# Geisinger Medicare 2021 Prior Authorization Criteria

GHP Medicare Formulary - Prior Authorization Criteria

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### **ABILIFY MYCITE**

#### Affected Drugs:

Abilify MyCite Abilify MyCite Maintenance Kit Abilify MyCite Starter Kit

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

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

**Required Medical Information:**Diagnosis of schizophrenia OR diagnosis of acute treatment of mania and mixed episodes or maintenance treatment of Bipolar I disorder as either monotherapy or as adjunct to lithium or valproate OR diagnosis of use as adjunctive treatment of major depressive disorder.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:N/A

#### Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of the need to monitor drug ingestion and documentation of access to a compatible smart phone. For schizophrenia and Bipolar I disorder: documentation of reason why aripiprazole oral tablets AND Abilify Maintena cannot be used. For adjunctive treatment of major depressive disorder: documentation of use as adjunctive therapy AND documentation of reason why aripiprazole oral tablets cannot be used.

#### ABRAXANE

Affected Drugs: Abraxane

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF BREAST CANCER OR DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) OR DIAGNOSIS OF METASTATIC ADENOCARCINOMA OF THE PANCREAS.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FOR BREAST CANCER: DOCUMENTATION OF FAILURE ON COMBINATION CHEMOTHERAPY FOR METASTATIC DISEASE OR RELAPSE WITHIN 6 MONTHS OF ADJUVANT CHEMOTHERAPY AND DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ANTHRACYCLINE AND DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO STANDARD PACLITAXEL THERAPY. FOR NSCLC: DOCUMENTATION OF ABRAXANE USED AS FIRST-LINE TREATMENT IN COMBINATION WITH CARBOPLATIN WHO ARE NOT CANDIDATES FOR CURATIVE SURGERY OR RADIATION THERAPY. FOR ADENOCARCINOMA OF PANCREAS: DOCUMENTATION OF USE IN COMBINATION WITH GEMCITABINE. Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

# Affected Drugs:

Actemra

Off-Label Uses:N/A

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

**Required Medical Information:**DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS. DX OF ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (JIA) AND PRESCRIPTION WRITTEN FOR IV FORMULATION. DX OF ACTIVE POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS AND PRESCRIPTION WRITTEN FOR IV FORMULATION. DX OF CHIMERIC ANTIGEN RECEPTOR (CAR) T CELL-INDUCED SEVERE OR LIFE-THREATENING CYTOKINE RELEASE SYNDROME.

**Age Restrictions:**FOR JIA and CRS: MUST BE 2 YEARS OF AGE OR OLDER. FOR RA: MUST BE 18 YEARS OF AGE OR OLDER.

#### Prescription Order Restrictions: RHEUMATOLOGIST

#### Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria:FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF (1) HUMIRA AND (2) RINVOQ ER OR XELJANZ. FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA AND XELJANZ. FOR CONTINUED THERAPY. MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION. DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT.

Affected Drugs: Actemra Actemra ACTPen

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS. DX OF GIANT CELL ARTERITIS. DX OF SYSTEMIC OR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS. DX OF SYSTEMIC SCLEROSIS ACCORDING TO THE AMERICAN COLLEGE OF RHEUMATOLOGY (ACR) AND EUROPEAN LEAGUE AGAINST RHEUMATISM (EULAR).

**Age Restrictions:**For giant cell arteritis and SSc-ILD: 18 years of age or older. For RA and SJIA/PJIA: must be 2 years of age or older.

Prescription Order Restrictions: RHEUMATOLOGIST or PULMONOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF (1) HUMIRA AND (2) RINVOQ ER OR XELJANZ. FOR GIANT CELL ARTERITIS, DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH ORAL GLUCOCORTICOIDS. FOR PJIA: FAILURE ON, CONTRAINDICATION TO OR INTOLERANCE TO A MINIMUM 3 MONTH TRIAL OF HUMIRA. FOR SSc-ILD: DOCUMENTATION OF GREATER THAN OR EQUAL TO 10% FIBROSIS ON A CHEST HIGH RESOLUTION COMPUTER TOMOGRAPHY and FVC GREATER THAN OR EQUAL TO 40% OF PREDICTED NORMAL and DLCO 30-89% OF PREDICTED NORMAL. DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

#### ACTIQ

#### **Affected Drugs:**

fentaNYL Citrate

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF USE TO MANAGE BREAKTHROUGH CANCER PAIN IN PATIENTS WITH CANCER

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**CONCOMITANT MORPHINE 60 MG/DAY OR MORE, TRANSDERMAL FENTANYL 25 MCG/H, OXYCODONE 30 MG/DAY, ORAL HYDROMORPHONE 8 MG/DAY, OR AN EQUIANALGESIC DOSE OF ANOTHER OPIOID FOR 1 WEEK OR LONGER.

