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## EMEND/APREPITANT

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**Affected Drugs:**

Aprepitant  
Emend  
Emend BiPack  
Emend TriPack

**Covered Uses:** All FDA-approved indications not otherwise excluded: Postoperative Nausea and Vomiting (R11.2), Cancer Chemotherapy-Induced Nausea and Vomiting (R11.2, T45.1X5A, T45.1X5D, T45.1X5S)

**Exclusion Criteria:** Concurrent use with Pimozide

**Required Medical Information:** 1) Diagnosis: a. acute or delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin, b. nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC)

**Age Restrictions:** 1) Oral Suspension: 6 months of age and older, 2) Capsules: 12 years of age and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** Per chemotherapy cycle

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## EMGALITY

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### **Affected Drugs:**

Emgality

Emgality (300 MG Dose)

**Covered Uses:** All FDA-approved indications not otherwise excluded: Migraine (ICD10: G43, G43.9), Cluster Headache (ICD10: G44.009)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Preventive Treatment of Migraine, or B) Treatment of Episodic Cluster Headache. 2) Document: A) For migraine: i) 4 or more migraine days per month, and ii) Therapeutic failure, contraindication or intolerance to 2 or more treatments (e.g., divalproex, propranolol, topiramate, etc.). B) For cluster headache: No additional medical information is required.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## EMSAM

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**Affected Drugs:**

Emsam

**Covered Uses:** All FDA-approved indications not otherwise excluded: Major Depressive Disorder (F32).

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Major depressive disorder

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Prior to initiation of selegiline therapy: discontinue contraindicated agents (ie, carbamazepine, SSRIs, serotonin norepinephrine reuptake inhibitors, clomipramine, imipramine, meperidine, tramadol, methadone, pentazocine, propoxyphene, or dextromethorphan) for 4 to 5 half-lives, which is approximately 5 weeks for fluoxetine and 1 week for most other agents

## ENBREL

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### Affected Drugs:

Enbrel  
Enbrel Mini  
Enbrel SureClick

**Covered Uses:** All FDA-approved indications not otherwise excluded Rheumatoid Arthritis (ICD10: M06, M06.9), Ankylosing Spondylitis (Rheumatic Disease causing Vertebrae Inflammation) (ICD10: M45, M45.9), Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), Plaque Psoriasis (ICD10: L40.0), Polyarticular Juvenile Idiopathic Arthritis (ICD10: M08.09)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) For reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). B) For reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA) and Juvenile Psoriatic Arthritis (JPsA). C) For reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA). D) For reducing signs and symptoms in patients with ankylosing spondylitis (AS). E) Treatment of chronic moderate to severe plaque psoriasis (PsO) in patients who are candidates for systemic therapy or phototherapy. 2) Document: A) For RA: Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, hydroxychloroquine, leflunomide). B) For PJIA and JPsA: Therapeutic failure to methotrexate. C) For PsA: Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine). D) For AS: Therapeutic failure to at least one nonsteroidal anti-inflammatory drug (NSAID) (e.g., celecoxib, naproxen, sulindac, etc.). E) For PsO: i) At least 3% BSA is affected or crucial body areas such as the hands, feet, face, scalp or genitals and ii) Prior use of at least one conventional drug (e.g., acitretin, cyclosporine, hydroxyurea, methotrexate, triamcinolone, etc.). F) For all indications: Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria: N/A**

## ENTECAVIR

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**Affected Drugs:**

Baraclude  
Entecavir

**Covered Uses:** All FDA-approved indications not otherwise excluded: Chronic Hepatitis B (B18.1)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Chronic Hepatitis B Virus Infection, 2) Document the following: a) Positive result in the Hepatitis B DNA Quantitative PCR Test (serum HBV DNA by PCR), b) Evidence of HBV replication for at least 6 months (serum HBeAg-positive), c) Chronic HBV infection for at least 6 months (serum HBsAg-positive), AND d) Liver function test: persistently elevated ALT levels, two or more times the upper limit of normal (greater than 2 x ULN), 3) To determine dosage regimen: a) indicate whether the patient is naive or experienced, 4) For experienced patients: document previous treatments.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## ENTYVIO

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**Affected Drugs:**

Entyvio

**Covered Uses:** All FDA-approved indications not otherwise excluded: Ulcerative Colitis (Ulcerated Colon) (ICD10: K51), Crohn's Disease (ICD10: K50, K50.9)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of moderately to severely active ulcerative colitis (UC), or B) Treatment of moderately to severely active Crohn's disease (CD). 2) Document: A) For UC: i) Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, hydrocortisone, mercaptopurine, mesalamine, sulfasalazine, etc.) and ii) Prior use of at least two formulary preferred drugs (e.g., Avsola, Humira, Renflexis, Stelara, Xeljanz, if available). B) For CD: Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, prednisone, mercaptopurine, mesalamine, methotrexate, etc.) and ii) Prior use of at least two formulary preferred drugs (e.g., Avsola, Humira, Renflexis, Stelara, if available). C) For all indications: Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate if intravenous infusion drugs are covered under the Pharmacy benefit. Normally these drugs are not covered under the Pharmacy benefit, validate coverage.

## ENTYVIO SC

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### **Affected Drugs:**

Entyvio Pen

**Covered Uses:** All FDA-approved indications not otherwise excluded: Ulcerative Colitis (Ulcerated Colon) (ICD10: K51), Crohn's Disease (ICD10: K50, K50.9)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of moderately to severely active ulcerative colitis (UC) or B) Treatment of moderately to severely active Crohn's disease (CD). 2) Document for UC: A) Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, hydrocortisone, mercaptopurine, mesalamine, sulfasalazine, etc.) and B) Prior use of at least two formulary preferred drugs (e.g., Avsola, Humira or preferred biosimilars, Renflexis, Stelara, Xeljanz, if available) and C) positive clinical response or remission with at least two doses of IV Entyvio for UC, 3) Document for CD: A) Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, prednisone, mercaptopurine, mesalamine, methotrexate, etc.), B) Prior use of at least two formulary preferred drugs (e.g., Avsola, Humira or preferred biosimilars, Renflexis, Stelara, if available) and C) positive clinical response or remission with at least two doses of IV Entyvio for CD. 4) Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Following the first two ENTYVIO intravenous doses administered at Week 0 and Week 2, ENTYVIO may be switched to subcutaneous injection at Week 6, 2) Recommended maintenance dose with subcutaneous injection is 108 mg once every two weeks

## ERIVEDGE

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**Affected Drugs:**

Erivedge

**Covered Uses:** All FDA-approved indications not otherwise excluded: Basal Cell Carcinoma of Skin (ICD10: C44.81, C44.91)

**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 and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## ERLEADA

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**Affected Drugs:**

Erleada

**Covered Uses:** All FDA-approved indications not otherwise excluded: Malignant Neoplasm of Prostate (Cancer of the Prostate Gland) (ICD10: C61, N42.30)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) metastatic castration-sensitive prostate cancer, or b) Non-metastatic castration-resistant prostate cancer. 2) Document: Patient is receiving a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, etc.) concurrently or had a bilateral orchiectomy.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## ESBRIET

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**Affected Drugs:**

Esbriet  
Pirfenidone

**Covered Uses:** All approved FDA indication not otherwise excluded: Pulmonary Interstitial Fibrosis (J84.112)

**Exclusion Criteria:** N/A

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

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## EVISTA/RALOXIFENE

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**Affected Drugs:**

Evista  
Raloxifene HCl

**Covered Uses:** All FDA-approved indications not otherwise excluded: Osteoporosis (M81), Malignant Neoplasm of Breast (C50, C50.1, C50.2, C50.3, C50.4, C50.5, C50.6, C50.8, C50.9, C50.919)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis, 2) Documentation of increased risk for breast cancer, 3) Age

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** If patient is 35 years or older and has an increased risk for breast cancer a \$0 copay is applied. If the patient does not have an increased risk for breast cancer regular copay applies.

## EXJADE/JADENU

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**Affected Drugs:**

Deferasirox  
Deferasirox Granules  
Exjade  
Jadenu  
Jadenu Sprinkle

**Covered Uses:** All FDA-approved indications not otherwise excluded: Chronic Iron Overload (ICD10: E83.11, E83.119)

**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) Creatinine clearance greater than 40 ml/min, 2) Document lack of severe hepatic impairment, 3) Bilirubin: a) 0.2 to 0.8mg/dL, 4) Platelets more than 50, 000/mcL.

**Age Restrictions:** 2 years of age and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** For oncology related indication, validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## FABRAZYME

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**Affected Drugs:**

Fabrazyme

**Covered Uses:** All FDA-approved indications not otherwise excluded: Fabry Disease (ICD10: E75.21).

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Fabry disease. 2) Document: Patients actual body weight (weight-based dosing).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate if intravenous administration drugs are covered under the Pharmacy benefit. Normally these treatments are not covered under the Pharmacy benefit, validate coverage.

## FASENRA

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### **Affected Drugs:**

Fasenra  
Fasenra Pen

**Covered Uses:** All FDA-approved indications not otherwise excluded: Asthma (ICD10: J45, J45.9, J45.90), Severe Persistent Asthma (ICD10: J45.5), Eosinophilic Granulomatosis with Polyangiitis (Churg-Strauss Syndrome) (ICD10: M30.1)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Add-On Maintenance Treatment of Severe Asthma with an Eosinophilic Phenotype or B) eosinophilic granulomatosis with polyangiitis (EGPA). 2) For asthma document: A) Blood eosinophil count greater than or equal to 150 cells/mcL (within 6 weeks of request), and B) Evidence of at least 3 consecutive months of therapy with high-dose of inhaled corticosteroids (ICS) in combination with other controller medications [e.g., long-acting beta agonist (LABAs), Leukotriene receptor antagonist (LTRAs) with oral corticosteroids (OCS) use], 3) For eosinophilic granulomatosis with polyangiitis (EGPA): Therapeutic failure, intolerance, or contraindication to systemic glucocorticoids (e.g., prednisone, methylprednisolone).

**Age Restrictions:** 1) For severe asthma: 6 years or older, 2) For EGPA: 18 years or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## FERRIPOX

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**Affected Drugs:**

Deferiprone

Ferriprox

**Covered Uses:** All FDA-approved indications not otherwise excluded: Iron Overload (Excessive Amount of Iron in the Body) (ICD10: E83.11, E83.119)

**Exclusion Criteria:** Transfusional iron overload in patients with other chronic anemias.

**Required Medical Information:** 1) Diagnosis: A) Treatment of transfusional iron overload in patients with thalassemia syndromes, or B) Treatment of transfusional iron overload in patients with sickle cell disease or other anemias. 2) Document: A) Absolute neutrophil count (ANC) (must be greater than 1,500/mm<sup>3</sup>, or 1.5 x 10<sup>9</sup>/L), B) CBC with differential, and C) Failure to current chelation therapy (e.g., deferasirox, deferoxamine, etc.).

**Age Restrictions:** 1) For oral tablets: 8 years of age or older, or 2) For oral solution: 3 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## FUZEON

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**Affected Drugs:**

Fuzeon

**Covered Uses:** All FDA-approved indications not otherwise excluded: Human Immunodeficiency Virus Disease (B20)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) HIV-1 infection, 2) Documentation: a. previous treatment, b. concurrent use with other antiretroviral drugs

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## GEMTESA

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### **Affected Drugs:**

Gemtesa

**Covered Uses:** All FDA-approved indications not otherwise excluded: Urinary Incontinence (ICD10: F98.0, N39.4, R32), Urinary Frequency (Frequent Urination) (ICD10: R35.0), Urinary Urgency (ICD10: R39.15), Overactive Bladder (ICD10: N32.81), Benign Prostatic Hypertrophy (Benign Enlargement of Prostate) (ICD10: N40)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency or B) Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia (BPH) 2) Document for treatment of OAB: A) Treatment failure, intolerance, or contraindication to an antimuscarinic agent (e.g., oxybutynin, trospium, or tolterodine, etc.) and B) Intolerance to mirabregon due to presence of cardiovascular comorbidities (e.g., hypertension, coronary artery disease, peripheral artery disease, cerebrovascular disease, arrhythmias, and valvular heart disease, etc.) 3) Document for treatment of OAB in males with BPH: A) Patient is currently receiving pharmacologic therapy for BPH [i.e. alpha blocker (tamsulosin, doxazosin), with or without a 5-alpha reductase inhibitor (finasteride, dutasteride)]

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## GENOTROPIN

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### Affected Drugs:

Genotropin  
Genotropin MiniQuick

**Covered Uses:** All FDA-approved indications not otherwise excluded: Growth Failure (ICD10: R62.52), Growth Hormone Deficiency (ICD10: E23.0), Prader-Willi Syndrome (ICD10: Q87.1)

**Exclusion Criteria:** 1) Active malignancy. 2) Active proliferative or severe non-proliferative diabetic retinopathy. 3) Acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental traumas, or those with acute respiratory failure. 4) Closed epiphyses for pediatric patients. 5) 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. 6) Underlying intracranial tumor, evidence of progression or recurrence. 7) Respiratory insufficiency.

**Required Medical Information:** 1) Diagnosis: A) Treatment of children with growth failure due to growth hormone deficiency (GHD). B) Treatment of children with Prader-Willi syndrome. C) Treatment of children that are small for gestational age (SGA). D) Treatment of children with Turner syndrome. E) Treatment of children with idiopathic short stature (ISS). F) Treatment of adults with either adult onset or childhood onset GHD. 2) For initial evaluation document: A) For GHD: Total or partial deficiency of endogenous growth hormone evidenced by one or more of the following indicators: i) Minimum of 2 or more abnormal growth hormone provocative tests (secretion of the growth hormone is less than 10ng/ml), ii) Delayed bone age of 2 or more years (2 standard deviations below the mean for chronological age), and/or iii) 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). B) For Prader-Willi syndrome: i) Characteristic karyotype and ii) Height below the tenth percentile for age. C) For small for gestational age (SGA) or idiopathic short stature (ISS): i) Patient has a documented birth weight and/or length that is two or more standard deviations (SD) below the mean for gestational age, or ii) At 24 months of age the patient failed to manifest catch-up growth evidenced by a height 2 or more standard deviations (SD) below the mean for age and sex. D) For Turner syndrome: No additional information is required. E) For adult GHD: Meets one of the following: i) Failed stimulation tests with peak levels below 5 g/L, ii) Three or more hormonal deficiencies requiring hormone replacement therapy, including growth hormone (e.g., thyroid-stimulating hormone, adrenocorticotrophic hormone, prolactin, luteinizing hormone, follicle-stimulating hormone, antidiuretic hormone, oxytocin, etc.), iii) Child onset GHD with no mutations embriopathic lesions or irreversible structural lesions/damage, low pre-treatment IGF-1 and failed stimulation test (peak below 5 g/L) prior to starting GH treatment. 3) For children over 12 years of age: evidence that epiphyses have not yet closed. 4) For renewals

document: A) For pediatric patients: Body composition has improved [e.g., growth rate remains above 2–2.5 cm/year (except for children with hypopituitarism)]. B) For adult patients: IGF-1 levels.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** For adult growth hormone deficiency, verify if it is cover under pharmacy benefits and it is not an exclusion.

## GILENYA

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### **Affected Drugs:**

Fingolimod HCl  
Gilenya

**Covered Uses:** All approved FDA indication not otherwise excluded: Relapsing, Remitting Multiple Sclerosis (ICD10: G35), Secondary Progressive Multiple Sclerosis (Secondary Progressive Multiple Sclerosis) (ICD10: G35), Clinically Isolated Syndrome (First Clinical Episode Suggestive of Multiple Sclerosis) (ICD10: G37.8)

**Exclusion Criteria:** 1) Recent myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with 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 msec, and 4) Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia (e.g., quinidine, procainamide, disopyramide) or Class III anti-arrhythmic drugs (e.g. amiodarone, sotalol, ibutilide, dofetilide)

**Required Medical Information:** 1) Diagnosis: Treatment of Relapsing Forms of Multiple Sclerosis (MS), to Include Clinically Isolated Syndrome, Relapsing Remitting Disease, and Active Secondary Progressive Disease. 2) Document (only for first prescription): Electrocardiogram (ECG) result (to determine preexisting conduction abnormalities, see Other Criteria). 3) Patients must have documented previous use and therapeutic failure, intolerance or contraindication to at least one generic therapeutic alternative (e.g., dimethyl fumarate, fingolimod, glatiramer acetate).

**Age Restrictions:** 10 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** If ECG result is not available, the physician needs to provide a statement indicating that the patient has been evaluated for cardiovascular risk and does not have preexisting conduction abnormalities nor meet exclusion criteria.

## GLP-1

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### **Affected Drugs:**

Mounjaro

Ozempic (0.25 or 0.5 MG/DOSE)

Ozempic (1 MG/DOSE)

Ozempic (2 MG/DOSE)

Rybelsus

Trulicity

**Covered Uses:** Type 2 Diabetes Mellitus (Type 2 Diabetes) (ICD10: E11)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Chart notes showing diagnosis of type 2 diabetes mellitus OR confirmed diagnosis of Diabetes Mellitus Type 2 by accepted lab testing per treatment guidelines (e.g FPG, 2-h PG, GLU, random plasma glucose, or A1C).

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** A1C greater than or equal to 6.5%. Fasting plasma glucose (FPG) is greater than or equal to 126 mg/dL. 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test).

## GRANIX

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**Affected Drugs:**

Granix

**Covered Uses:** All FDA-approved indications not otherwise excluded: Neutropenia (Disorder with a Low Number of Neutrophils) (ICD10: D70, D70.9)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. 2) Document: A) For prophylaxis of neutropenia: Current myelosuppressive anti-cancer drugs or radiation. B) For management of neutropenia: complete blood count (CBC) with differential results [to confirm low neutrophils count – absolute neutrophil count (ANC) lower than 1500/mcL for neutropenia or 500/mcL for severe neutropenia]. C) Patient's actual body weight (weight-based dosing).