#### ADAKVEO

Affected Drugs:

Adakveo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of diagnosis of sickle cell disease.

Age Restrictions: MUST BE 16 YEARS OF AGE OR OLDER

Prescription Order Restrictions: by or in consultation with a hematologist

Coverage Duration:12 MONTHS

**Other Criteria**:Documentation of number of vasoocclusive crises in the previous 12 months. Documentation of intolerance to, contraindication or therapeutic failure on 3 month trial of hydroxyurea AND Endari. Reauthorization will require documentation of continued or sustained improvement in the acute complications of sickle cell disease (i.e., decrease in vasoocclusive crises, hospitalizations, and number of acute chest syndrome (ACS) occurrences).

# Affected Drugs:

Adasuve

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF USE FOR THE ACUTE TREATMENT OF AGITATION ASSOCIATED WITH SCHIZOPHRENIA OR BIPOLAR I DISORDER. DOCUMENTATION THAT THERE IS NO CURRENT DIAGNOSIS OR HISTORY OF ASTHMA, COPD, OR OTHER LUNG DISEASE ASSOCIATED WITH BRONCHOSPASM.

Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE IMMEDIATE RELEASE FORMULARY ANTIPSYCHOTIC INCLUDING BUT NOT LIMITED TO ARIPIPRAZOLE, CHLORPROMAZINE, HALOPERIDOL, OLANZAPINE, QUETIAPINE, RISPERIDONE, OR ZIPRASIDONE. MUST BE ADMINISTERED IN AN ENROLLED HEALTHCARE FACILITY WITH IMMEDIATE, ON-SITE RESOURCES TO MANAGE BRONCHOSPASM AND/OR RESPIRATORY DISTRESS. Affected Drugs: Adcetris

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Dx of classical Hodgkin Lymphoma (cHL) AND documentation of failure of autologous hematopoietic stem cell transplant or failure of at least 2 multi-agent chemotherapy regimens in those who are not candidates for auto-HSCT or documentatation of use as consolidation treatment following auto-HSCT in patients with high risk or relapse or progression post-auto-HSCT. Dx of systemic anaplastic large cell lymphoma AND documentation of failure of at least 1 prior multi-agent chemotherapy regimen. Dx of primary cutaneous anaplastic large cell lymphoma or CD30 expressing mycosis fungoides AND documentation of failure of prior radiation or systemic therapy. Dx of previously untreated stage III or IV cHL AND documentation that medication will be used in combination with chemotherapy.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: for stage III or IV cHL: 6 months. All other indications: remainder of contract year

**Other Criteria:**Subsequent approval will require documentation of continued disease improvement or lack of disease progression. Authorization beyond 6 months for stage III or IV cHL will require documentation of well-controlled, peer-reviewed literature with evidence to support treatment beyond 6 months.

### ADCIRCA

#### Affected Drugs:

Alyq Tadalafil (PAH)

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF PULMONARY ARTERIAL HYPERTENSION.

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**DOCUMENTATION OF ONE OF THE FOLLOWING: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL AND LETAIRIS or DOCUMENTATION OF USE AS FIRST LINE THERAPY IN COMBINATION WITH LETAIRIS IN PATIENTS WITH WHO GROUP 1 PAH

Affected Drugs:

Adempas

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**WHO FUNCTIONAL CLASS II, III, OR IV SYMPTOMS AND EITHER DOCUMENTATION OF WHO GROUP 1 PULMONARY ARTERIAL HYPERTENSION OR CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) (WHO GROUP 4) WHICH IS INOPERABLE OR PREVIOUSLY TREATED SURGICALLY.