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 3 months

**Other Criteria:** 1) Validate if covered under the Pharmacy benefit. 2) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## HADLIMA

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### Affected Drugs:

Hadlima

Hadlima PushTouch

**Covered Uses:** All FDA-approved indications not otherwise excluded: Rheumatoid Arthritis (ICD10: M06, M06.9), Ulcerative Colitis (Ulcerated Colon) (ICD10: K51), Crohn's Disease (ICD10: K50, K50.9), Ankylosing Spondylitis (Rheumatic Disease causing Vertebrae Inflammation) (ICD10: M45, M45.9), Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), Plaque Psoriasis (ICD10: L40.0), Polyarticular Juvenile Idiopathic Arthritis (ICD10: M08.09), Hidradenitis Suppurativa (Hidradenitis Suppurativa) (ICD-10): L73.2, Uveitis (Inflammation of Uveal Tract of Eye) (ICD-10: H44.139)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) For rheumatoid arthritis (RA): Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active RA. B) For polyarticular juvenile idiopathic arthritis (PJIA): Reducing signs and symptoms of moderately to severely active polyarticular JIA. C) For psoriatic arthritis (PsA): Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with active PsA. D) For ankylosing spondylitis (AS): Reducing signs and symptoms in patients with active AS. E) For Crohn's disease (CD): Treatment of moderately to severely active CD. F) For ulcerative colitis (UC): Treatment of moderately to severely active UC. G) For plaque psoriasis (PsO): Treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. H) For hidradenitis suppurativa (HS): Treatment of moderate to severe HS. I) For uveitis (UV): Treatment of non-infectious intermediate, posterior, and panuveitis. 2) Document: A) For RA: Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, hydroxychloroquine, leflunomide). B) For PJIA: Therapeutic failure to methotrexate. C) For PsA: Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine). D) For AS: Therapeutic failure to at least one nonsteroidal anti-inflammatory drug (NSAID) (e.g., celecoxib, naproxen, sulindac, etc.). E) For CD: Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, prednisone, mercaptopurine, mesalamine, methotrexate, etc.). F) For UC: Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, hydrocortisone, mercaptopurine, mesalamine, sulfasalazine, etc.). G) For PsO: i) At least 3% BSA is affected or crucial body areas such as the hands, feet, face, scalp or genitals, and ii) Prior use of at least one conventional drug (e.g., acitretin, cyclosporine, hydroxyurea, methotrexate, triamcinolone, etc.). H) For HS and UV: No additional medical information is required. I) For all indications: Only for biologic therapy-naïve patients: Physician's certification stating

tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## HEMLIBRA

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**Affected Drugs:**

Hemlibra

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hemophilia A (D66)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with Hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors, 2) Document patients actual body weight

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** One-time approval

**Other Criteria:** Routine prophylaxis to reduce the frequency of bleeding episodes is an FDA approved indication, but is usually not covered under the Pharmacy benefit, validate coverage

## HUMIRA

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### **Affected Drugs:**

Humira (1 Pen)  
Humira (2 Pen)  
Humira (2 Syringe)  
Humira-CD/UC/HS Starter  
Humira-Ped<40kg Crohns Starter  
Humira-Ped>=40kg Crohns Start  
Humira-Ps/UV/Adol HS Starter  
Humira-Psoriasis/Uveit Starter

**Covered Uses:** All FDA-approved indications not otherwise excluded: Rheumatoid Arthritis (ICD10: M06, M06.9), Ulcerative Colitis (Ulcerated Colon) (ICD10: K51), Crohn's Disease (ICD10: K50, K50.9), Ankylosing Spondylitis (Rheumatic Disease causing Vertebrae Inflammation) (ICD10: M45, M45.9), Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), Uveitis (Inflammation of Uveal Tract of Eye) (ICD10: H44.139), Plaque Psoriasis (ICD10: L40.0), Hidradenitis Suppurativa (ICD10: L73.2), Polyarticular Juvenile Idiopathic Arthritis (ICD10: M08.09)

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

**Required Medical Information:** 1) Diagnosis: A) For rheumatoid arthritis (RA): Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active RA. B) For polyarticular juvenile idiopathic arthritis (PJIA): Reducing signs and symptoms of moderately to severely active polyarticular JIA. C) For psoriatic arthritis (PsA): Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with active PsA. D) For ankylosing spondylitis (AS): Reducing signs and symptoms in patients with active AS. E) For Crohn's disease (CD): Treatment of moderately to severely active CD. F) For ulcerative colitis (UC): Treatment of moderately to severely active UC. G) For plaque psoriasis (PsO): Treatment of patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. H) For hidradenitis suppurativa (HS): Treatment of moderate to severe HS. I) For uveitis (UV): Treatment of non-infectious intermediate, posterior, and panuveitis. 2) Document: A) For RA: Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, hydroxychloroquine, leflunomide). B) For PJIA: Therapeutic failure to methotrexate. C) For PsA: Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine). D) For AS: Therapeutic failure to at least one nonsteroidal anti-inflammatory drug (NSAID) (e.g., celecoxib, naproxen, sulindac, etc.). E) For CD: Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, prednisone, mercaptopurine,

mesalamine, methotrexate, etc.). F) For UC: Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, hydrocortisone, mercaptopurine, mesalamine, sulfasalazine, etc.). G) For PsO: i) At least 3% BSA is affected or crucial body areas such as the hands, feet, face, scalp or genitals, and ii) Prior use of at least one conventional drug (e.g., acitretin, cyclosporine, hydroxyurea, methotrexate, triamcinolone, etc.). H) For HS and UV: No additional medical information is required. I) For all indications: i) Prior use of preferred biosimilars (Amjevita and Hadlima) and ii) Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

**Age Restrictions:** 1) For RA, PsA, AS and PsO: 18 years of age or older. 2) For PJIA: 2 years of age or older. 3) For CD: 6 years of age or older. 4) For UC: 5 years of age or older. 5) For HS: 12 years of age or older. 6) For uveitis: 2 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## **IBANDRONATE**

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**Affected Drugs:**

Boniva

Ibandronate Sodium

**Covered Uses:** All FDA-approved indications not otherwise excluded: Osteoporosis (M81)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) postmenopausal women with osteoporosis

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## IBRANCE

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### Affected Drugs:

Ibrance

**Covered Uses:** All FDA-approved indications not otherwise excluded: All approved FDA indication not otherwise excluded: Hormone Receptor-Positive, HER2 Negative Breast Cancer (ICD10: C50, C50.0, C50.01, C50.011, C50.012, C50.019, C50.02, C50.021, C50.022, C50.029, C50.1, C50.11, C50.111, C50.112, C50.119, C50.12, C50.121, C50.122, C50.129, C50.2, C50.21, C50.211, C50.212, C50.219, C50.22, C50.221, C50.222, C50.229, C50.3, C50.31, C50.311, C50.312, C50.319, C50.32, C50.321, C50.322, C50.329, C50.4, C50.41, C50.411, C50.412, C50.419, C50.42, C50.421, C50.422, C50.429, C50.5, C50.51, C50.511, C50.512, C50.519, C50.52, C50.521, C50.522, C50.529, C50.6, C50.61, C50.611, C50.612, C50.619, C50.62, C50.621, C50.622, C50.629, C50.8, C50.81, C50.811, C50.812, C50.819, C50.82, C50.821, C50.822, C50.829, C50.9, C50.91, C50.911, C50.912, C50.919, C50.92, C50.921, C50.922, C50.929)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative advanced or metastatic breast cancer, B) Endocrine-resistant, PIK3CA-mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test. 2) Document: A) For advanced or metastatic breast cancer HR positive, HER2 negative: i) Used in combination with an aromatase inhibitor (i.e. letrozole, exemestane, anastrozole) or fulvestrant, ii) If used in combination with fulvestrant, document disease progression following endocrine therapy. B) For Endocrine-resistant, PIK3CA-mutated, HR-positive, HER2-negative breast cancer: i) Used in combination with inavolisib and fulvestrant, ii) therapy is used following recurrence on or after completing adjuvant endocrine therapy, iii) Mutation in PIK3CA gene.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## ICLUSIG

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**Affected Drugs:**

Iclusig

**Covered Uses:** All FDA-approved indications not otherwise excluded: Chronic Myelocytic Leukemia (ICD10: C92.10), Philadelphia Chromosome + Acute Lymphocytic Leukemia (ICD10: C91.0, C91.00)

**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, d. chronic phase (CP) chronic myeloid leukemia (CML) OR e. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL), 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 OR c. disease is newly diagnosed and will be given in combination with chemotherapy, 6) For CP-CML document the following: resistance or intolerance to at least two prior kinase inhibitors.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## IMATINIB

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### Affected Drugs:

Gleevec  
Imatinib Mesylate

**Covered Uses:** All FDA-approved indications not otherwise excluded: Systemic Mastocytosis (ICD10: D47.02, D89.40), Myeloproliferative Neoplasm (ICD10: D47, D47.9, D47.Z9), Myelodysplastic Syndrome (ICD10: D46, D46.9), Hypereosinophilia Syndrome (ICD10: D72.1), Gastrointestinal Stromal Tumor (ICD10: C49.4, C49.A, C49.A0), Philadelphia Chromosome + Chronic Myelocytic Leukemia (ICD10: C92.1, C92.10), Philadelphia Chromosome + Acute Lymphocytic Leukemia (ICD10: C91.0, C91.00), Dermatofibrosarcoma Protuberans (ICD10: C44.09, C44.19, C44.199, C44.1991, C44.1992, C44.599, C44.69, C44.99)

**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 previously treated Ph+CML document: failure to interferon-alpha therapy, 3) For adults with Ph+ALL document: disease relapse, 4) For pediatric Ph+ALL document: a. newly diagnosed AND b. prescribed in combination with chemotherapy, 5) For DFSP document: disease is unresectable, recurrent and/or metastatic, 6) 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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## IMBRUVICA

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### **Affected Drugs:**

Imbruvica

**Covered Uses:** All FDA-approved indications not otherwise excluded: Chronic Lymphocytic Leukemia (ICD10: C91.1), Graft Versus Host Disease (ICD10: D89.81, D89.813), Waldenstrom Macroglobulinemia (ICD10: C88.0), Small Lymphocytic Lymphoma (ICD10: C85.8, C85.80)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a. chronic lymphocytic leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) with or without 17p deletion, b. Waldenstrom's macroglobulinemia (WM), OR c. chronic graft versus host disease (cGVHD). 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 and older, For cGVHD: 1 year of age and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## IMCIVREE

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**Affected Drugs:**

Imcivree

**Covered Uses:** All FDA-approved indications not otherwise excluded: Obesity (ICD10: E66.8, E66.9)

**Exclusion Criteria:** 1) Obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign. 2) Other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity.

**Required Medical Information:** 1) Diagnosis: For chronic weight management (obesity) due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency or Obesity due to Bardet Biedl Syndrome. 2) Document: A) For first prescription: i) Genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) and ii) Patient's actual body weight and body mass index (BMI). B) For renewals: Patient lost at least 5% of baseline body weight or BMI.

**Age Restrictions:** 1) 2 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** For FEHB renewals: Validate patients are currently enrolled in obesity management program.

## INCRELEX

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**Affected Drugs:**

Increlex

**Covered Uses:** All FDA-approved indications not otherwise excluded: Growth Failure (R62.52)

**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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## **INJECTABLE MULTIPLE SCLEROSIS**

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### **Affected Drugs:**

Avonex Pen  
Avonex Prefilled  
Betaseron  
Copaxone  
Glatiramer Acetate  
Plegridy  
Plegridy Starter Pack

**Covered Uses:** All approved FDA indication not otherwise excluded: Relapsing, Remitting Multiple Sclerosis (ICD10: G35), Secondary Progressive Multiple Sclerosis (ICD10: G35), Clinically Isolated Syndrome (First Clinical Episode Suggestive of Multiple Sclerosis) (ICD10: G37.8)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Relapsing Forms of Multiple Sclerosis (MS), to Include Clinically Isolated Syndrome, Relapsing-Remitting Disease, and Active Secondary Progressive Disease. 2) Patients must have documented previous use and therapeutic failure, intolerance or contraindication to at least one generic therapeutic alternative (e.g., dimethyl fumarate, fingolimod, glatiramer acetate).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## INLYTA

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**Affected Drugs:**

Inlyta

**Covered Uses:** All FDA-approved indications not otherwise excluded: Advanced Renal Cell Carcinoma (ICD10: C64, C64.9)

**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 (e.g., pazopanib, sorafenib, sunitinib, interferon alpha, interleukin-2, etc.).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## INTELENCE

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**Affected Drugs:**

Etravirine  
Intelligence

**Covered Uses:** All FDA-approved indications not otherwise excluded: Human Immunodeficiency Virus Disease (B20)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Documentation of viral strains resistant to an NNRTI (non-nucleoside reverse transcriptase inhibitors) and other antiretroviral agents

**Age Restrictions:** 6 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## INTRON A

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### **Affected Drugs:**

Intron A

**Covered Uses:** All FDA-approved indications not otherwise excluded: Malignant Melanoma (C43, C43.9), Kaposi Sarcoma (C46, C46.9), Hairy Cell Leukemia (C91.41), Follicular Lymphoma (C82.9), Condylomata Acuminata (A63.0), Chronic Hepatitis C (B18.2).

**Exclusion Criteria:** 1) Autoimmune hepatitis, 2) Decompensated liver disease

**Required Medical Information:** 1) Diagnosis: a) Hairy Cell Leukemia, b) Malignant Melanoma, c) Follicular Lymphoma, d) Condylomata Acuminata, e) AIDS-Related Kaposi Sarcoma, or f) Chronic Hepatitis C, 2) For Follicular Lymphoma document: a) Concurrent use with anthracycline-containing regimen (i.e. doxorubicin, epirubicin, etc).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Validate if injectable chemotherapies are covered under the Pharmacy benefit. Normally these treatments are not covered under the Pharmacy benefit, validate coverage. 2) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## JAKAFI

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### **Affected Drugs:**

Jakafi

**Covered Uses:** All FDA-approved indications not otherwise excluded: Polycythemia Vera (ICD10: D45), Graft Versus Host Disease (Bone Marrow Transplant Attacking Host's Tissue) (ICD10: D89.81, D89.813), Myelofibrosis (ICD10: D75.81)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of intermediate or high-risk myelofibrosis (MF), including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis. B) Treatment of polycythemia vera (PV). C) Treatment of steroid-refractory acute graft-versus-host disease (GVHD). D) Treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy. 2) 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  $100 \times 10^9/L$  (document CBC test results), 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). 3) Document if the patient has polycythemia vera (PV): Patient had an inadequate response to or is intolerant to hydroxyurea. 4) Document if patient has steroid-refractory acute graft-versus-host disease (GVHD). 5) For cGVHD: document failure of one or more lines of systemic therapy [e.g., prednisone, methotrexate, cyclosporine, tacrolimus, mycophenolate, Imbruvica (ibrutinib), etc.].

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 1) For MF: Initial: 6 months, renewals: 12 months, 2) For PV and GVHD: 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## JESDUVROQ

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### **Affected Drugs:**

Jesduvroq

**Covered Uses:** All FDA-approved indications not otherwise excluded: Anemia in Chronic Kidney Disease (Anemia in Chronic Kidney Disease) (ICD-10: D63.1, D63.8)

**Exclusion Criteria:** A) Concomitant use with CYP2C8 inhibitors (Gemfibrozil) or B) Patients with uncontrolled hypertension.

**Required Medical Information:** 1) Diagnosis: Anemia in Chronic Kidney Disease (CKD) 2) Documentation of: A) Receiving hemodialysis (HD) or peritoneal dialysis (PD) for at least 4 months, B) Hemoglobin levels are less than 11 g/dL within no more than 4 weeks, C) Failure, intolerance or contraindication of at least 1 or more Erythropoietin Stimulating Agent (ESA) AND D) Ferritin levels greater than 100 mcg/mL and Transferrin saturation greater than 20% measured within no more than 4 weeks OR D) Supplemental iron therapy is prescribed concomitantly if Ferritin levels are less than 100 mcg/mL and Transferrin saturation is less than 20%. For renewals, documentation of: A) Increase in hemoglobin levels from baseline (but less than 12 g/dL).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 6 months

**Other Criteria:** Based on the prescribing information for Jesduvroq, do not continue beyond 24 weeks of therapy if a clinically meaningful increase in Hb level is not achieved. Not indicated for treatment of anemia of chronic kidney disease in patients who are not on dialysis. Therapy should be discontinued if hemoglobin levels are greater than 12 g/dL.