Age Restrictions:N/A

Prescription Order Restrictions: CARDIOLOGIST OR PULMONOLOGIST

#### Coverage Duration:6 MONTHS

Other Criteria: CHRONIC-THROMBOEMBOLIC PULMONARY HYPERTENSION: DOCUMENTATION OF A BASELINE 6-MINUTE WALKING DISTANCE. 6 MONTH REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF AN IMPROVEMENT IN 6-MINUTE WALKING DISTANCE FROM BASELINE OR IMPROVED OR STABLE DIAGNOSIS OF WHO FUNCTIONAL CLASS. PULMONARY ARTERIAL HYPERTENSION: DOCUMENTATION OF A BASELINE 6-MINUTE WALKING DISTANCE. FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO BOSENTAN, OR DOCUMENTATION OF USE IN COMBINATION WITH BOSENTAN. 6 MONTH REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF AN IMPROVEMENT IN 6-MINUTE WALKING DISTANCE FROM BASELINE OR IMPROVED OR STABLE DIAGNOSIS OF WHO FUNCTIONAL CLASS.

#### AFINITOR

# Affected Drugs:

Afinitor Everolimus

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

#### Exclusion Criteria:N/A

**Required Medical Information:**DX OF RENAL CELL CARCINOMA. DX OF HORMONE-RECEPTOR POSITIVE, HER-2 NEGATIVE ADVANCED BREAST CANCER. DX OF PROGRESSIVE NEUROENDOCRINE TUMORS OF PANCREATIC ORIGIN (PNET) THAT IS UNRESCTABLE, LOCALLY ADVANCED OR METASTATIC. DX OF PROGRESSIVE, WELL DIFFERENTIATED, NON-FUNCTIONAL NEUROENDOCRINE TUMORS OF GASTROINTESTINAL (GI) ORIGIN OR LUNG ORIGIN THAT ARE UNRESECTABLE, LOCALLY ADVANCED, OR METASTATIC. DX OF SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) ASSOCIATED WITH TUBEROUS SCLEROSIS (TS) WHO REQUIRE THERAPEUTIC INTERVENTION BUT ARE NOT CANDIDATES FOR CURATIVE SURGICAL RESECTION. DX OF RENAL ANGIOMYOLIPOMA AND TUBUEROUS SCLEROSIS COMPLEX/SPORADIC LYMPHANGIOLEIOMYMATOSIS NOT REQUIRING IMMEDIATE SURGERY.

#### Age Restrictions:N/A

**Prescription Order Restrictions:**ONCOLOGIST, NEPHROLOGIST, UROLOGIST, or NEUROLOGIST

#### Coverage Duration:12 MONTHS

Other Criteria:FOR RENAL CELL CARCINOMA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SUTENT or NEXAVAR AND OPDIVO. FOR BREAST CANCER: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO PREVIOUS ENDOCRINE THERAPY TREATMENT AND EVEROLIMUS MUST BE USED IN COMBINATION WITH AN AROMATASE INHIBITOR. FOR RENAL ANGIOMYOLIPOMA AND TUBUEROUS SCLEROSIS COMPLEX/SPORADIC LYMPHANGIOLEIOMYMATOSIS: AT LEAST ONE ANGIOMYOLIPOMA OF GREATER THAN OR EQUAL TO 3CM IN LONGEST DIAMETER ON CT/MRI BASED ON LOCAL RADIOLOGY ASSESSMENT. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### AFINITOR DISPERZ

#### Affected Drugs:

Afinitor Disperz Everolimus

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

Exclusion Criteria:N/A

**Required Medical Information:**Diagnosis of Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) who require therapeutic intervention but are not candidates for curative surgical resection OR adjunctive treatement of of Tuberous Sclerosis Complex (TSC) associated partial-onset seizures

#### Age Restrictions:N/A

#### Prescription Order Restrictions: ONCOLOGIST OR NEUROLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**For TSC associated partial onset seizures: documentation of a therapeutic failure on, intolerance to, or contraindication to 2 anti-epileptic drug (AED) regimens. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

#### AIMOVIG

# Affected Drugs:

Aimovig

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

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

**Required Medical Information:**Diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria AND documentation of the number of baseline migraine or headache days per month.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:N/A

#### Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**Provider attestation of a therapeutic failure on, intolerance to, or contraindication to at least two of the following: one beta blocker (i.e., metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine. Attestation that medication is not being used concurrently with botulinum toxin OR if being used in combination attestation of the following: therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND attestation of a therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist. Reauthorization will require attestation of continued or sustained reduction in migraine or headache frequency or a decrease in severity or duration of migraine AND either attestation that the medication is not being used concurrently with botulinum toxin OR if the request is for combination use with Botox attestation of the following: previous therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND either attestation that the medication is not being used concurrently with botulinum toxin OR if the request is for combination use with Botox attestation of the following: previous therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND attestation of a previous therapeutic failure on a minimum 6 month trial of at least one CGRP antagonist without the concomitant use of Botox AND attestation of a previous therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist.