## KESIMPTA

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**Affected Drugs:**

Kesimpta

**Covered Uses:** All FDA-approved indications not otherwise excluded: Relapsing, Remitting Multiple Sclerosis (ICD10: G35), Secondary Progressive Multiple Sclerosis (ICD10: G35), Clinically Isolated Syndrome (First Clinical Episode Suggestive of Multiple Sclerosis) (ICD10: G37.8)

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

**Required Medical Information:** 1) Diagnosis: Treatment of Relapsing Forms of Multiple Sclerosis (MS), to Include 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]. 3) Patients must have documented previous use and therapeutic failure, intolerance or contraindication to at least one generic therapeutic alternative (e.g., dimethyl fumarate, fingolimod, glatiramer acetate).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## KEVZARA

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### **Affected Drugs:**

Kevzara

**Covered Uses:** All FDA-approved indications not otherwise excluded: Rheumatoid Arthritis (ICD10: M06, M06.9), Polymyalgia Rheumatica (Polymyalgia Rheumatica) (ICD-10: M35.3), Polyarticular Juvenile Idiopathic Arthritis (ICD10: M08.09)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of moderately to severely active rheumatoid arthritis (RA) in patients who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs), B) Treatment of polymyalgia rheumatica (PMR) in patients who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper or C) Treatment of active polyarticular juvenile idiopathic arthritis (PJIA). 2) Document: A) For RA a) Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, hydroxychloroquine, leflunomide), b) Prior use of at least two formulary preferred drugs (e.g., Avsola, Enbrel, Humira, Orencia, Renflexis, Rinvoq, Xeljanz, if available), B) For PMR: failure to therapy with corticosteroids or intolerance to corticosteroid taper (at least one PMR flare while attempting taper) C) For PJIA: i) Therapeutic failure to methotrexate, ii) Prior use of Enbrel and Humira or preferred biosimilars (i.e Hadlima, adalimumab-adaz), and iii) patients actual body weight and D) Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

**Age Restrictions:** 1) For PJIA: adults and pediatric patients weighing 63 kg or more, 2) For RA and PMR: 18 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## KISQALI

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### Affected Drugs:

Kisqali (200 MG Dose)	Kisqali (400 MG Dose)
Kisqali (600 MG Dose)	Kisqali Femara (200 MG Dose)
Kisqali Femara (400 MG Dose)	Kisqali Femara (600 MG Dose)

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hormone Receptor-Positive, HER2 Negative Breast Cancer (C50, C50.0, C50.01, C50.011, C50.012, C50.019, C50.02, C50.021, C50.022, C50.029, C50.1, C50.11, C50.111, C50.112, C50.119, C50.12, C50.121, C50.122, C50.129, C50.2, C50.21, C50.211, C50.212, C50.219, C50.22, C50.221, C50.222, C50.229, C50.3, C50.31, C50.311, C50.312, C50.319, C50.32, C50.321, C50.322, C50.329, C50.4, C50.41, C50.411, C50.412, C50.419, C50.42, C50.421, C50.422, C50.429, C50.5, C50.51, C50.511, C50.512, C50.519, C50.52, C50.521, C50.522, C50.529, C50.6, C50.61, C50.611, C50.612, C50.619, C50.62, C50.621, C50.622, C50.629, C50.8, C50.81, C50.811, C50.812, C50.819, C50.82, C50.821, C50.822, C50.829, C50.9, C50.91, C50.911, C50.912, C50.919, C50.92, C50.921, C50.922, C50.929)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: i) advanced or metastatic breast cancer or ii) stage II and III early breast cancer at high risk of recurrence, 2) For advanced or metastatic breast cancer: If used in combination with an aromatase inhibitors (e.g., anastrozole, exemestane, letrozole), document: a) used as initial endocrine based therapy, or If used in combination with fulvestrant, document: a) used as initial endocrine based therapy or with disease progression following endocrine therapy, 3) For stage II and III early breast cancer at high risk of recurrence document: used in combination with an aromatase inhibitors (e.g., anastrozole, exemestane, letrozole) as adjuvant treatment, 4) For all indications document: Bio-markers test results evidencing: a) Human epidermal growth factor receptor 2 (HER2)-negative, b) Positive hormone receptor (HR), AND 5) Only for advanced or metastatic breast cancer: Document intolerance or contraindication to least one of the following: a) Ibrance or b) Verzenio .

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## KORLYM

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**Affected Drugs:**

Korlym  
miFEPRIStone

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hyperglycemia (R73, R73.9)

**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 surgery or are not candidates for surgery, 2) Negative pregnancy affirmation

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## KOSELUGO

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**Affected Drugs:**

Koselugo

**Covered Uses:** All FDA-approved indications not otherwise excluded: Neurofibromatosis Type I (ICD10: Q85.0, Q85.00, Q85.01)

**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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) The recommended dosage is 25 mg/m<sup>2</sup>. 2) Do not administer to patients who are unable to swallow a whole capsule (cannot be chewed, dissolved nor open). 3) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## KUVAN

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**Affected Drugs:**

Kuvan

Sapropterin Dihydrochloride

**Covered Uses:** All FDA-approved indications not otherwise excluded: Phenylketonuria (E70.1)

**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:** N/A

**Coverage Duration:** Initial: 3 months, renewals: 12 months

**Other Criteria:** N/A

## KYNMOBI

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**Affected Drugs:**

Kynmobi

Kynmobi Titration Kit

**Covered Uses:** All FDA-approved indications not otherwise excluded: Parkinson's Disease (ICD10: G20)

**Exclusion Criteria:** Concomitant use of 5HT3 antagonists (e.g., alosetron, dolasetron, granisetron, ondansetron, palonosetron, etc.)

**Required Medical Information:** 1) Diagnosis: Acute, intermittent treatment of "off" episodes in patients with Parkinson's disease. 2) Document: Current Parkinson's disease treatment (e.g., carbidopa/levodopa, entacapone, etc.)

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## LETAIRIS

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**Affected Drugs:**

Ambrisentan  
Letairis

**Covered Uses:** All FDA-approved indications not otherwise excluded: Pulmonary Arterial Hypertension (I27.0)

**Exclusion Criteria:** 1) Pregnancy, 2) Idiopathic Pulmonary Fibrosis

**Required Medical Information:** 1) Diagnosis of Pulmonary Arterial Hypertension, WHO Group 1.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## LIDOCAINE PATCH

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**Affected Drugs:**

Lidocaine  
Lidoderm

**Covered Uses:** All approved FDA indication not otherwise excluded Postherpetic Neuralgia (B02.20), Allodynia (R44.8)

**Exclusion Criteria:** N/A

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

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## LINZESS

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**Affected Drugs:**

Linzess

**Covered Uses:** All FDA-approved indications not otherwise excluded: Constipation associated with Irritable Bowel Syndrome (ICD10: K58, K58.1, K58.9, K59.0, K59.00), Chronic Idiopathic Constipation (ICD10: K59.0, K59.00, K59.04)

**Exclusion Criteria:** 1) Known or suspected mechanical gastrointestinal obstruction

**Required Medical Information:** 1) Diagnosis: A. irritable bowel syndrome with constipation, B. chronic idiopathic constipation or C. Functional Constipation (FC) in pediatric patients

**Age Restrictions:** IBS or CIC: 18 years of age or older, FC: 6 to 17 years of age

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Chronic Idiopathic Constipation: 145 mcg capsules and 72mcg capsules, 2) irritable bowel syndrome: predominant constipation: 290mcg capsules, 3) Functional Constipation: 72 mcg capsules

## LONSURF

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**Affected Drugs:**

Lonsurf

**Covered Uses:** All approved FDA indication not otherwise excluded: Malignant Neoplasm of Colon (Cancer of the Colon) (ICD10: C18, C18.9), Malignant Neoplasm of Rectum (Cancer of the Rectum) (ICD10: C20, C21.8), Adenocarcinoma of the Stomach (ICD10: C16, C16.9), Gastro-Esophageal Junction Adenocarcinoma (Stomach-Esophagus Junction Cancer) (ICD10: C16.0)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) For metastatic colorectal cancer: A) 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 AND B) Prescribed as a single agent or in combination with bevacizumab 2) 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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## LUPRON DEPOT PED

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**Affected Drugs:**

Lupron Depot-Ped (1-Month)

Lupron Depot-Ped (3-Month)

Lupron Depot-Ped (6-Month)

**Covered Uses:** All FDA-approved indications not otherwise excluded: Central Precocious Puberty (ICD10: E22.8)

**Exclusion Criteria:** Pregnancy

**Required Medical Information:** 1) Diagnosis: Treatment of central precocious puberty. 2) Document: A) For all patients: actual body weight (weight-based dosing).

**Age Restrictions:** Pediatric patients 1 year of age or older until appropriate time point for the onset of puberty (12 years for males and 11 years for females).

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate if treatments that need to be administered by a healthcare professional are covered under the Pharmacy benefit. Normally these treatments are not covered under the Pharmacy benefit, validate coverage.

## LUPRON DEPOT/LEUPROLIDE

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**Affected Drugs:**

Lupron Depot (1-Month)

Lupron Depot (3-Month)

Lupron Depot (4-Month)

Lupron Depot (6-Month)

**Covered Uses:** All FDA-approved indications not otherwise excluded: Malignant Neoplasm of Prostate (Cancer of the Prostate Gland) (ICD10: C61, N42.30)

**Exclusion Criteria:** N/A

**Required Medical Information:**1) Diagnosis: Treatment of advanced prostatic cancer.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## LUPRON ENDO

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### **Affected Drugs:**

Lupron Depot (1-Month)

Lupron Depot (3-Month)

**Covered Uses:** All FDA-approved indications not otherwise excluded: Uterine Fibroids (D25, D25.9), Endometriosis (N80, N80.9)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Endometriosis or B) Uterine leiomyomata (fibroids). 2) Document: A) For endometriosis including pain relief and reduction of endometriotic lesions: No additional information is required. B) For initial management of the painful symptoms of endometriosis and for the management of recurrence of symptoms: Prescribed in combination with norethindrone acetate. C) For preoperative hematologic improvement of women with anemia caused by fibroids (uterine leiomyomata): Document concomitant use of iron therapy.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 1) For endometriosis initial and recurrent treatment: 6 months. 2) For uterine leiomyomata initial and recurrent treatment: 3 months

**Other Criteria:** N/A

## LYNPARZA

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### Affected Drugs:

Lynparza

**Covered Uses:** All FDA-approved indications not otherwise excluded: Malignant Neoplasm of Ovary (Cancer of the Ovary) (ICD10: C56, C56.2, C56.9), Hormone-Refractory Malignant Neoplasm of Prostate (Cancer of the Prostate Gland that is Resistant to Hormones) (ICD10: C61), Pancreatic Adenocarcinoma (ICD10: C25, C25.9), HER2-Negative Breast Cancer (ICD10: C50), Malignant Neoplasm of Fallopian Tube (Fallopian Tube Cancer) (ICD10: C57.0, C57.00), Malignant Neoplasm of Peritoneum (Cancer within the Abdominal Cavity) (ICD10: C48, C48.2, C48.8)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of advanced or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. B) Treatment of breast cancer. C) Treatment of pancreatic cancer. Or D) Treatment of prostate cancer. 2) For ovarian cancer document: A) Prescribed for the maintenance treatment of patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin). B) Prescribed in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability. C) Prescribed for the maintenance treatment of patients with deleterious or suspected deleterious germline or somatic BRCA-mutated recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin). 3) For breast cancer document: A) Prescribed for the adjuvant treatment of patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Or B) Prescribed for the treatment of patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. 4) For pancreatic cancer document: Prescribed for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. 5) For prostate cancer document: Prescribed for the treatment of patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC)

who have progressed following prior treatment with enzalutamide or abiraterone OR deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) and Lynparza is prescribed in combination with abiraterone and prednisone or prednisolone

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## MAVENCLAD

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### **Affected Drugs:**

Mavenclad (10 Tabs)  
Mavenclad (4 Tabs)  
Mavenclad (5 Tabs)  
Mavenclad (6 Tabs)  
Mavenclad (7 Tabs)  
Mavenclad (8 Tabs)  
Mavenclad (9 Tabs)

**Covered Uses:** All FDA-approved indications not otherwise excluded: Multiple Sclerosis (G35)

**Exclusion Criteria:** 1) Patients with current malignancy 2) Pregnant women and women/men of reproductive potential who do not plan to use effective contraception, 3) HIV infection, 4) Active chronic infections (e.g., hepatitis or tuberculosis), and 5) Women intending to breastfeed during treatment or for ten days after the last dose

**Required Medical Information:** 1) Diagnosis: Treatment of Relapsing Forms of Multiple Sclerosis (MS), to Include Clinically Isolated Syndrome, Relapsing-Remitting Disease, and Active Secondary Progressive Disease. 2) Document: A) HIV, tuberculosis, Hepatitis B and Hepatitis C test results (all must be negative), and B) Patient's actual body weight (weight-based dosing). 3) Patients must have documented previous use and therapeutic failure, intolerance or contraindication to at least one generic therapeutic alternative (e.g., dimethyl fumarate, fingolimod, glatiramer acetate).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Its use is not recommended for use in patients with clinically isolated syndrome (CIS).

## MAVYRET

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### **Affected Drugs:**

Mavyret

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hepatitis C, Genotype 1 (B17.1, B17.10, B18.2, B19.2), Hepatitis C, Genotype 2 (B17.1, B17.10, B18.2), Hepatitis C, Genotype 3 (B17.1, B17.10, B18.2), Hepatitis C, Genotype 4 (B17.1, B17.10, B18.2), Hepatitis C, Genotype 5 (B17.1, B18.2, B19), Hepatitis C, Genotype 6 (B17.1, B18.2, B19)

**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) If patient is cirrhotic then document liver's compensated or decompensated status, 4) Document liver transplant status. 5) Document quantitative HCV RNA viral load. 6) Indicate if patient is naive or experienced (i.e. prior use status of Peg-IFN, Ribavirin, HCV Protease or Polymerase inhibitors).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 weeks – Refer to Other Criteria

**Other Criteria:** Duration according to the clinical scenario assessed by the pharmacist in full compliance with the updated HCV guidelines recommendations at the time.

## MAYZENT

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### **Affected Drugs:**

Mayzent

Mayzent Starter Pack

**Covered Uses:** All FDA-approved indications not otherwise excluded: Relapsing, Remitting Multiple Sclerosis (ICD10: G35), Secondary Progressive Multiple Sclerosis (ICD10: G35), Clinically Isolated Syndrome (First Clinical Episode Suggestive of Multiple Sclerosis) (ICD10: G37.8)

**Exclusion Criteria:** 1) Patients with a CYP2C9\*3/\*3 genotype, 2) In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure, and 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: Treatment of Relapsing Forms of Multiple Sclerosis (MS), to Include Clinically Isolated Syndrome, Relapsing-Remitting Disease, and Active Secondary Progressive Disease. 2) Document (only for first prescription): A) Patient has been tested for CYP2C9 variants to determine genotype, and B) Electrocardiogram (ECG) result (to determine preexisting conduction abnormalities, see Other Criteria). 3) Patients must have documented previous use and therapeutic failure, intolerance or contraindication to at least one generic therapeutic alternative (e.g., dimethyl fumarate, fingolimod, glatiramer acetate).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) If ECG result is not available, the physician needs to provide a statement indicating that the patient has been evaluated for cardiovascular risk and does not have preexisting conduction abnormalities nor meet exclusion criteria. 2) Validate package insert for additional dosage information.

## MEKINIST

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### Affected Drugs:

Mekinist

**Covered Uses:** All FDA-approved indications not otherwise excluded: Malignant Neoplasm of Thyroid (ICD10: C73, C75.9), Malignant Melanoma (C43, C43.9), Non-Small-Cell Lung Carcinoma (ICD10: C34, C34.9, C34.90), Malignant Solid Tumor (Cancerous Solid Tumor), Malignant Glioma of Brain (Malignant Glioma of Brain) (ICD10: C71, C71.9, C72.9)

**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) e. unresectable metastatic solid tumors OR f. low-grade glioma (LGG) 2) For melanoma with involvement of lymph node(s), document the following: a) positive results for BRAF V600E or V600K mutations as detected by an FDA-approved test, 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 as detected by an FDA-approved test, 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 as detected by an FDA-approved test 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 as detected by an FDA-approved test, b) no satisfactory locoregional treatment option, AND c) must be used in combination with dabrafenib, 6) For unresectable or metastatic solid tumors: a. positive results for BRAF V600E mutation, b. patient has progressed following prior treatment or has no alternative treatment options, AND c. must be used in combination with dabrafenib. 7) For low grade glioma: a. positive results for BRAF V600E mutation, b. prescribed in combination with dabrafenib, 8) For pediatric patients: Actual Body Weight (weight-based dosing)

**Age Restrictions:** 1) For low grade glioma (LGG) and unresectable or metastatic solid tumors: 1 year of age and older, 2) For all other indications: 18 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## MEKTOVI

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**Affected Drugs:**

Mektovi

**Covered Uses:** All FDA-approved indications not otherwise excluded: Malignant Melanoma (C43, C43.9), Non-Small-Cell Lung Carcinoma (Non-Small-Cell Lung Cancer) (ICD-10: C34, C34.9, C34.90)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Unresectable or metastatic melanoma or b) metastatic non-small cell lung cancer (NSCLC), 2) For melanoma: a) Positive BRAF V600E or V600K mutation test, b) prescribed in combination with encorafenib, 3) For NSCLC: a) BRAF V600E mutation test, b) prescribed in combination with encorafenib

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## MEPSEVII

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**Affected Drugs:**

Mepsevii

**Covered Uses:** All FDA-approved indications not otherwise excluded: Mucopolysaccharidosis Type VII (E76.29)

**Exclusion Criteria:** N/A

**Required Medical Information:**1) Diagnosis: Mucopolysaccharidosis VII (MPS VII, Sly syndrome).

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## MODAFINIL

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**Affected Drugs:**

Modafinil  
Provigil

**Covered Uses:** All FDA-approved indications not otherwise excluded: Improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy (G47.4, G47.41), Obstructive Sleep Apnea (G47.33), Shift Work Disorder (G47.26)

**Exclusion Criteria:** 1) Patients with known hypersensitivity to modafinil or armodafinil.

**Required Medical Information:** 1) Diagnosis: a) Narcolepsy, b) Obstructive Sleep Apnea, OR c) Shift Work Disorder.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## MYTESI

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**Affected Drugs:**

Mytesi

**Covered Uses:** All FDA-approved indications not otherwise excluded: Human Immunodeficiency Virus Enteropathy (B20, K52.9)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: non-infectious diarrhea, 2) Document the following: a) HIV/AIDS patients, AND b) patient is currently on anti-retroviral therapy

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Coverage will be provided if at least two (2) anti-diarrheal agents have been tried

## NEXAVAR

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**Affected Drugs:**

NexAVAR

SORafenib Tosylate

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hepatic Carcinoma (Liver Carcinoma) (ICD10: C22, C22.0, C22.8, C22.9), Endometrial Carcinoma (ICD10: C54.1), Renal Cell Carcinoma (Kidney Cell Carcinoma) (ICD10: C64, C64.1, C64.2, C64.9), Differentiated Thyroid Carcinoma (ICD10: C73)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of Differentiated Thyroid Cancer (DTC), B) Treatment of Renal Cell Cancer (RCC), C) Treatment of Hepatocellular Carcinoma (HCC), or D) Treatment of Advanced Endometrial Carcinoma. 2) Document: A) For DTC: Tumor is locally recurrent or metastatic, progressive, failure or unresponsive to radioactive iodine treatment. B) For RCC: i) Patient has advanced RCC, used one prior-angiogenic therapy (e.g., Sutent, Torisel, Inlyta, Nexavar, Votrient or Avastin plus Interferon), and prescribed in combination with everolimus, or ii) Prescribed in combination with pembrolizumab for the first line treatment of advanced RCC. C) For HCC: Disease is unresectable. D) For advanced endometrial carcinoma: i) Prescribed in combination with pembrolizumab, ii) Disease is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), and iii) Patient has disease progression following prior systemic therapy and not a candidate for curative surgery or radiation.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## NILUTAMIDE

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**Affected Drugs:**

Nilandron  
Nilutamide

**Covered Uses:** All FDA-approved indications not otherwise excluded: Malignant Neoplasm of Prostate (Cancer of the Prostate Gland) (ICD10: C61, N42.30)

**Exclusion Criteria:**1) Severe hepatic impairment. 2) Severe respiratory insufficiency

**Required Medical Information:**1) Diagnosis: Treatment of metastatic prostate cancer. 2) Document: A) Prescribed in combination with surgical castration, and B) Liver function test results.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## NINLARO

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**Affected Drugs:**

Ninlaro

**Covered Uses:** All FDA-approved indications not otherwise excluded: Multiple Myeloma (C90.0, C90.00)

**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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Indicated on days 1, 8, and 15 of a 28-day cycle. 2) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## **NITYR/ORFADIN**

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**Affected Drugs:**

Nitisinone  
Nityr  
Orfadin

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hereditary Tyrosinemia Type I (E70.21).

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Hereditary tyrosinemia type 1

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## NURTEC

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**Affected Drugs:**

Nurtec

**Covered Uses:** All FDA-approved indications not otherwise excluded: Migraine (Migraine Headache) (ICD10: G43, G43.9)

**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: i) Therapeutic failure, contraindication or intolerance to at least two triptans (e.g., eletriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan, etc.), and ii) Number of migraine episodes in the last 30 days. B) For preventive treatment: i) Therapeutic failure, contraindication or intolerance to at least two preventive treatments (e.g., divalproex, propranolol, topiramate, etc.), and ii) Patient is suffering four or more migraine days per month

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## OCREVUS

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**Affected Drugs:**

Ocrevus

**Covered Uses:** All FDA-approved indications not otherwise excluded: Relapsing, Remitting Multiple Sclerosis (ICD10: G35), Secondary Progressive Multiple Sclerosis (ICD10: G35), Clinically Isolated Syndrome (First Clinical Episode Suggestive of Multiple Sclerosis) (ICD10: G37.8)

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

**Required Medical Information:** 1) Diagnosis: A) Treatment of Relapsing Forms of Multiple Sclerosis (MS), to Include Clinically Isolated Syndrome, Relapse-Remitting Disease and Active Secondary Progressive Disease, or B) Treatment of Primary Progressive MS. 2) Document: (for first prescription only): Hepatitis B test result (must be negative). 3) Patients must have documented previous use and therapeutic failure, intolerance or contraindication to at least one generic therapeutic alternative (e.g., dimethyl fumarate, fingolimod, glatiramer acetate).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## OCREVUS ZUNOVO

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**Affected Drugs:**

Ocrevus Zunovo

**Covered Uses:** All FDA-approved indications not otherwise excluded: Relapsing, Remitting Multiple Sclerosis (ICD10: G35), Secondary Progressive Multiple Sclerosis (ICD10: G35), Clinically Isolated Syndrome (First Clinical Episode Suggestive of Multiple Sclerosis) (ICD10: G37.8)

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

**Required Medical Information:** 1) Diagnosis: A) Treatment of Relapsing Forms of Multiple Sclerosis (MS), to Include Clinically Isolated Syndrome, Relapse-Remitting Disease and Active Secondary Progressive Disease, or B) Treatment of Primary Progressive MS. 2) Document: (for first prescription only): Hepatitis B test result (must be negative).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## OCTREOTIDE/SANDOSTATIN

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**Affected Drugs:**

Octreotide Acetate

SandoSTATIN

**Covered Uses:** All FDA-approved indications not otherwise excluded: Diarrhea (R19.7), Flushing of Face and/or Neck (R23.2), Acromegaly (E22.0)

**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:** 12 months

**Other Criteria:** N/A

## OFEV

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**Affected Drugs:**

Ofev

**Covered Uses:** All approved FDA indication not otherwise excluded: Pulmonary Interstitial Fibrosis (J84.112), Systemic Sclerosis-Associated Interstitial Lung Disease (ICD10: J84.1, J84.9, M34.81)

**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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## OLUMIANT

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**Affected Drugs:**

Olumiant

**Covered Uses:** All FDA-approved indications not otherwise excluded: Rheumatoid Arthritis (ICD10: M06, M06.9), Alopecia Areata (ICD10: L63)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of moderately to severely active rheumatoid arthritis (RA) in patients who have had an inadequate response to one or more TNF antagonist therapies, B) Treatment of alopecia areata 2) For RA document: A) Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, hydroxychloroquine, leflunomide), B) Prior use of at least two formulary preferred drugs (e.g., Avsola, Enbrel, Humira, Orenzia, Renflexis, Rinvoq, Xeljanz, if available), C) If available, prior use of at least one formulary non-preferred drug (e.g., Kevzara), 3) For Alopecia Areata: A) document disease is severe (Severity of Alopecia Tool (SALT) score of 50 or higher) B) Document prior use of topical and/or intralesional corticosteroids. 4) For all indications (only for biologic therapy-naïve patients): Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 1) For RA and Alopecia Areata: 12 months

**Other Criteria:** Validate if alopecia areata treatments are covered under the pharmacy benefit. Dosages with indication for Alopecia Areata: 2 mg and 4 mg tablets. Olumiant 4 mg tablets are FDA approved for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO. Outpatient use for this indication is not recommended.

## OPIOID PARTIAL AGONISTS

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**Affected Drugs:**

Buprenorphine HCl  
Buprenorphine HCl-Naloxone HCl  
Suboxone  
Zubsolv

**Covered Uses:** All FDA-approved indications not otherwise excluded: Opioid Dependence (F11, F11.2, F11.9, F11.988, F11.99)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document the following: a) opioid dependence AND b) patient is not receiving other opioids written by a different prescriber

**Age Restrictions:** 16 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 6 months

**Other Criteria:** 1) Quantity of up to 120 units/ 30day supply allowed for Suboxone

## OPSUMIT

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**Affected Drugs:**

Opsumit

**Covered Uses:** All FDA-approved indications not otherwise excluded: Pulmonary Arterial Hypertension (ICD10: I27.0)

**Exclusion Criteria:** Pregnancy.

**Required Medical Information:** 1) Diagnosis of Pulmonary Arterial Hypertension, WHO Group 1, 2) Document (for first prescription): a. Cardiac catheterization results

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## ORENCIA

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### **Affected Drugs:**

Orencia  
Orencia ClickJect

**Covered Uses:** All FDA-approved indications not otherwise excluded: Rheumatoid Arthritis (ICD10: M06, M06.9), Juvenile Idiopathic Arthritis (Juvenile Rheumatoid Arthritis) (ICD10: M08.0, M08.00), Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), Graft Versus Host Disease (Bone Marrow Transplant Attacking Host's Tissue) (ICD10: D89.81, D89.813)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of moderately to severely active rheumatoid arthritis (RA), B) Treatment of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA), C) Treatment of active psoriatic arthritis (PsA), or D) Prophylaxis of acute graft versus host disease (aGVHD). 2) Document: A) For RA: Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, hydroxychloroquine, leflunomide). B) For PJIA: Therapeutic failure to methotrexate. C) For PsA: Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine). D) For aGVHD: i) Prescribed in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus, etc.) and methotrexate, and ii) Patients is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor. 3) Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

**Age Restrictions:** 1) For RA: 18 years of age or older. 2) For PJIA, PsA and aGVHD: 2 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## ORLADEYO

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**Affected Drugs:**

Orladeyo

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hereditary Angioedema (ICD10: D84.1)

**Exclusion Criteria:**1) Treatment of acute HAE attacks.

**Required Medical Information:**1) Diagnosis: For prophylaxis to prevent attacks of hereditary angioedema (HAE). 2) Document: A) For the first prescription: i) Low C1-INH (C1 esterase inhibitor) levels (normal levels are 16 mg/dL) or low C4 level (if C1-inh level is normal) [normal C4 levels are 12-72 mg/dL (males) and 13-75 mg/dL (females)], ii) Type of hereditary angioedema (must be Type I or II) and iii) Suffered more than one severe event per month or disabling attacks that lasted more than 5 days per month. B) For renewals: Positive response to treatment (reduction in number of attacks experienced).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:**1) For initial prescription: 3 months, or 2) For renewals: 12 months

**Other Criteria:** N/A

## ORSERDU

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### **Affected Drugs:**

Orserdu

**Covered Uses:** All FDA-approved indications not otherwise excluded: Estrogen Receptor-Positive, HER2 Negative Breast Cancer (Estrogen Receptor-Positive, HER2 Negative Breast Cancer (ICD-10: C50, C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.1, C50.11, C50.111, C50.112, C50.119, C50.12, C50.121, C50.122, C50.129, C50.2, C50.21, C50.211, C50.212, C50.219, C50.22, C50.221, C50.222, C50.229, C50.3, C50.31, C50.311, C50.312, C50.319, C50.32, C50.321, C50.322, C50.329, C50.4, C50.41, C50.411, C50.412, C50.419, C50.42, C50.421, C50.422, C50.429, C50.5, C50.51, C50.511, C50.512, C50.519, C50.52, C50.521, C50.522, C50.529, C50.6, C50.61, C50.611, C50.612, C50.619, C50.62, C50.621, C50.622, C50.629, C50.8, C50.81, C50.811, C50.812, C50.819, C50.82, C50.821, C50.822, C50.829, C50.9, C50.91, C50.911, C50.912, C50.919, C50.92, C50.921, C50.922, C50.929, Z17.0)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: treatment of postmenopausal women or adult men with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy (i.e. letrozole, exemestane, anastrozole, fulvestrant) including a CDK 4/6 inhibitor: Kisqali (ribociclib), Ibrance (palbociclib), Verzenio (abemaciclib) 2) Document biomarker test results evidencing: ER-positive, HER2-negative, ESR1-mutation

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## OTEZLA

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### **Affected Drugs:**

Otezla

**Covered Uses:** All FDA-approved indications not otherwise excluded: Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), Psoriasis (ICD10: L40, L40.9), Oral Ulcers of Behcet's Syndrome (Oral Ulcerations due to Behcet Syndrome) (ICD10: M35.2)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of active psoriatic arthritis (PsA), B) Treatment of plaque psoriasis (PsO) in patients who are candidates for phototherapy or systemic therapy, or C) Treatment of oral ulcers associated with Behcet's Disease. 2) Document: A) For PsA: i) Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine) and ii) Prior use of at least two formulary preferred drugs (e.g., Avsola, Enbrel, Humira, Orencia, Renflexis, Rinvoq, Skyrizi, Stelara, Taltz, Xeljanz, if available). B) For PsO: i) At least 5% BSA is affected or crucial body areas such as the hands, feet, face, or genitals, ii) Prior use of at least one conventional drug (e.g., acitretin, cyclosporine, hydroxyurea, methotrexate, triamcinolone, etc.) and iii) Prior use of at least two formulary preferred drugs (e.g., Avsola, Enbrel, Humira, Renflexis, Skyrizi, Stelara, Taltz, if available). C) For Behcet's Disease: No additional medical information is required.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## PEGASYS/PEGINTRON

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### **Affected Drugs:**

Pegasys

Pegasys ProClick

**Covered Uses:** All approved FDA indication not otherwise excluded: Chronic Hepatitis C (B18.2), Chronic Hepatitis B (B18.1)

**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:** For the first prescription only: 1) Document hepatitis B virus (HBV) diagnosis with one of the following: a) DNA HBV or by PCR, b) hepatitis B (HB)e antigen (Ag) or HBs Ag during more than six months. 2) Document hepatitis C virus (HCV) diagnosis with one of the following: a) HCV genotype, b) HCV RNA levels, c) Liver function tests (ALT levels greater than 2 ULN), d) Complete blood counts (CBC) – baseline. 2) Creatinine Clearance (CRCL).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** For HCV the duration is established according to the clinical scenario assessed by the pharmacist in full compliance with the updated HCV guidelines recommendations at the time.  
2) 48wks for HBV

**Other Criteria:** PEGASYS and ribavirin should be used with caution in patients with baseline neutrophil counts less than 1,500 cells/mm, with baseline platelet counts less than 90,000 cells/mm or baseline hemoglobin less than 10 g/dL. PEGASYS therapy should be discontinued, at least temporarily, in patients who develop severe decreases in neutrophil and/or platelet counts.

## PEMAZYRE

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**Affected Drugs:**

Pemazyre

**Covered Uses:** All FDA-approved indications not otherwise excluded: Cholangiocarcinoma (Cancer of the Bile Duct) (ICD10: C22.1)

**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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Recommended dose is 13.5 mg orally once daily for 14 consecutive days followed by 7 days off therapy in 21-day cycles. 2) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## PLEGRIDY

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**Affected Drugs:**

Plegridy

Plegridy Starter Pack

**Covered Uses:** All FDA-approved indications not otherwise excluded: Relapsing, Remitting Multiple Sclerosis (ICD10: G35), Secondary Progressive Multiple Sclerosis (ICD10: G35), Clinically Isolated Syndrome (First Clinical Episode Suggestive of Multiple Sclerosis) (ICD10: G37.8)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Relapsing Forms of Multiple Sclerosis (MS), to Include Clinically Isolated Syndrome, Relapsing-Remitting Disease, and Active Secondary Progressive Disease. 2) Patients must have documented previous use and therapeutic failure, intolerance or contraindication to at least one generic therapeutic alternative (e.g., dimethyl fumarate, fingolimod, glatiramer acetate).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## PLENITY

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**Affected Drugs:**

Plenity

Plenity Welcome Kit

**Covered Uses:** All FDA-approved indications not otherwise excluded: Exogenous Obesity (ICD10: E66.0, E66.9)

**Exclusion Criteria:** Pregnancy

**Required Medical Information:** 1. Diagnosis: For the management of Obesity in conjunction with diet and exercise. 2. Required Medical Information: Body mass index (BMI) 25-40 kg/m<sup>2</sup> 3) For renewals: At least a 5% reduction from baseline body weight

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 3 months

**Other Criteria:** For FEHB renewals: Validate patient is currently enrolled in obesity management program.

## POMALYST

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**Affected Drugs:**

Pomalyst

**Covered Uses:** All FDA-approved indications not otherwise excluded: Multiple Myeloma (ICD10: C90.0, C90.00), Kaposi's Sarcoma (ICD10: C46, C46.9)

**Exclusion Criteria:** Pregnancy

**Required Medical Information:** 1) Diagnosis: A) Treatment of Multiple Myeloma (MM), or B) Treatment of Kaposi Sarcoma (KS). 2) Document: A) For MM: i) Prescribed in combination with dexamethasone, and ii) Disease progression on or within 60 days of completion of the last treatment with at least 2 therapies including lenalomide and a proteasome inhibitor (e.g., bortezomib). B) For KS: i) Patient is HIV-negative, or ii) Patient has AIDS-related KS and failed highly active antiretroviral therapy (HAART).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Because of its embryo-fetal risk, Pomalyst is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), the "POMALYST REMS" program, and requires prescriber and pharmacy certification and special documentation. 2) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## PROLIA

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### **Affected Drugs:**

Prolia

**Covered Uses:** All FDA-approved indications not otherwise excluded: Osteoporosis (ICD10: M81), Postmenopausal Osteoporosis (ICD10: M81.0), Bone Resorption (Removal or Loss of Bone Tissue) (ICD10: M89.5, M89.50), Glucocorticoid-Induced Osteoporosis (Osteoporosis caused by Glucocorticoid Drugs) (ICD10: M81.8, T38.0X5A, T38.0X5D, T38.0X5S)

**Exclusion Criteria:** 1) Hypocalcemia. 2) Pregnancy.

**Required Medical Information:** 1) Diagnosis: A) Treatment of postmenopausal women with osteoporosis at high risk for fracture, B) Treatment to increase bone mass in men with osteoporosis at high risk for fracture, C) Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture, D) Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer, E) Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. 2) Document: A) Serum calcium levels are within normal limits, and B) Bone density test result (T-score = -2.5 for osteoporosis diagnosis).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) High risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. 2) Validate if treatments that need to be administered by a healthcare professional are covered under the Pharmacy benefit. Normally these treatments are not covered under the Pharmacy benefit, validate coverage.