#### AJOVY

# Affected Drugs:

Ajovy

Off-Label Uses:N/A

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

**Required Medical Information:**Documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria AND documentation of the number of baseline migraine or headache days per month.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:N/A

#### Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria**:Documentation of a therapeutic failure on, intolerance to, or contraindication to Emgality and Aimovig. Documentation that medication is not being used concurrently with botulinum toxin OR if being used in combination documentation of the following: therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND documentation of a therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist. Reauthorization will require documentation of continued or sustained reduction in migraine or headache frequency or a decrease in severity or duration of migraine AND either documentation use with Botox documentation of the following: previous therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND either documentation the medication is not being used concurrently with botulinum toxin OR if the request is for combination use with Botox documentation of the following: previous therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND documentation of a previous therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of Botox AND documentation of a previous therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of Botox AND documentation of a previous therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of Botox AND documentation of a previous therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist.

# Affected Drugs:

Akynzeo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**:DOCUMENTATION OF USE FOR THE PREVENTION OF CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING IN PATIENTS WHO ARE RECEIVING MODERATELY TO HIGHLY EMETOGENIC CHEMOTHERAPY, INCLUDING, BUT ARE NOT LIMITED TO REGIMENS CONTAINING BENDAMUSTINE, CARBOPLATIN, CISPLATIN, CYCLOPHOSPHAMIDE, DACARBAZINE, DOXORUBICIN, IFOSFAMIDE, IRINOTECAN, OXALIPLATIN, AND TEMOZOLOMIDE

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

#### ALDURAZYME

#### Affected Drugs:

Aldurazyme

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF HURLER FORM OF MPS I OR HURLER-SCHEIE FORM OF MPS I OR SCHEIE FORM OF MPS WITH MODERATE TO SEVERE SYMPTOMS

Age Restrictions:N/A

**Prescription Order Restrictions:**METABOLIC SPECIALIST OR GENETICIST WITH EXPERIENCE TREATING MUCOPOLYSACCHARIDOSIS

Coverage Duration:12 MONTHS

Other Criteria:N/A

GHP Medicare Formulary - Prior Authorization Criteria

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#### ALECENSA

Affected Drugs:

Alecensa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF ALK-POSITIVE, METASTATIC NON-SMALL CELL LUNG CANCER.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

#### ALINIA

#### Affected Drugs:

Alinia Nitazoxanide

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DOCUMENTATION OF DIARRHEA CAUSED BY GIARDIA LAMBLIA OR CRYPTOSPORIDIUM PARVUM

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**N/A

GHP Medicare Formulary - Prior Authorization Criteria

### ALIQOPA

Affected Drugs: Aliqopa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of relpased follicular lymphoma (FL) with documentation of failure on, intolerance to, or contraindication to at least two prior systemic therapies

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression

GHP Medicare Formulary - Prior Authorization Criteria

#### Affected Drugs:

Palonosetron HCI

Off-Label Uses:N/A

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

**Required Medical Information:**Documentation of use for prevention of chemotherapy induced nausea or vomiting from low or minimally emetogenic chemotherapy OR documentation of use for prevention of acute or delayed nausea and vomiting associated with initial and repeat courses of moderately or highly emetogenic chemotherapy

#### Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

#### Coverage Duration:12 MONTHS

**Other Criteria:**For low or minimally emetogenic chemotherapy: treatment failure or contraindication to granisetron or ondansetron. Treatment failure is defined as an allergy, intolerable side effects, significant drug-drug interaction, or lack of efficacy

## ALUNBRIG

#### Affected Drugs:

Alunbrig

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of ALK-positive, metastatic non-small cell lung cancer

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## Affected Drugs:

Amondys 45

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

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

**Required Medical Information:**Diagnosis of Duchenne's Muscular Dystrophy confirmed by genetic testing with mutation of the DMD gene that is amenable by exon 45 skipping confirmed by a genetic counselor AND documentation that medication is being given concurrently with oral corticosteroids unless contraindicated or intolerant AND documentation that the patient is ambulatory (able to walk with assistance, not wheelchair bound) as proven by documentation of a 6-minute walk test distance within the past 3 months of initiation of Amondys