## PROMACTA

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### **Affected Drugs:**

Eltrombopag Olamine  
Promacta

**Covered Uses:** All FDA-approved indications not otherwise excluded: Aplastic Anemia (ICD10: D61.9), Thrombocytopenia (ICD10: D69.6), Immune Thrombocytopenic Purpura (ICD10: D69.3)

**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 all indications document: Complete blood count (CBC) test result. 3) For chronic ITP document: A) Inadequate response or intolerant to corticosteroids, immunoglobulins, or splenectomy. And B) The patient has low platelet levels counts at baseline (i.e., less than 50,000mm<sup>3</sup>). 4) For thrombocytopenia with chronic hepatitis C document: A) Evidence that the patient is on or will initiate interferon-based therapy. And B) The patient has low platelet levels counts at baseline (i.e., less than 75,000mm<sup>3</sup>). 5) For severe aplastic anemia document: A) Prescribed in combination with standard immunosuppressive therapy for first-line treatment or documented failure to immunosuppressive therapy. And B) The patient has low platelet levels counts at baseline (i.e., less than 30,000mm<sup>3</sup>). 6) For renewals document: A) CBC test result. And B) Patient continues to respond to therapy with this drug (e.g., platelet count has increased).

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## **PROSTAGLANDIN VASODILATORS INJECTABLE**

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**Affected Drugs:**

Epoprostenol Sodium

Flolan

Remodulin

Treprostinil

Veletri

**Covered Uses:** All FDA-approved indications not otherwise excluded: Pulmonary Arterial Hypertension (I27.0)

**Exclusion Criteria:** Patient requires nitrate therapy on a regular or intermittent basis

**Required Medical Information:**1) Diagnosis of Pulmonary Arterial Hypertension, WHO Group 1.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## **PULMOZYME**

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**Affected Drugs:**

Pulmozyme

**Covered Uses:** All FDA-approved indications not otherwise excluded: Cystic Fibrosis (ICD10: E84, E84.9)

**Exclusion Criteria:** N/A

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

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## QSYMIA

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**Affected Drugs:**

Phentermine-Topiramate ER

Qsymia

**Covered Uses:** All FDA-approved indications not otherwise excluded: Obesity (E66, E66.9)

**Exclusion Criteria:** 1) Pregnancy. 2) Glaucoma. 3) Hyperthyroidism. 4) During or within 14 days of taking monoamine oxidase inhibitors.

**Required Medical Information:** 1) Diagnosis: As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management. 2) Document For adults: Body mass index (BMI) greater than or equal to 30 kg/m<sup>2</sup>, or greater than or equal to 27 kg/m<sup>2</sup> in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). 3) For pediatric patients 12 years or age or older document BMI in the 95th percentile or greater standardized for age or sex 3) For renewals: At least a 5% reduction in baseline body weight (actual BMI or weight and height).

**Age Restrictions:** 12 years of age and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 3 months

**Other Criteria:** For FEHB renewals: Validate patient is currently enrolled in obesity management program.

## RANEXA

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**Affected Drugs:**

Ranexa  
Ranolazine ER

**Covered Uses:** All FDA-approved indications not otherwise excluded: Stable Angina Pectoris (ICD10: I20, I20.8, I20.9)

**Exclusion Criteria:** 1) Concurrent use of CYP3A inducers (e.g., rifampin, rifabutin, rifapentine, phenobarbital, phenytoin, and carbamazepine). 2) Concurrent use of strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir, and saquinavir), 3) Hepatic cirrhosis.

**Required Medical Information:** 1) Diagnosis: chronic angina

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## RECLAST

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### **Affected Drugs:**

Reclast  
Zoledronic Acid

**Covered Uses:** All FDA-approved indications not otherwise excluded: Osteoporosis (ICD10: M81), Paget's Disease of Bone (ICD10: M88, M88.9), Postmenopausal Osteoporosis (ICD10: M81.0), Glucocorticoid-Induced Osteoporosis (Osteoporosis caused by Glucocorticoid Drugs) (ICD10: M81.8, T38.0X5A, T38.0X5D, T38.0X5S)

**Exclusion Criteria:** 1) Hypocalcemia. 2) Patients with creatinine clearance less than 35 mL/min and in those with evidence of acute renal impairment.

**Required Medical Information:** 1) Diagnosis: A) Treatment and prevention of postmenopausal osteoporosis. B) Treatment to increase bone mass in men with osteoporosis. C) Treatment and prevention of glucocorticoid-induced osteoporosis. Or D) Treatment of Paget's disease of bone in men and women 2) Document (for all indications): A) Corrected calcium level is within normal limit. And B) Serum creatinine level is within normal limit. 3) For osteoporosis: A) T-score test result (must be -2.5 or lower). B) Therapeutic failure, contraindication, or intolerance to previous osteoporosis therapy. 4) For osteoporosis prevention: A) T-score test result (must be between -1.0 and -2.5). B) Therapeutic failure, contraindication, or intolerance to previous preventive osteoporosis therapy. 5) For Paget's disease: No additional medical information is required.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate if intravenous infusion drugs are covered under the Pharmacy benefit. Normally these drugs are not covered under the Pharmacy benefit, validate coverage.

## REGRANEX

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**Affected Drugs:**

Regranex

**Covered Uses:** All FDA-approved indications not otherwise excluded: Dermal Ulcer (L98.4)

**Exclusion Criteria:** 1) Not to be used in the treatment of pressure ulcers and venous stasis ulcers, 2) Not to be used on exposed joints tendons, ligaments, and bone, 3) Not to be used in wounds that close by primary intention, 4) Neoplasm at the site of application

**Required Medical Information:** 1) Document presence of dorsalis pedis or posttibial pulse

**Age Restrictions:** Patients 16 years or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## RENVELA/SEVELAMER

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**Affected Drugs:**

Renagel  
Renvela  
Sevelamer Carbonate  
Sevelamer HCl

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hyperphosphatemia (E83.39)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Documentation of inadequate response or intolerance to calcium based phosphate binders (calcium acetate or carbonate) for a minimum of 8 weeks (first prescription) or albumin-corrected serum calcium level greater than or equal to 9.5 mg/dL (or maximum per lab facility) and the patient is not being treated with vitamin D, 2) Documentation of the following laboratory measure criteria: a) Serum phosphorus levels greater than 4.5 mg/dL (or maximum per lab facility).

**Age Restrictions:** 6 years or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## REPATHA

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### **Affected Drugs:**

Repatha  
Repatha Pushtronex System  
Repatha SureClick

**Covered Uses:** All FDA-approved indications not otherwise excluded: Cerebrovascular Accident (Cerebrovascular Accident or Stroke) (ICD10: I63, I63.9), Hyperlipidemia (High Amount of Fats in the Blood) (ICD10: E78.5), Atherosclerotic Disease (Disease involving Lipid Deposits in the Arteries) (ICD10: I70, I70.90), Familial Homozygous Hypercholesterolemia (Inherited Homozygous Hypercholesterolemia) (ICD10: E78.0, E78.00, E78.01), Familial Heterozygous Hypercholesterolemia (Inherited Heterozygous Hypercholesterolemia) (ICD10: E78.0), Myocardial Revascularization Procedure (Procedure to Reestablish Blood Supply to the Heart) (0210093), Myocardial Infarction (Heart Attack) (ICD10: I21.9), Unstable Angina Pectoris (ICD10: I20.0)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of Primary Hyperlipidemia, B) Treatment of Heterozygous Familial Hypercholesterolemia (HeFH), C) Treatment of Homozygous Familial Hypercholesterolemia (HoFH), or D) To Reduce the Cardiovascular Risk in the Presence of Clinical Atherosclerotic Cardiovascular Disease (ASCVD). 2) Document (only for first prescription): A) Baseline LDL-C Level greater than 70 mg/dL (lipid panel results), and B) One of the following: i) 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 ii) Therapeutic failure, adverse effects, or intolerance to at least 2 high intensity statins (e.g., atorvastatin greater or equal than 40 mg, rosuvastatin greater or equal than 20 mg) or 2 moderate intensity statins in combination with ezetimibe.

**Age Restrictions:** 1) For CVD: 18 years of age or older, 2) For HeFH and HoFH: 10 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**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).

## RESTASIS

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**Affected Drugs:**

cycloSPORINE

Restasis

Restasis MultiDose

**Covered Uses:** All FDA-approved indications not otherwise excluded: Keratoconjunctivitis Sicca (H16.229)

**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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## REVLIMID

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### **Affected Drugs:**

Lenalidomide  
Revlimid

**Covered Uses:** All FDA-approved indications not otherwise excluded: Multiple Myeloma (ICD10: C90.0, C90.00), Follicular Lymphoma (ICD10: C82, C82.90), Mantle Cell Lymphoma (ICD10: C83.1), Marginal Zone Lymphoma (ICD10: C85.1, C85.10), Transfusion Dependent Anemia in Myelodysplastic Syndromes (ICD10: D46, D46.0, D46.1, D46.2, D46.20, D46.21, D46.22, D46.4, D46.9, D46.C, D46.Z)

**Exclusion Criteria:** Pregnancy.

**Required Medical Information:** 1) Diagnosis: A) Treatment of multiple myeloma (MM), B) Maintenance treatment of multiple myeloma following autologous hematopoietic stem cell transplantation (auto-HSCT), C) Treatment of transfusion-dependent anemia, D) Treatment of mantle cell lymphoma (MCL), E) Treatment of follicular lymphoma (FL), or F) Treatment of marginal zone lymphoma (MZL). 2) Document: A) For MM: Prescribed in combination with dexamethasone. B) For MM (auto-HSCT): No additional medical information is required. C) For transfusion dependent anemia: Low- or intermediate-1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities. D) For MCL: Progressed or relapsed after at least 2 therapies, including bortezomib. E) For FL and MZL: i) Therapeutic failure to at least one prior therapy, and ii) Prescribed in combination with a rituximab product. 3) For women in reproductive age: pregnancy status.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## RIBAVIRIN

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**Affected Drugs:**

Ribavirin

**Covered Uses:** All approved FDA indication not otherwise excluded: Chronic Hepatitis C (B18.2), Respiratory Syncytial Virus Infection (B97.4)

**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:** 1) Rebetol: 3 years and older, 2) Copegus: 5 years and older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** Initial: 12 weeks. For renewal: 12 months Refer to Other Criteria

**Other Criteria:** Duration according to the clinical scenario assessed by the pharmacist in full compliance with the updated HCV guidelines recommendations at the time.

## RILUZOLE/RILUTEK

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**Affected Drugs:**

Rilutek

Riluzole

**Covered Uses:** All FDA-approved indications not otherwise excluded: Amyotrophic Lateral Sclerosis (ICD10: G12.21)

**Exclusion Criteria:** N/A

**Required Medical Information:**1) Diagnosis: Treatment of amyotrophic lateral sclerosis (ALS).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## RINVOQ

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### **Affected Drugs:**

Rinvoq  
Rinvoq LQ

**Covered Uses:** All FDA-approved indications not otherwise excluded: Atopic Dermatitis (ICD10: L20, L20.9), Rheumatoid Arthritis (ICD10: M06, M06.9), Ulcerative Colitis (Ulcerated Colon) (ICD10: K51), Ankylosing Spondylitis (Rheumatic Disease-causing Vertebrae Inflammation) (ICD10: M45, M45.9), Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), non-radiographic axial spondylarthritis, Crohn's Disease (Crohn's Disease) (ICD10: K50, K50.9), Giant-Cell Arteritis (Artery Inflammation in the Temple Area) (ICD10: D48.1)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of moderate to severely active rheumatoid arthritis (RA), B) Treatment of active psoriatic arthritis (PsA), C) Treatment of refractory, moderate to severe atopic dermatitis (AD), D) Treatment of moderately to severely active ulcerative colitis (UC), E) Treatment of moderate to severely active Crohn's Disease (CD) F) Treatment of active ankylosing spondylitis (AS), G) Treatment of moderate to severely active Crohns Disease (CD), H) Treatment of active polyarticular juvenile idiopathic arthritis, I) Treatment of Giant Cell Arteritis (GCA). 2) Document: A) For RA: i) Previous use/intolerance of at least 1 or more DMARDs and/or methotrexate and ii) Inadequate response or intolerance to one or more TNF blockers. B) For PsA, UC, CD, AS: Inadequate response or intolerance to one or more TNF blockers. C) For nr-axSpA: i) Inadequate response or intolerance to one or more TNF blockers and ii) Therapeutic failure to at least one NSAIDs (e.g., diclofenac, ibuprofen, naproxen, etc.). D) For AD: Disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. E) For PJIA: inadequate response or intolerance to one or more TNF blockers. F) For GCA: No additional information is required. 3) Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy. 4) For pediatric patients prescribed Rinvoq LQ only document: Actual Body Weight (weight-based dosing)

**Age Restrictions:** 1) For AD: 12 years of age or older, 2) For PsA and PJIA: 2 years of age or older or 2) For all other indications: 18 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) For Ulcerative Colitis (UC): The recommended induction dosage is 45 mg once daily for 8 weeks. The recommended maintenance dosage is 15 mg once daily. A maintenance dosage of 30 mg once daily may be considered for patients with refractory, severe, or extensive disease, 2) For Crohn's Disease (CD): The recommended induction dosage is 45 mg once daily for 12 weeks. The recommended maintenance dosage is 15 mg once daily. A maintenance dosage of 30 mg once daily may be considered for patients with refractory, severe, or extensive disease.

## SABRIL

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**Affected Drugs:**

Sabril  
Vigabatrin

**Covered Uses:** All FDA-approved indications not otherwise excluded: Focal Seizures with Impaired Awareness (G40.20)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Refractory Complex Partial Seizures as adjunctive therapy, OR b) Infantile Spasms as monotherapy, 2) For refractory complex partial seizures document: a) Previous therapies, 3) For pediatric patients only: Document actual body weight.

**Age Restrictions:** 1) For refractory complex partial seizures: 2 years of age or older, 2) For infantile spasms: 1 month to 2 years of age.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Refer to the Package Insert for dosing recommendations.

## SAXENDA

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**Affected Drugs:**

Liraglutide -Weight Management  
Saxenda

**Covered Uses:** All FDA-approved indications not otherwise excluded: Obesity (ICD10: E66, E66.9)

**Exclusion Criteria:** 1) Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2. 2) Pregnancy.

**Required Medical Information:** 1) Diagnosis: As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management. 2) Document (for initial prescription): A) For adults: Body mass index (BMI) of 30 kg/m<sup>2</sup> or greater (obese), or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)]. B) For pediatric patients: Body weight above 60 kg and an initial BMI corresponding to 30 kg/m<sup>2</sup> for adults (obese). C) For renewals: At least a 5% reduction in baseline body weight (actual BMI or weight and height).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 3 months

**Other Criteria:** Validate if weight management drugs are covered under the Pharmacy benefit. Normally these drugs are not covered under the Pharmacy benefit, validate coverage. For FEHB renewals: Validate patient is currently enrolled in obesity management program.

## SELARSDI

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### **Affected Drugs:**

Selarsdi

**Covered Uses:** All FDA-approved indications not otherwise excluded: Ulcerative Colitis (Ulcerated Colon) (ICD10: K51, K51.90), Crohn's Disease (ICD10: K50, K50.9), Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), Plaque Psoriasis (ICD10: L40.0)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of moderate to severe plaque psoriasis (PsO) in patients who are candidates for phototherapy or systemic therapy. B) Treatment of active psoriatic arthritis (PsA). C) Treatment of moderately to severely active Crohn's disease (CD). D) Treatment of moderately to severely active ulcerative colitis (UC). 2) Document: A) For PsO: i) At least 3% BSA is affected or crucial body areas such as the hands, feet, face, scalp, or genitals, and ii) Prior use of at least one conventional drug (e.g., acitretin, cyclosporine, hydroxyurea, methotrexate, triamcinolone, etc.). B) For PsA: i) Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine). C) For CD: i) Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, prednisone, mercaptopurine, mesalamine, methotrexate, etc.). D) For UC: i) Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, hydrocortisone, mercaptopurine, mesalamine, sulfasalazine, etc.). E) For all indications: Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

**Age Restrictions:** 1) CD and UC: 18 years of age or older. 2) For PsO and PsA: 6 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## SELZENTRY

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### **Affected Drugs:**

Maraviroc  
Selzentry

**Covered Uses:** All FDA-approved indications not otherwise excluded: Human Immunodeficiency Virus Disease (ICD10: B20)

**Exclusion Criteria:** Contraindicated in patients with severe renal impairment or end-stage renal disease (ESRD) (CrCl less than 30 mL per minute) who are concomitantly taking potent CYP3A inhibitors or inducers [e.g., clarithromycin, cobicistat, elvitegravir/ritonavir, itraconazole, ketoconazole, nefazodone, protease inhibitors (except tipranavir/ritonavir), telithromycin, carbamazepine, efavirenz, etravirine, phenobarbital, phenytoin, and rifampin].

**Required Medical Information:** 1) Diagnosis: Treatment of CCR5-tropic HIV-1 Infection. 2) Document: A) Patient is positive for CCR5 tropism (only for first prescription), B) Prescribed in combination with other antiretroviral agents (HIV drugs), and C) Creatinine clearance (CrCl), or patients actual body weight and serum creatinine.

**Age Restrictions:** 2 years of age and older weighing at least 2 Kg

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Follow Package insert instructions for dose administration. 2) If CrCl (mL/min) is not provided it can be calculated using the Cockcroft and Gault equation:  $CrCl = \{(140 - \text{age}) \times \text{weight}\} / (\text{Scr} \times 72)$  (x 0.85 for females), weight in kg.