#### Age Restrictions:N/A

#### Prescription Order Restrictions: NEUROLOGIST OR GENETIC SPECIALIST

#### Coverage Duration:6 MONTHS

**Other Criteria**:Documentation of a dose consistent with the FDA approved labeling. Reauthorization will require documentation of continued benefit from treatment, documentation of continued concurrent use with oral corticosteroids, documentation of a dose consistent with FDA approved labeling, and documentation that the patient remains ambulatory as proven by documentation of a follow up 6 minute walk test distance within the past 6 months

## Affected Drugs:

Trihexyphenidyl HCI

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF EXTRAPYRAMIDAL SIDE EFFECTS (EPS) OR PARKINSON'S DISEASE

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**PRIOR AUTHORIZATION APPLIES ONLY TO MEMBERS 65 YEARS OF AGE AND OLDER WHO WILL BE EVALUATED FOR APPROPRIATE USE OF HIGH RISK MEDICATION. DIAGNOSIS OF EPS WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AMANTADINE. DIAGNOSIS OF PARKINSON'S WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: CARBIDOPA/LEVODOPA, PRAMIPEXOLE, ROPINIROLE.

## APTIOM

#### Affected Drugs:

Aptiom

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DIAGNOSIS OF PARTIAL ONSET SEIZURES

Age Restrictions: MUST BE 4 YEARS OF AGE OR OLDER

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ALTERNATIVES ONE OF WHICH MUST BE OXCARBAZEPINE.

## ARALAST

#### Affected Drugs:

Aralast NP Prolastin-C

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF PANACINAR EMPHYSEMA

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION OF A DECLINE IN FORCED EXPIRATORY VOLUME IN 1 SECOND (FEV1) DESPITE OPTIMAL MEDICAL THERAPY (BRONCHODILATORS, CORTICOSTEROIDS, OXYGEN IF INDICATED) AND DOCUMENTATION OF PHENOTYPE ASSOCIATED WITH CAUSING SERUM ALPHA 1-ANTITRYPSIN OF LESS THAN 80 MG/DL AND DOCUMENTATION OF AN ALPHA 1-ANTITRYPSIN SERUM LEVEL BELOW THE VALUE OF 35% OF NORMAL (LESS THAN 80 MG/DL).

## Affected Drugs:

Aranesp (Albumin Free)

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

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

**Required Medical Information:**TX OF ANEMIA OF CHRONIC RENAL INSUFFICIENCY, CHRONIC RENAL FAILURE, INCLUDING ESRD and HEMOGLOBIN (HGB) MUST BE LESS THAN OR EQUAL TO 10GM/DL FOR NEW STARTS or LESS THAN 10 GM/DL FOR CONTINUATION OF THERAPY FOR CKD NOT ON DIALYSIS, LESS THAN 11 GM/DL FOR CKD ON DIALYSIS, OR LESS THAN 12 GM/DL FOR PEDIATRIC CKD, OR DOCUMENTATON THAT THE DOSE WILL BE REDUCED OR INTERRUPTED. TX OF ANEMIA IN NON-MYELOID MALIGNANCY - MUST BE ON ANEMIA CAUSING CHEMO AND THERE IS A MINIMUM OF TWO ADDITIONAL MONTHS OF PLANNED CHEMOTHERAPY and HGB MUST BE LESS THAN OR EQUAL TO 10GM/DL FOR NEW STARTS or LESS THAN 10 GM/DL FOR CONTINUATION OF THERAPY or DOCUMENTATON THAT THE DOSE WILL BE REDUCED OR INTERRUPTED. FOR ALL INDICATIONS: DOCUMENTATION OF ADEQUATE IRON STORES W/ SERUM FERRITIN GREATER THAN 100 NG/ML OR TRANSFERRIN LEVEL SATURATION GREATER THAN 20% OR A HISTORY OF CHELATION THERAPY FOR IRON.

#### Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

#### Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATION WILL REQUIRE REPEAT HGB (WITHIN 3 MONTHS OF REAUTH) AND FERRITIN OR TSAT LEVELS (WITHIN 6 MONTHS OF REAUTH). THIS DRUG MAY BE EITHER BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION.