## SENSIPAR

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**Affected Drugs:**

Cinacalcet HCl

Sensipar

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hypercalcemia (ICD10: E83.52), Secondary Hyperparathyroidism (ICD10: E21.1), Primary Hyperparathyroidism (ICD10: E21.0)

**Exclusion Criteria:**1) Serum calcium levels less than 8.4mg/Dl

**Required Medical Information:**1) Diagnosis

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## SILDENAFIL/REVATIO

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**Affected Drugs:**

Revatio  
Sildenafil Citrate

**Covered Uses:** All FDA-approved indications not otherwise excluded: Pulmonary Hypertension (ICD10: I27.20)

**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.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## SILIQ

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### **Affected Drugs:**

Siliq

**Covered Uses:** All FDA-approved indications not otherwise excluded: Plaque Psoriasis (ICD10: L40.0)

**Exclusion Criteria:** Crohn's disease.

**Required Medical Information:** 1) Diagnosis: Treatment of moderate to severe plaque psoriasis (PsO) in patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies. 2) Document: A) At least 3% BSA is affected or crucial body areas such as the hands, feet, face, scalp or genitals, B) Prior use of at least one conventional drug (e.g., acitretin, cyclosporine, hydroxyurea, methotrexate, triamcinolone, etc.), C) Prior use of at least two formulary preferred drugs (e.g., Avsola, Enbrel, Humira, Renflexis, Skyrizi, Stelara, Taltz, if available), and D) Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## SIRTURO

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**Affected Drugs:**

Sirturo

**Covered Uses:** All FDA-approved indications not otherwise excluded: Pulmonary Tuberculosis (Lung Tuberculosis) (ICD10: A15.0, A15.9)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Pulmonary Multi-Drug Resistant Tuberculosis (MDR-TB). 2) Document: A) No other effective treatment is available for the patient, B) Prescribed in combination with at least 3 other anti-mycobacterial drugs to which the patient's MDR-TB isolate has been shown to be susceptible, and C) Patient's actual body weight.

**Age Restrictions:** 5 years of age or older weighting at least 15kg

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 24 weeks

**Other Criteria:** If susceptibility test is unavailable may be prescribed in combination with at least 4 other drugs to which patient's MDR-TB isolate is likely to be susceptible.

## SIVEXTRO

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**Affected Drugs:**

Sivextro

**Covered Uses:** All FDA-approved indications not otherwise excluded: Skin and Skin Structure Infection (ICD10: L08, L08.9)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Acute Bacterial Skin and/or Skin Structure Infections (ABSSSI).

**Age Restrictions:** 26 weeks gestational age (and weighing at least 1 kg) and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 6 days

**Other Criteria:** 1) For the injection dosage form: Validate if intravenous infusion drugs are covered under the Pharmacy benefit. Normally these drugs are not covered under the Pharmacy benefit, validate coverage.

## SKYRIZI

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### **Affected Drugs:**

Skyrizi  
Skyrizi (150 MG Dose)  
Skyrizi Pen

**Covered Uses:** All FDA-approved indications not otherwise excluded: Plaque Psoriasis (ICD10: L40.0), Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), Crohn's Disease (ICD10: K50, K50.9)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy. B) Treatment of active psoriatic arthritis (PsA) C) Moderate to Severe Crohn's disease (CD) or D) Moderate to severely active Ulcerative Colitis (UC) 2) For PsO document: A) At least 3% BSA or crucial body areas such as the hands, feet, face, scalp or genitals and B) Prior use of at least one conventional drug (e.g., acitretin, cyclosporine, hydroxyurea, methotrexate, triamcinolone, etc.). 3) For PsA document: Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, Leflunomide, sulfasalazine) 4) For Crohn's Disease document: A) Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, prednisone, mercaptopurine, mesalamine, methotrexate, 5) For UC: Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, hydrocortisone, mercaptopurine, mesalamine, sulfasalazine, etc.) 6) Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Refer to Package insert for dosing considerations. CD and UC indications require induction doses with intravenous formulation.

## **SODIUM PHENYL BUTYRATE**

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**Affected Drugs:**

Buphenyl  
Sodium Phenylbutyrate

**Covered Uses:** All FDA-approved indications not otherwise excluded: Urea Cycle Metabolism Disorder (E72.2)

**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:** 12 months

**Other Criteria:** N/A

## **SOFOSBUVIR-VELPATASVIR**

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### **Affected Drugs:**

Sofosbuvir-Velpatasvir

**Covered Uses:** All approved FDA indication not otherwise excluded: Hepatitis C, Genotype 1 (ICD10: B17.1, B17.10, B18.2, B19.2), Hepatitis C, Genotype 2 (ICD10: B17.1, B17.10, B18.2), Hepatitis C, Genotype 3 (ICD10: B17.1, B17.10, B18.2), Hepatitis C, Genotype 4 (ICD10: B17.1, B17.10, B18.2), Hepatitis C, Genotype 5 (ICD10: B17.1, B18.2, B19), Hepatitis C, Genotype 6 (ICD10: B17.1, B18.2, B19)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Chronic Hepatitis C (HCV) Genotype 1, 2, 3, 4, 5 or 6. 2) Document: a) Hepatic fibrosis status by one of the following: i) Clinical evidence stating the cirrhosis status as attested by the prescribing physician, ii) Liver biopsy METAVIR score, or alternative scoring equivalent, iii) Radiological imaging of the liver, iv) Transient elastography (FibroScan) score, v) FibroTest (FibroSure) score, or vi) APRI score, b) For cirrhotic patients: compensated or decompensated status, c) For decompensated cirrhosis: prescribed in combination with weight-based ribavirin, d) Liver transplant status, e) Quantitative HCV RNA viral load, f) Indicate if patient is naive or experienced (i.e. prior use status of PEG-IFN, RBV, HCV protease or polymerase inhibitors), g) For pediatric patients: actual body weight.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 weeks

**Other Criteria:** Duration of 12 weeks for genotypes 1, 2, 3, 4, 5 and 6, 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.

## SOMATULINE DEPOT

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**Affected Drugs:**

Lanreotide Acetate  
Somatuline Depot

**Covered Uses:** All FDA-approved indications not otherwise excluded: Acromegaly (E22.0), Carcinoid Syndrome (E34.0), Gastroenteropancreatic Neuroendocrine Tumor (D3A.098)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) acromegaly OR b) locally advanced or metastatic gastroenteropancreatic neuroendocrine tumor (GEP-NET), 2) For acromegaly: Patient meets the following criteria for initiation of therapy: a) Pre-treatment high IGF-1 level for age/gender and b) 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, 3) For continuation of therapy for acromegaly: a) IGF-1 level decreased or normalized, 4) For locally advanced or metastatic GEP-NETs: document disease is unresectable or widely spread.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## SOMAVERT

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**Affected Drugs:**

Somavert

**Covered Uses:** All FDA-approved indications not otherwise excluded: Acromegaly (E22.0)

**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, 2) For continuation of therapy: a) IGF-1 level decreased or normalized.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## SPRYCEL

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**Affected Drugs:**

Dasatinib

Sprycel

**Covered Uses:** All FDA-approved indications not otherwise excluded: Chronic Myelocytic Leukemia (ICD10: C92.10), Acute Lymphocytic Leukemia (ICD10: C91.0, C91.00)

**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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## STELARA

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### Affected Drugs:

Stelara

**Covered Uses:** All FDA-approved indications not otherwise excluded: Ulcerative Colitis (Ulcerated Colon) (ICD10: K51, K51.90), Crohn's Disease (ICD10: K50, K50.9), Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), Plaque Psoriasis (ICD10: L40.0)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of moderate to severe plaque psoriasis (PsO) in patients who are candidates for phototherapy or systemic therapy. B) Treatment of active psoriatic arthritis (PsA). C) Treatment of moderately to severely active Crohn's disease (CD). D) Treatment of moderately to severely active ulcerative colitis (UC). 2) Document: A) For PsO: i) At least 3% BSA is affected or crucial body areas such as the hands, feet, face, scalp or genitals, and ii) Prior use of at least one conventional drug (e.g., acitretin, cyclosporine, hydroxyurea, methotrexate, triamcinolone, etc.). B) For PsA: Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine). C) For CD: Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, prednisone, mercaptopurine, mesalamine, methotrexate, etc.). D) For UC: Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, hydrocortisone, mercaptopurine, mesalamine, sulfasalazine, etc.). E) For all indications: Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

**Age Restrictions:** 1) CD and UC: 18 years of age or older. 2) For PsO and PsA: 6 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## STIMATE NASAL

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**Affected Drugs:**

Stimate

**Covered Uses:** All FDA-approved indications not otherwise excluded: Von Willebrand Disease (D68.0), Hemophilia A (D66)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Hemophilia A with Factor VIII coagulant activity levels greater than 5% or b) Mild to Moderate von Willebrand s disease (Type I) with Factor VIII levels greater than 5%, 2) Document: Patients Factor VIII levels

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## STIVARGA

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### **Affected Drugs:**

Stivarga

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hepatic Carcinoma (C22, C22.0, C22.8, C22.9), Malignant Neoplasm of Colon (C18, C18.9), Malignant Neoplasm of Rectum (C20, C21.8), Gastrointestinal Stromal Tumor (C49.4, C49.A, C49.A0)

**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, 5) For hepatocellular carcinoma document: previous treatment with sorafenib.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## SUTENT

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**Affected Drugs:**

SUNItinib Malate

Sutent

**Covered Uses:** All FDA-approved indications not otherwise excluded: Renal Cell Carcinoma (Kidney Cell Carcinoma) (ICD10: C64, C64.1, C64.2, C64.9), Gastrointestinal Stromal Tumor (Stromal Tumor of Digestive Tract) (ICD10: C49.4, C49.A, C49.A0), Pancreatic Neuroendocrine Carcinoma (Cancerous Neuroendocrine Tumor of Pancreatic Origin) (ICD10: C25.4)

**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 and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## **SYMPROIC**

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**Affected Drugs:**

Symproic

**Covered Uses:** All approved FDA indication not otherwise excluded: Opioid-Induced Constipation (F11, F11.99, K59.03, T40.605A, T40.605D)

**Exclusion Criteria:**1) Patients with known or suspected gastrointestinal obstruction or at increased risk of recurrent obstruction

**Required Medical Information:**1) Diagnosis: opioid induced constipation (OIC) in adult patients with chronic non-cancer pain

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## SYNAGIS

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**Affected Drugs:**

Synagis

**Covered Uses:** All FDA-approved indications not otherwise excluded: Respiratory Syncytial Virus Infection (B97.4)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV), 2) Document: a) History of premature birth (less than or equal to 35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season, b) Bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season, OR c) Hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season, d) Patient's weight: recommended dose is 15 mg/kg, 2) Only for patients that have not started on Synagis, for all indications: intolerance or contraindication to Beyfortus

**Age Restrictions:** 24 months of age or younger

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 6 months

**Other Criteria:** 1) The first dose of Synagis should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season, 2) Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season, 3) Patients undergoing cardio-pulmonary bypass should receive an additional dose of Synagis as soon as possible after the cardio-pulmonary bypass procedure.

## SYNAREL

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**Affected Drugs:**

Synarel

**Covered Uses:** All FDA-approved indications not otherwise excluded: Endometriosis (N80, N80.9), Central Precocious Puberty (E22.8).

**Exclusion Criteria:** Pregnancy

**Required Medical Information:** 1) Diagnosis: a) Central precocious puberty (CPP), OR b) Endometriosis, 2) For central precocious puberty document: a) Measurement of blood concentrations of total sex steroids, luteinizing hormone (LH) and follicle stimulating hormone (FSH) following stimulation with a GnRH analog, b) Assessment of bone age versus chronological age, c) Patient's height and weight measurements, d) Diagnostic imaging of the brain (to rule out intracranial tumor), e) Pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), f) Human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor), AND g) Adrenal steroids levels (to exclude congenital adrenal hyperplasia).

**Age Restrictions:** 1) For CPP: 2 year of age or older until appropriate time point for the onset of puberty (12 years for males and 11 years for females). 2) For endometriosis: 18 years of age or older.

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## TABRECTA

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**Affected Drugs:**

Tabrecta

**Covered Uses:** All FDA-approved indications not otherwise excluded: Non-Small-Cell Lung Carcinoma (Non-Small-Cell Lung Cancer) (ICD10: C34, C34.9, C34.90)

**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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## TAFINLAR

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### Affected Drugs:

Tafinlar

**Covered Uses:** All FDA-approved indications not otherwise excluded: Malignant Neoplasm of Thyroid (ICD10: C73, C75.9), Malignant Melanoma (C43, C43.9), Non-Small-Cell Lung Carcinoma (ICD10: C34, C34.9, C34.90), Malignant Solid Tumor (Cancerous Solid Tumor), Malignant Glioma of Brain (ICD10: C71, C71.9, C72.9)

**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 (NSCLC) OR D) Locally advanced or metastatic anaplastic thyroid cancer (ATC), E) Unresectable metastatic solid tumors OR F) Low-grade glioma (LGG). 2) Document: A) For melanoma with involvement of lymph node(s), document the following: a) positive results for BRAF V600E or V600K mutations as detected by an FDA-approved test, b) complete resection, c) must be used in combination with trametinib, B) For unresectable or metastatic melanoma, document the following: a) positive results for BRAF V600E or V600K mutations as detected by an FDA-approved test, 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, C) For metastatic non-small cell lung cancer NSCLC document the following: a) positive results for BRAF V600E mutations as detected by an FDA-approved test AND b) must be used in combination with trametinib, D) For locally advanced or metastatic anaplastic thyroid cancer ATC: document the following: a) positive results for BRAF V600E mutation as detected by an FDA-approved test, b) no satisfactory locoregional treatment options, AND c) must be used in combination with trametinib, 6) For unresectable or metastatic solid tumors: a) positive results for BRAF V600E mutation, b) patient has progressed following prior treatment or has no alternative treatment options, AND c) must be used in combination with trametinib. 7) For low grade glioma LGG: a) positive results for BRAF V600E mutation, b) prescribed in combination with trametinib, 8) 3) For pediatric patients: a) Actual body weight (weight-based dosing)

**Age Restrictions:** 1) For low grade glioma (LGG and unresectable or metastatic solid tumors: 1 year of age and older, 2) For all other indications: 18 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## TALTZ

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### **Affected Drugs:**

Taltz

**Covered Uses:** All FDA-approved indications not otherwise excluded: Ankylosing Spondylitis (Rheumatic Disease causing Vertebrae Inflammation) (ICD10: M45, M45.9), Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), Plaque Psoriasis (ICD10: L40.0), Non-Radiographic Axial Spondyloarthritis (Arthritis of Spine with Normal X-ray) (ICD10: M46.80, M46.87, M46.88)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of moderate-to-severe plaque psoriasis (PsO) for patients who are candidates for systemic therapy or phototherapy. B) Treatment of active psoriatic arthritis (PsA). C) Treatment of ankylosing spondylitis (AS). D) Treatment of active non-radiographic axial spondyloarthritis (nr-AxSpA) with objective signs of inflammation. 2) Document: A) For PsO: i) At least 3% of BSA is affected or crucial body areas such as the hands, feet, face, scalp, or genitals, and ii) Prior use of at least one conventional drug (e.g., acitretin, cyclosporine, hydroxyurea, methotrexate, triamcinolone, etc.). B) For PsA: Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine). C) For AS: Therapeutic failure to at least one nonsteroidal anti-inflammatory drug (NSAID) (e.g., celecoxib, naproxen, sulindac, etc.). D) For nr-AxSpA: Therapeutic failure to at least one NSAIDs (e.g., diclofenac, ibuprofen, naproxen, etc.). E) For all indications: Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

**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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## TAMOXIFEN

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### **Affected Drugs:**

Tamoxifen Citrate

**Covered Uses:** All FDA-approved indications not otherwise excluded: Malignant Neoplasm of Breast (C50, C50.1, C50.2, C50.3, C50.4, C50.5, C50.6, C50.8, C50.9, C50.919), Metastatic Malignant Neoplasm of Breast (C79.81), Node-Negative Malignant Neoplasm of Breast (C50, C50.019, C50.029, C50.119, C50.129, C50.219, C50.229, C50.319, C50.329, C50.419, C50.429, C50.519, C50.529, C50.619, C50.629, C50.819, C50.829, C50.9, C50.919, C50.929), Node-Positive Malignant Neoplasm of Breast (C50.9, C77, C77.9), Intraductal Breast Carcinoma (D05.90)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis, 2) Documentation of increased risk for breast cancer, 3) Age

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) If patient is 35 years or older and has an increased risk for breast cancer a \$0 copay is applied. If the patient does not have an increased risk for breast cancer regular copay applies. 2) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## TARCEVA

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**Affected Drugs:**

Erlotinib HCl  
Tarceva

**Covered Uses:** All FDA-approved indications not otherwise excluded: Metastatic Non-Small-Cell Lung Carcinoma (C78.00), Locally Advanced Unresectable Malignant Pancreas Neoplasm (C25, C25.9), Metastatic Malignant Neoplasm of Pancreas (C25, C25.9, C79, C79.9)

**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: i) completion of four cycles of platinum-based first-line chemotherapy without disease progression AND ii) Tarceva 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 and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## TASIGNA

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**Affected Drugs:**

Nilotinib HCl

Tasigna

**Covered Uses:** All FDA-approved indications not otherwise excluded: Philadelphia Chromosome + Chronic Myelocytic Leukemia (ICD10: C92.1, C92.10)

**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 adult patients, document: A) Resistance or intolerance to prior therapy including imatinib, and B) 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-CP and CML-AP pediatric patients, document: Patient is resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## TAZORAC

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**Affected Drugs:**

Tazarotene  
Tazorac

**Covered Uses:** All FDA-approved indications not otherwise excluded: Plaque Psoriasis (L40.0), Acne Vulgaris (L70.0)

**Exclusion Criteria:**1) Pregnancy

**Required Medical Information:**1) Diagnosis: a. Plaque psoriasis, OR b. Mild to moderate facial acne vulgaris. 2) Document: Females of child-bearing potential should provide negative pregnancy test within 2 weeks prior to initiating treatment and use an effective method of contraception during treatment, b. For plaque psoriasis document up to 20% body surface area involvement.

**Age Restrictions:** 12 years of age and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## TECFIDERA

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**Affected Drugs:**

Dimethyl Fumarate  
Dimethyl Fumarate Starter Pack  
Tecfidera

**Covered Uses:** All FDA-approved indications not otherwise excluded: Relapsing, Remitting Multiple Sclerosis (ICD10: G35), Secondary Progressive Multiple Sclerosis (ICD10: G35), Clinically Isolated Syndrome (First Clinical Episode Suggestive of Multiple Sclerosis) (ICD10: G37.8)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of Relapsing Forms of Multiple Sclerosis (MS), to Include Clinically Isolated Syndrome, Relapsing-Remitting Disease, and Active Secondary Progressive Disease. 2) Patients must have documented previous use and therapeutic failure, intolerance or contraindication to at least one generic therapeutic alternative (e.g., dimethyl fumarate, fingolimod, glatiramer acetate).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## TEMOZOLOMIDE

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**Affected Drugs:**

Temodar  
Temozolomide

**Covered Uses:** All FDA-approved indications not otherwise excluded: Refractory Anaplastic Astrocytoma (ICD10: C72.9), Glioblastoma Multiforme of the Brain (ICD10: C71, C71.9)

**Exclusion Criteria:**1) Pregnancy.

**Required Medical Information:**1) Diagnosis: a. Newly Diagnosed Glioblastoma multiforme of brain, b. Anaplastic astrocytoma of brain, 2) For Glioblastoma multiforme of brain: document treatment is concomitantly with radiotherapy and then as maintenance treatment, 3) For Anaplastic astrocytoma of brain: document disease is refractory after progression on nitrosourea and procarbazine

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** 1) Pneumocystis pneumonia (PCP) – PCP prophylaxis required for all patients receiving concomitant TEMODAR and radiotherapy for the 42-day regimen for the treatment of newly diagnosed glioblastoma multiforme. 2) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## TERIPARATIDE

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### **Affected Drugs:**

Teriparatide

**Covered Uses:** All FDA-approved indications not otherwise excluded: Osteoporosis (ICD10: M81), Postmenopausal Osteoporosis (ICD10: M81.0), Glucocorticoid-Induced Osteoporosis (Osteoporosis caused by Glucocorticoid Drugs) (ICD10: M81.8, T38.0X5A, T38.0X5D, T38.0X5S)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of postmenopausal women with osteoporosis at high risk of fracture or patient has failed or intolerant to other available osteoporosis therapy, B) To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or intolerant to other available osteoporosis therapy, or C) Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or patient has failed or intolerant to other available osteoporosis therapy. 2) Document: Bone density test result (T-score less than or equal to -2.5 for osteoporosis diagnosis).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) High risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. 2) Therapy will be discontinued after a lifetime total of 24 months of treatment.

## TEZSPIRE

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**Affected Drugs:**

Tezspire

**Covered Uses:** All FDA-approved indications not otherwise excluded: Asthma (ICD10: J45, J45.9, J45.90), Severe Persistent Asthma (ICD10: J45.5)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: For the add-on maintenance treatment of severe asthma. 2) Document: A) Evidence of at least 3 consecutive months of therapy with high-dose inhaled corticosteroids (ICS) in combination with other controller medications [e.g., Long-acting beta agonist (LABAs), Leukotriene receptor antagonist (LTRAs) with oral corticosteroids (OCS) use] and B) Two or more asthma exacerbations requiring systemic corticosteroid treatment or one asthma exacerbation resulting in hospitalization in the past 12 months.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate if treatments that need to be administered by a healthcare professional are covered under the Pharmacy benefit. Normally these treatments are not covered under the Pharmacy benefit, validate coverage.

## THALOMID

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**Affected Drugs:**

Thalomid

**Covered Uses:** All FDA-approved indications not otherwise excluded: Multiple Myeloma (ICD10: C90.0, C90.00), Erythema Nodosum Leprosum (ICD10: A30.8)

**Exclusion Criteria:**1) 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:** N/A

**Coverage Duration:**12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## **THERAPY FOR MUCOPOLYSACCHARIDOSES**

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### **Affected Drugs:**

Naglazyme

**Covered Uses:** All FDA-approved indications not otherwise excluded: Mucopolysaccharidosis Type IH (ICD10: E76.0, E76.01), Mucopolysaccharidosis Type IS (ICD10: E76.0, E76.03), Mucopolysaccharidosis Type I H/S (ICD10: E76.0, E76.02), Mucopolysaccharidosis Type II (ICD10: E76.1), Mucopolysaccharidosis Type VI (ICD10: E76.29), Mucopolysaccharidosis Type IVA (ICD10: E76.210)

**Exclusion Criteria:** Patients with Mucopolysaccharidosis types III, or VII

**Required Medical Information:** 1) Diagnosis: a) For Aldurazyme: Mucopolysaccharidosis I (MPS I), b) For Elaprase: Mucopolysaccharidosis II (MPS II), c) For Naglazyme: Mucopolysaccharidosis VI (MPS VI), d) For Vimizim: Mucopolysaccharidosis IVA (MPS IVA, Morquio A syndrome)

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## TIBSOVO

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### **Affected Drugs:**

Tibsovo

**Covered Uses:** All FDA-approved indications not otherwise excluded: Acute Myelocytic Leukemia (ICD10: C92.0, C92.5, C92.6), Cholangiocarcinoma (Cancer of the Bile Duct) (ICD10: C22.1), Myelodysplastic Syndrome (Preleukemia) (ICD-10: C94.6, D46, D46.9)

**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), c) Relapsed or refractory Myelodysplastic Syndromes (MDS) or d) 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 and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## **TOBRAMYCIN/TOBI**

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### **Affected Drugs:**

Bethkis  
Tobi  
Tobi Podhaler  
Tobramycin

**Covered Uses:** All FDA-approved indications not otherwise excluded: Pseudomonas Pulmonary Infection in Cystic Fibrosis (E84.0, J15.1)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Document diagnosis: a) Cystic Fibrosis, b) Bronchiectasis

**Age Restrictions:** 1) Patients 6 years of age and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Tobramycin is administered BID in alternating periods of 28 days. After 28 days of therapy, patients should stop tobramycin therapy for the next 28 days, and then resume therapy for the next 28 day on/28 day off cycle.

## TRACLEER

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**Affected Drugs:**

Bosentan  
Tracleer

**Covered Uses:** All FDA-approved indications not otherwise excluded: Pulmonary Arterial Hypertension (ICD10: I27.0)

**Exclusion Criteria:** 1) Pregnancy, 2) Concomitant use with cyclosporine or glyburide.

**Required Medical Information:** 1) Provide CBC, 2) Provide Liver Function tests, 3) Document previous use of Adcirca or Ventavis

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## TRIPTODUR

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**Affected Drugs:**

Triptodur

**Covered Uses:** All FDA-approved indications not otherwise excluded: Precocious Puberty (E30.1).

**Exclusion Criteria:** Pregnancy

**Required Medical Information:** 1) Diagnosis: a) Central Precocious Puberty (CPP), 2) For precocious puberty document: a) Measurement of blood concentrations of total sex steroids, luteinizing hormone (LH) and follicle stimulating hormone (FSH) following stimulation with a GnRH analog, b) Assessment of bone age versus chronological age, c) Patients height and weight measurements, d) Diagnostic imaging of the brain (to rule out intracranial tumor), e) Pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), f) Human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor), AND g) Adrenal steroids levels (to exclude congenital adrenal hyperplasia).

**Age Restrictions:** Pediatric patients 2 year of age or older until appropriate time point for the onset of puberty (12 years for males and 11 years for females)

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## TROGARZO

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**Affected Drugs:**

Trogarzo

**Covered Uses:** All FDA-approved indications not otherwise excluded: Human Immunodeficiency Virus Disease (B20)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: human immunodeficiency virus type 1 (HIV-1). 2) Documented multidrug resistant HIV-1 infection including evidence of resistance to ONE medication from EACH of the following classes, as measured by resistance testing during the past 6 months: i. Protease inhibitor (PI), ii. Nucleoside reverse transcriptase inhibitors (NRTI), iii. Non-nucleoside reverse transcriptase inhibitors (NNRTI). 3) The patient has a RNA viral load greater than 1,000 copies/mL (submission of viral load required). 4) Trogarzo is used in combination with an optimized background regimen of anti-retroviral therapy (ART).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## TRUVADA

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### **Affected Drugs:**

Emtricitabine-Tenofovir DF  
Truvada

**Covered Uses:** All FDA-approved indications not otherwise excluded: Human Immunodeficiency Virus (HIV) Disease (B20), Pre-Exposure Prophylaxis of HIV (HIV Infection Risk Reduction Before Potential Exposure) (ICD10: Z20.6, Z41.9)

**Exclusion Criteria:** For PrEP: Contraindicated in individuals with unknown or positive HIV-1 status.

**Required Medical Information:** 1) Diagnosis: A) Treatment of HIV-1 infection, or B) HIV-1 pre-exposure prophylaxis (PrEP). 2) Document: A) For HIV-1 infection: No other medical information is required. B) For PrEP: i) Negative HIV-1 status test (result lecture date must be less than 30 days), ii) Patient is at risk of acquiring HIV-1 infection, and iii) Patient's actual body weight.

**Age Restrictions:** 1) For HIV-1 Treatment: Adults and pediatric patients weighing at least 17 kg, 2) For HIV-1 PrEP: Adults and adolescents weighing at least 35 kg

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) At risk individuals include: has partner(s) known to be HIV-1 infected, or engages in sexual activity within a high prevalence area or social network and has additional risk factors for HIV-1 acquisition, such as: inconsistent or no condom use, diagnosis of sexually transmitted infections, exchange of sex for commodities (such as money, food, shelter, or drugs), use of illicit drugs or alcohol dependence, incarceration, or partner(s) of unknown HIV-1 status with any of the factors listed above. 2) For patients that have an increased risk of HIV-1 and a negative HIV-1 status test a \$0 copayment will be applied (PPACA – Preventive Therapy). If the patient does not have an increased risk for HIV-1 a regular copayment will apply. 3) Recommended PrEP dosage is one 200 mg/300 mg tablet once daily.

## TYKERB

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### **Affected Drugs:**

Lapatinib Ditosylate

Tykerb

**Covered Uses:** All FDA-approved indications not otherwise excluded: HER2 Positive Breast Carcinoma (C50, C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.1, C50.11, C50.111, C50.112, C50.119, C50.12, C50.121, C50.122, C50.129, C50.2, C50.21, C50.211, C50.212, C50.219, C50.22, C50.221, C50.222, C50.229, C50.3, C50.31, C50.311, C50.312, C50.319, C50.32, C50.321, C50.322, C50.329, C50.4, C50.41, C50.411, C50.412, C50.419, C50.42, C50.421, C50.422, C50.429, C50.5, C50.51, C50.511, C50.512, C50.519, C50.52, C50.521, C50.522, C50.529, C50.6, C50.61, C50.611, C50.612, C50.619, C50.62, C50.621, C50.622, C50.629, C50.8, C50.81, C50.811, C50.812, C50.819, C50.82, C50.821, C50.822, C50.829, C50.9, C50.91, C50.911, C50.912, C50.919, C50.92, C50.921, C50.922, C50.929)

**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, 3) 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 and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## **TYMLOS**

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### **Affected Drugs:**

Tymlos

**Covered Uses:** All approved FDA indication not otherwise excluded: Postmenopausal Osteoporosis (ICD10: M81.0)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) Treatment of postmenopausal women with osteoporosis at high risk for fracture or b) To increase bone mass in men with osteoporosis at high risk for fracture 2) Document: A) For postmenopausal women with osteoporosis: Bone density test result (T-score less or equal to -2.5 for osteoporosis diagnosis), B) For men with osteoporosis: 1) Documented multiple risk factors for fracture OR failure or intolerance to other available osteoporosis therapy

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) High risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. 2) Therapy will be discontinued after a lifetime total of 24 months of treatment.

## TYVASO

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**Affected Drugs:**

Tyvaso  
Tyvaso Refill Kit  
Tyvaso Starter Kit

**Covered Uses:** All FDA-approved indications not otherwise excluded: Pulmonary Arterial Hypertension (ICD10: I27.0)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of pulmonary arterial hypertension (PAH, WHO Group 1), or B) Treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO Group 3)

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## UBRELVY

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**Affected Drugs:**

Ubrelyv

**Covered Uses:** All FDA-approved indications not otherwise excluded: Migraine (Migraine Headache) (ICD10: G43, G43.9)

**Exclusion Criteria:** Concomitant use with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin).

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

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Not indicated for the preventive treatment of migraine. 2) The safety of treating more than 8 migraines in a 30-day period has not been established.

## ULORIC

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**Affected Drugs:**

Febuxostat  
Uloric

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hyperuricemia (R78.89)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Gout, 2) For the first prescription only: a. Documentation of prior use, contraindication or intolerance to allopurinol.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## VELPHORO

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**Affected Drugs:**

Velphoro

**Covered Uses:** All approved FDA indication not otherwise excluded: Hyperphosphatemia D/T Renal Insufficiency (E83.3, E83.30, E83.39, N19)

**Exclusion Criteria:** N/A

**Required Medical Information:**1) Diagnosis: Chronic Kidney Disease on dialysis

**Age Restrictions:** 9 years of age and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## VELSIPITY

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**Affected Drugs:**

Velsipity

**Covered Uses:** All FDA-approved indications not otherwise excluded: Ulcerative colitis (Ulcerated colon) (ICD 10: K51)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of moderate to severely active ulcerative colitis in adults. 2) Document: A) Only for first prescription: Electrocardiogram (ECG) result (to determine preexisting conduction abnormalities, see Other Criteria). B) Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, hydrocortisone, mercaptopurine, mesalamine, sulfasalazine, etc.). C) Prior use of at least two formulary preferred drugs (e.g., Avsola, Humira or preferred biosimilars, Renflexis, Stelara, Xeljanz, if available).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** If ECG result is not available, the physician needs to provide a statement indicating that the patient has been evaluated for cardiovascular risk and does not have preexisting conduction abnormalities nor meet exclusion criteria.

## VEMLIDY

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**Affected Drugs:**

Vemlidy

**Covered Uses:** All approved FDA indication not otherwise excluded: Chronic Hepatitis B (B18.1)

**Exclusion Criteria:** 1) Child-Pugh B or C hepatic impairment, 2) Estimated CrCl less than 15mL/min (ESRD)

**Required Medical Information:** 1) Diagnosis: chronic hepatitis B virus infection, 2) Document the following: a) Hepatitis B surface antigen (HBsAg), b) Liver Function Test, 3) HIV-1 negative or on treatment, 4) Renal Function Test (CrCl, serum creatinine)

**Age Restrictions:** 6 years of age and older weighing at least 25 kg

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## VENCLEXTA

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**Affected Drugs:**

Venclexta

Venclexta Starting Pack

**Covered Uses:** All FDA-approved indications not otherwise excluded: Chronic Lymphocytic Leukemia (C91.1), Acute Myelocytic Leukemia (C92.0, C92.5, C92.6), Small Lymphocytic Lymphoma (C85.8, C85.80)

**Exclusion Criteria:** Concomitant use of strong inhibitors of CYP3A4 during initiation and ramp-up phase (first 5 weeks of treatment) (i.e. ketoconazole, clarithromycin, conicaptan, indinavir, itraconazole, lopinavir, ritonavir, telaprevir, posaconazole, and voriconazole)

**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 or alone, 3) For newly-diagnosed AML: a) In combination with azacitidine or decitabine or low-dose cytarabine, b) If patient is 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:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## VENTAVIS

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**Affected Drugs:**

Ventavis

**Covered Uses:** All FDA-approved indications not otherwise excluded: Pulmonary Arterial Hypertension (ICD10: I27.0)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Treatment of pulmonary arterial hypertension (PAH, WHO Group 1).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## VERQUVO

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**Affected Drugs:**

Verquvo

**Covered Uses:** All FDA-approved indications not otherwise excluded: Cardiac Failure (Heart Failure) (ICD10: I50, I50.9)

**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) New York Heart Association functional classification II-IV (NYHA class II-IV), B) Left ventricular ejection fraction (LVEF) equal to or less than 45%, C) Patient was hospitalized for heart failure (within 6 months) or required outpatient IV diuretics (within 3 months), and D) Concomitant or prior treatment with angiotensin-converting enzyme inhibitor (ACEI)/angiotensin receptor blocker (ARB)/angiotensin receptor-neprilysin inhibitor (ARNI) and beta-blocker.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## VERZENIO

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### Affected Drugs:

Verzenio

**Covered Uses:** All approved FDA indication not otherwise excluded: Hormone Receptor-Positive, HER2 Negative Breast Cancer (ICD10: C50, C50.0, C50.01, C50.011, C50.012, C50.019, C50.02, C50.021, C50.022, C50.029, C50.1, C50.11, C50.111, C50.112, C50.119, C50.12, C50.121, C50.122, C50.129, C50.2, C50.21, C50.211, C50.212, C50.219, C50.22, C50.221, C50.222, C50.229, C50.3, C50.31, C50.311, C50.312, C50.319, C50.32, C50.321, C50.322, C50.329, C50.4, C50.41, C50.411, C50.412, C50.419, C50.42, C50.421, C50.422, C50.429, C50.5, C50.51, C50.511, C50.512, C50.519, C50.52, C50.521, C50.522, C50.529, C50.6, C50.61, C50.611, C50.612, C50.619, C50.62, C50.621, C50.622, C50.629, C50.8, C50.81, C50.811, C50.812, C50.819, C50.82, C50.821, C50.822, C50.829, C50.9, C50.91, C50.911, C50.912, C50.919, C50.92, C50.921, C50.922, C50.929)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Prescribed for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence. 2) Prescribed in combination with an aromatase inhibitor (e.g., anastrozole, exemestane, letrozole, etc.) as initial endocrine-based therapy for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. 3) Prescribed in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy. 4) Prescribed as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## VIREAD