Affected Drugs: Arcalyst

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF CRYOPYRIN-ASSOCIATED PERIODIC SYNDROME (CAPS), INCLUDING FAMILIAL COLD AUTOINFLAMMATORY SYNDROME (FCAS), AND MUCKLE-WELLS SYNDROME (MWS) SUPPORTED BY DOCUMENTATION OF GENETIC TESTING TO IDENTIFY THE CIAS1/NLRP-3 GENE MUTATION. Dx of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) supported by documentation of a homozygous or compound heterozygous mutation in IL 1 RN (Interleukin 1 Receptro Antagonist gene) AND documentation that medication is being used for maintenance of remission of DIRA. Dx of Recuurent Pericarditis (RP) as evidenced by a recurrence of pericarditis after a symptom free interval of 4 to 6 weeks or longer following a documented epeisode of acute pericarditis.

Age Restrictions: FOR RECURRENT PERICARDITIS: 12 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**IMMUNOLOGIST, RHEUMATOLOGIST, PEDIATRICIAN, ALLERGIST CARDIOLOGIST, GENETICIST, DERMATOLOGIST OR PROVIDER SPECIALIZING IN THE TREATMENT OF AUTOINFLAMMATORY DISORDERS

Coverage Duration:3 MONTHS INITIAL, 12 MONTHS CONTINUATION

**Other Criteria:**FOR CAPS: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO KINERET AND ILARIS. REAUTHORIZATION WITH REQUIRE CONTINUED IMPROVEMENT IN THE SIGNS AND SYMPTOMS OF THE DISEASE. For DIRA: Documentat of a member weight reater tha or equal to 10 kg AND documentation of remission of DIRA that was indcuced by anakinra AND documentation of therapeutic failure, intolerance or contraindication of continuing anakinra. For RP: documentation of a therapeutic failure on, intolerance to, or contraindication to (1) colchicine AND (2) a nonsteroidal antiinflammatory drug (NSAID) or aspirin. Reauthorization will require medical record documentation showing maintenance or improvement of condition.

### **ARISTADA INITIO**

## Affected Drugs:

Aristada Initio

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

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

**Required Medical Information:**Documentation of a diagnosis of schizophrenia AND documentation that medication is being used for treatment initiation with transition to Aristada.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:N/A

#### Coverage Duration:1 MONTH

**Other Criteria:**Documentation that Aristada Initio will be given as a single dose in combination with one 30 mg dose of oral aripiprazole and the first month's dose of Aristada. Documentation of a therapeutic failure on or intolerance to the oral equivalent form of the medication.

#### ARRANON

## Affected Drugs:

Arranon

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF T-CELL ACUTE LYMPHOBLASTIC LEUKEMIA OR T-CELL LYMPHOBLASTIC LYMPHOMA

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**DOCUMENTATION OF FAILURE TO RESPOND TO, OR RELAPSE FOLLOWING TREATMENT WITH A MINIMUM OF 2 CHEMOTHERAPY REGIMENS. Reauthorizations will require documentation of continued disease improvement or lack of disease progression

## ARZERRA

#### Affected Drugs:

Arzerra

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION THAT CLL IS REFRACTORY TO BOTH FLUDARABINE AND ALEMTUZUMAB or FOR PREVIOUSLY UNTREATED: DOCUMENTATION OF USE IN COMBINATION WITH CHLORAMBUCIL AND DOCUMENTATION OF INABILITY TO USE FLUDARABINE or FOR RELAPSE: DOCUMENTATION OF USE IN COMBINATION WITH FLUDARABINE AND CYCLOPHOSPHAMIDE or FOR EXTENDED TREATMENT: DOCUMENTATION OF COMPLETE OR PARTIAL RESPONSE AFTER AT LEAST TWO LINES OF THERAPY FOR RECURRENT OR PROGRESSIVE DISEASE. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

#### ASPARAGINASE

#### Affected Drugs:

Erwinase Erwinaze

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DOCUMENTATION OF TREATMENT OF PATIENT WITH ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) WHO HAS DEVELOPED A HYPERSENSITIVITY TO E.COLI DERIVED ASPARAGINASE (PEGASPARGASE)

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**N/A

## ASTAGRAF

Affected Drugs:

Astagraf XL

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of kidney transplant.

Age Restrictions: Must be 4 years of age or older

**Prescription Order Restrictions**:TRANSPLANT SPECIALIST OR PHYSICIAN EXPERIENCED IN IMMUNOSUPPRESSIVE THERAPY

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:** If greater than 18 years of age: documentation of rationale for not using Envarsus XR if clinically appropriate.