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**Affected Drugs:**

Tenofovir Disoproxil Fumarate  
Viread

**Covered Uses:** All FDA-approved indications not otherwise excluded: Human Immunodeficiency Virus Disease (B20), Chronic Hepatitis B (B18.1)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: a) HIV-1 infection, b) chronic hepatitis B, 2) For HIV: treatment is in combination with other antiretroviral agents

**Age Restrictions:** 1) For HIV-1 infection: 2 years of age or older, 2) For chronic hepatitis B: 12 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## VITAMIN D ANALOGS

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**Affected Drugs:**

Doxercalciferol  
Paricalcitol  
Zemplar

**Covered Uses:** All FDA-approved indications not otherwise excluded: Secondary Hyperparathyroidism (E21.1)

**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): a) Serum Phosphorous: i) For CKD Stage 3 and 4 levels should be 2.7-4.6 mg/dL, ii) For CKD Stage 5 levels should be 3.5-5.5mg/dL, b) Plasmatic IPTH: i) For CKD Stage 3 levels should be greater than 70 pg/mL, ii) For CKD Stage 4 levels should be greater than 110 pg/mL, iii) For CKD Stage 5 levels should be greater than 300pg/mL, c) CMP

**Age Restrictions:** 10 years or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## VONVENDI

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**Affected Drugs:**

Vonvendi

**Covered Uses:** All FDA-approved indications not otherwise excluded: Von Willebrand Disease (ICD10: D68.0)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: Von Willebrand Disease (VWD) for: A) On-demand treatment and control of bleeding episodes, B) Perioperative management of bleeding, or C) Routine prophylaxis to reduce the frequency of bleeding episodes in patients with severe Type 3 von Willebrand disease receiving on-demand therapy. 2) Document: A) Type and severity of bleeding, B) Patient's actual body weight, and C) Factor deficiency level.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 1) For on-demand or perioperative treatment: 1 month, or 2) For routine prophylaxis: 3 months

**Other Criteria:** 1) Validate if drugs that requires intravenous infusion administration are covered under the Pharmacy benefit. Normally these drugs are not covered under the Pharmacy benefit. 2) For dosage and administration refer to package insert. 3) Routine prophylaxis to reduce the frequency of bleeding episodes is usually not covered under the Pharmacy benefit, validate coverage. 4) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## VOTRIENT

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**Affected Drugs:**

PAZOPanib HCl

Votrient

**Covered Uses:** All FDA-approved indications not otherwise excluded: Advanced Renal Cell Carcinoma (C64, C64.9), Advanced Soft Tissue Sarcoma (C49, C49.9)

**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 and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## VPRIV

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**Affected Drugs:**

Vpriv

**Covered Uses:** All FDA-approved indications not otherwise excluded: Gaucher Disease Type 1 (E75.22)

**Exclusion Criteria:**1) Type 2 or 3 Gaucher disease

**Required Medical Information:**1) Diagnosis: type 1 Gaucher disease

**Age Restrictions:** 4 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## XALKORI

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### **Affected Drugs:**

Xalkori

**Covered Uses:** All FDA-approved indications not otherwise excluded: Non-Small-Cell Lung Carcinoma (ICD10: C34, C34.9, C34.90), Systemic Anaplastic Large Cell Lymphoma (ICD10: C84.68, C84.78), Myofibroblastic Tumor (Inflammatory Myofibroblastic Tumor)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Metastatic non-small cell lung cancer (NSCLC), B) Relapsed or refractory systemic anaplastic large cell lymphoma (ALCL) or C) Inflammatory myofibroblastic tumor (IMT). 2) Document: A) For NSCLC: Positive results for anaplastic lymphoma kinase (ALK) or ROS-1 mutation, 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), C) For IMT: i) Tumor is unresectable, recurrent or refractory, ii) Positive results for anaplastic lymphoma kinase (ALK) and iii) For pediatric patients: Patient's body surface area (BSA) or actual body weight and height (BSA-based dosing)

**Age Restrictions:** 1) For NSCLC: 18 years of age and older, 2) For ALCL and IMT: 1 year of age and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) FDA-approved companion diagnostic tests are FoundationOne CDx, VENTANA ALK (D5F3) CDx Assay, Oncomine Dx Target Test, and Vysis ALK Break Apart FISH Probe Kit. 2) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## XELJANZ

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### **Affected Drugs:**

Xeljanz  
Xeljanz XR

**Covered Uses:** All FDA-approved indications not otherwise excluded: Rheumatoid Arthritis (ICD10: M06, M06.9), Ulcerative Colitis (Ulcerated Colon) (ICD10: K51), Ankylosing Spondylitis (Rheumatic Disease causing Vertebrae Inflammation) (ICD10: M45, M45.9), Psoriatic Arthritis (Psoriasis associated with Arthritis) (ICD10: L40.5, L40.50), Polyarticular Juvenile Idiopathic Arthritis (ICD10: M08.09)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Treatment of moderately to severely active rheumatoid arthritis (RA) in patients who have had an inadequate response or intolerance to Methotrexate. B) Treatment of active psoriatic arthritis (PsA) in patients who have had an inadequate response or intolerance to methotrexate. C) Treatment of active ankylosing spondylitis (AS). D) Treatment of moderately to severely active ulcerative colitis (UC) in patients who have had an inadequate response or who are intolerant to TNF blockers. E) Treatment of active polyarticular course juvenile idiopathic arthritis (PJIA). 2) Document: A) For RA: i) Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, hydroxychloroquine, leflunomide) and ii) Inadequate response or intolerance to one or more TNF blockers. B) For PsA: i) Therapeutic failure to at least one disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine) and ii) Inadequate response or intolerance to one or more TNF blockers. C) For AS: i) Therapeutic failure to at least one nonsteroidal anti-inflammatory drug (NSAID) (e.g., celecoxib, naproxen, sulindac, etc.) and ii) Inadequate response or intolerance to one or more TNF blockers. D) For UC: i) Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, hydrocortisone, mercaptopurine, mesalamine, sulfasalazine, etc.) and ii) Inadequate response or intolerance to one or more TNF blockers. E) For PJIA (only for Xeljanz and Xeljanz Oral Solution): i) Therapeutic failure to methotrexate, ii) Inadequate response or intolerance to one or more TNF blockers and iii) Patient's actual body weight (weight-based dosing). F) For all indications: Only for biologic therapy-naïve patients: Physician's certification stating tuberculosis (TB) status or result of a TB detection test with a reading date less than 12 months before the start of therapy.

**Age Restrictions:** 1) For AS, PsA, RA, or UC: 18 years of age or older. 2) For PJIA (Xeljanz and Xeljanz Oral Solution): 2 years of age or older

**Prescription Order Restrictions:** N/A

**Coverage Duration:**12 months

**Other Criteria:** N/A

## XENICAL

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**Affected Drugs:**

Xenical

**Covered Uses:** All FDA-approved indications not otherwise excluded: Obesity (ICD10: E66, E66.9)

**Exclusion Criteria:** 1) Pregnancy. 2) Chronic malabsorption syndrome. 3) Cholestasis.

**Required Medical Information:** 1) Diagnosis: A) For obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet, or B) To reduce the risk for weight regain after prior weight loss. 2) Document: Body mass index (BMI) greater than or equal to 30 kg/m<sup>2</sup>, or greater than or equal to 27 kg/m<sup>2</sup> in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). 3) For renewals: At least a 5% reduction in baseline body weight (actual BMI or weight and height).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 3 months

**Other Criteria:** For FEHB renewals: Validate patient is currently enrolled in obesity management program.

## XIFAXAN

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**Affected Drugs:**

Xifaxan

**Covered Uses:** All FDA-approved indications not otherwise excluded: Irritable Bowel Syndrome (K58, K58.9), Hepatic Encephalopathy (K72.9, K72.90)

**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: 12 months

**Other Criteria:** For IBS-D, therapy will be discontinued after a lifetime total of 42 days.

## **XIIDRA**

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**Affected Drugs:**

Xiidra

**Covered Uses:** All FDA-approved indications not otherwise excluded: Dry Eye Syndrome (H04.12)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Failure to conventional lubricants or corticosteroids agents. If patient had corneal issues, does not require previous use of lubricants.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** N/A

## XOLAIR

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### Affected Drugs:

Xolair

**Covered Uses:** All FDA-approved indications not otherwise excluded: Asthma (ICD10: J45, J45.9, J45.90), Chronic Idiopathic Urticaria (Persistent Hives of Unknown Cause) (ICD10: L50.1), Severe Persistent Asthma (ICD10: J45.5), Nasal Polyposis (Presence of Polyps in the Nose) (ICD10: J33, J33.9)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Moderate to severe persistent asthma, B) Chronic idiopathic urticaria, C) Nasal polyps or D) For the reduction of IgE-mediated food allergic reactions. 2) Document: A) For asthma: i) Positive skin test or in vitro reactivity to a perennial aeroallergen, ii) Symptoms are inadequately controlled with corticosteroids and another controller therapy (e.g., long-acting beta agonist or leukotriene receptor antagonist) for at least 3 months, and iii) Patient's actual body weight and serum total IgE level (IU/mL, for dose validation). B) For urticaria: Therapeutic failure to antihistamine, leukotriene inhibitors or immunosuppressive therapies. C) For nasal polyps: i) Prescribed as add-on maintenance treatment (validate other treatment), ii) Inadequate response or contraindication to nasal corticosteroids and iii) Serum total IgE level (IU/mL, for dose validation), D) For IgE mediated food allergic reactions: i) Documentation of patient history of severe allergic reactions (i.e hives, persistent coughing, vomiting) to foods (i.e peanut, milk, egg, wheat, cashew, hazelnut, walnut) AND ii) Patient's actual body weight and serum total IgE level (IU/mL, for dose validation)

**Age Restrictions:** 1) For asthma: 6 years of age or older, 2) For urticaria: 12 years of age or older, 3) For nasal polyps: 18 years of age or older, 4) For IgE mediated food allergic reactions: 1 year of age and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Xolair prefilled syringe may be self-administered by patients 12 years of age and older under adult supervision, for pediatric patients 1 -11 years Xolair prefilled syringe should be administered by a caregiver. Xolair autoinjectors are not intended for patients under 12 years of age. Refer to package insert for dosing recommendations.

## XTANDI

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**Affected Drugs:**

Xtandi

**Covered Uses:** All FDA-approved indications not otherwise excluded: Hormone-Refractory Malignant Neoplasm of Prostate (ICD10: C61)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Diagnosis: A) Metastatic castration-resistant prostate cancer (mCRPC), B) Non-metastatic castration resistant prostate cancer (nmCRPC), C) Metastatic castration-sensitive prostate cancer (mCSPC) or D) Non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis. 2) For mCRPC, nmCRPC and mCSPC Document: Patient is receiving a gonadotropin-releasing hormone (GnRH) analog concurrently (e.g., leuprolide, goserelin, triptorelin, or histrelin) or had a bilateral orchiectomy. 3) Patients with nmCSPC with biochemical recurrence at high risk for metastasis may be treated with or without a GnRH analog.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## XYREM

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**Affected Drugs:**

Xyrem

**Covered Uses:** All FDA-approved indications not otherwise excluded: Narcolepsy (G47.4, G47.41), Cataplexy with associated Narcolepsy (G47.411)

**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:** 12 months

**Other Criteria:** N/A

## ZAVESCA/MIGLUSTAT

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**Affected Drugs:**

migLUstat  
Zavesca

**Covered Uses:** All FDA-approved indications not otherwise excluded: Gaucher s Disease (E75.22)

**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:** 12 months

**Other Criteria:** N/A

## **ZEJULA**

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### **Affected Drugs:**

Zejula

**Covered Uses:** All approved FDA indication not otherwise excluded: Malignant Neoplasm of Ovary (Cancer of the Ovary) (ICD10: C56, C56.2, C56.9), Malignant Neoplasm of Fallopian Tube (Fallopian Tube Cancer) (ICD10: C57.0, C57.00), Malignant Neoplasm of Peritoneum (Cancer of the Abdominal Cavity) (ICD10: C48, C48.2, C48.8)

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

**Required Medical Information:** 1) Diagnosis: A) Maintenance Treatment of Adult Patients with Advanced Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Advanced Cancer), B) Maintenance Treatment of Adult Patients with Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Recurrent Cancer). 2) Document: A) For Maintenance Treatment of Advanced Cancer: Patient is in a complete or partial response to first-line platinum-based chemotherapy (e.g., carboplatin, cisplatin). B) For Maintenance Treatment of Recurrent Cancer: 1) Patients has deleterious or suspected deleterious germline BRCA-mutated disease AND 2) Patient is in a complete or partial response to platinum-based chemotherapy (e.g., carboplatin, cisplatin). C) For First-Line Maintenance Treatment of Advanced Ovarian Cancer: i) Patient's actual body weight and ii) Platelet count.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** 1) Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## ZELBORAF

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**Affected Drugs:**

Zelboraf

**Covered Uses:** All FDA-approved indications not otherwise excluded: Metastatic Malignant Melanoma (C43, C43.9, C79.9), Unresectable Melanoma (C43, C43.9), Erdheim-Chester Disease (C94.6, D47.1, D76.3)

**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 and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## ZEPOSIA

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### **Affected Drugs:**

Zeposia

Zeposia 7-Day Starter Pack

Zeposia Starter Kit

**Covered Uses:** All FDA-approved indications not otherwise excluded: Ulcerative Colitis (ICD10: K51), Relapsing, Remitting Multiple Sclerosis (ICD10: G35), Secondary Progressive Multiple Sclerosis (ICD10: G35), Clinically Isolated Syndrome (First Clinical Episode Suggestive of Multiple Sclerosis) (ICD10: G37.8)

**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 (all indications): Electrocardiogram (ECG) result (to determine preexisting conduction abnormalities, see Other Criteria). B) For MS: Patients must have documented previous use and therapeutic failure, intolerance or contraindication to at least one generic therapeutic alternative (e.g., dimethyl fumarate, fingolimod, glatiramer acetate). C) For UC: i) Therapeutic failure to at least one conventional drug (e.g., azathioprine, budesonide, hydrocortisone, mercaptopurine, mesalamine, sulfasalazine, etc.) and ii) Prior use of at least one formulary preferred drugs (e.g. infliximab biosimilar, Humira or preferred biosimilar, Stelara or biosimilar, Xeljanz, if available).

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** If ECG result is not available, the physician needs to provide a statement indicating that the patient has been evaluated for cardiovascular risk and does not have preexisting conduction abnormalities nor meet exclusion criteria.

## ZOLINZA

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**Affected Drugs:**

Zolinza

**Covered Uses:** All FDA-approved indications not otherwise excluded: Cutaneous T-Cell Lymphoma (C84.09, C84.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

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## ZURZUVAE

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**Affected Drugs:**

Zurzuvae

**Covered Uses:** All FDA-approved indications not otherwise excluded: Postpartum Depression (F53.0)

**Exclusion Criteria:** N/A

**Required Medical Information:** 1) Physician attestation of moderate to severe PPD diagnosis 2) Patient is less than or equal to 12 months PP, 3) Patient has therapeutic failure or contraindication to at least two generic SSRI or SNRI (e.g fluoxetine, sertraline, venlafaxine) for PPD

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 14 days

**Other Criteria:** N/A

## ZYDELIG

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**Affected Drugs:**

Zydelig

**Covered Uses:** All FDA-approved indications not otherwise excluded: Chronic Lymphocytic Leukemia (ICD10: C91.1)

**Exclusion Criteria:** History of toxic epidermal necrolysis

**Required Medical Information:** 1) Diagnosis: Treatment of relapsed chronic lymphocytic leukemia (CLL). 2) Document: 1) Prescribed in combination with rituximab, and 2) Therapeutic failure to at least one prior systemic therapy.

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

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## ZYTIGA

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**Affected Drugs:**

Abiraterone Acetate

Zytiga

**Covered Uses:** All FDA-approved indications not otherwise excluded: Metastatic Hormone-Refractory Prostate (C61, C79, C79.9), Metastatic High-Risk Castration-Sensitive Prostate Cancer (Z19.1)

**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 of age and older

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:** Validate that the treatment regimen is following the most up to date NCCN guidelines recommendations.

## ZYVOX/LINEZOLID

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### **Affected Drugs:**

Linezolid

Zyvox

**Covered Uses:** All FDA-approved indications not otherwise excluded: Uncomplicated Skin and Skin Structure Infection (ICD10: L08, L08.9), Complicated Skin & Skin Structure Infection (ICD10: L08, L08.9), Community Acquired Pneumonia (ICD10: J18, J18.9), Hospital-Acquired Pneumonia (ICD10: J18.9, Y95), Infection due to Enterococcus (ICD10: B95, B95.2), Resistance to Vancomycin (ICD10: Z16.21)

**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), vasopressive agents (e.g. epinephrine, norepinephrine), or dopaminergic agents (e.g. dopamine, dobutamine) (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.

**Age Restrictions:** N/A

**Prescription Order Restrictions:** N/A

**Coverage Duration:** 10 to 28 days (see Other Criteria)

**Other Criteria:** For type of infections specific coverage duration refer to package insert

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