GHP Medicare Formulary - Prior Authorization Criteria

Affected Drugs: Austedo

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information**:Diagnosis of Huntingtons disease AND documentation of symptoms of chorea AND documentation of baseline total maximal chorea score prior to initiating therapy AND either evaluation by a psychiatrist if there is a history of prior suicide attempt, bipolar disorder, or major depressive disorder OR documentation of a mental health evaluation performed by the prescriber. Diagnosis of tardive dyskinesia as evidenced by either moderate to severe abnormal body movements (AIMS score 3 or 4) in at least 1 body area or mild abnormal body movements (AIMS score 1 or 2) in 2 or more body areas AND documentation of no other causes of involuntary movements AND documentation of baseline AIMS score prior to initiating therapy AND if the symptoms are related to use of a first-generation antipsychotic, documentation that a switch to a second generation antipsychotic has been attempted and did not resolve symptoms OR provider rationale as to why a switch to a second generation antipsychotic would not be appropriate.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**BY OR IN CONSULTATION WITH PSYCHIATRIST, NEUROLOGIST OR MOVEMENT DISORDER SPECIALIST

## Coverage Duration:12 MONTHS

**Other Criteria:**For Huntingtons: therapeutic failure on, intolerance to or contraindication to tetrabenazine. For tardive dykinesia: therapeutic failure on, intolerance to, or contraindication to valbenazine. Reauthorization for huntingtons will require documentation of an improvement in chorea as evidenced by a reduction in the total maximal chorea score from baseline. Reauthorization for tardive dyskinesia will require documentation of an improvement in symptoms as evidenced by a reduction for tardive dyskinesia will require documentation of an improvement in symptoms as evidenced by a reduction from baseline AIMS score.

## Affected Drugs:

Ayvakit

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of unresectable or metastatic gastrointestinal stromal tumor (GIST) AND documentation of a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation. Diagnosis of Advanced Systemic Mastocytosis (AdvSM), including: aggressive sysemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).

## Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**ONCOLOGIST, HEMATOLOGIST, ALLERGIST OR IMMUNOLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**For AdvSM: documentation of a platelet count greater than or equal to 50 x 109/L. Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

Affected Drugs: Balversa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Dx of locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 or FGFR2 genetic alterations, that has progressed during or following at least one prior line of platinum-based chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-based chemotherapy

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: ONCOLOGIST OR UROLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### BANZEL

## Affected Drugs:

Banzel Rufinamide

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

Exclusion Criteria:N/A

**Required Medical Information:**DX OF LENNOX-GASTAUT SYNDROME or FOR USE IN REFRACTORY PARTIAL SEIZURES AS DEFINED AS FAILURE ON TWO FORMULARY SEIZURE MEDICATIONS

Age Restrictions: MUST BE 1 YEAR OF AGE OR OLDER

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**N/A

Affected Drugs: Bavencio

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF METASTATIC MERKEL CELL CARCINOMA (MCC). DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA WITH ONE OF THE FOLLOWING: DISEASE PROGRESSION DURING OR FOLLOWING PLATINUM-CONTAINING CHEMOTHERAPY or DISEASE PROGRESSION WITHIN 12 MONTHS OF NEOADJUVANT OR ADJUVANT TREATMENT WITH PLATINUM-CONTAINING CHEMOTHERAPY or FOR USE AS MAINTENANCE TREATMENT WITH NO PROGRESSION FOLLOWING FIRST-LINE PLATINUM CONTAINING CHEMOTHERAPY. DIAGNOSIS OF ADVANCED RENAL CELL CARCINOMA AND DOCUMENTATION OF USE AS FIRST LINE TREATMENT IN COMBINATION WITH AXITINIB.

Age Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS RENEWAL

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs: Baxdela

Off-Label Uses:N/A

## Exclusion Criteria:N/A

**Required Medical Information**:Documentation of either a diagnosis of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following: Staphylococcus aureus (including methicillin-resistant (MRSA) and methicillin-susceptible (MSSA) isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, or Pseudomonas aeruginosa OR Documentation of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (MSSA isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila, or Mycloplasma pneumoniae AND documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity OR documentation that therapy was initiated during an inpatient setting.

## Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**WRITTEN BY OR IN CONSULTATION WITH A INFECTIOUS DISEASE PROVIDER

#### **Coverage Duration:2 WEEKS**

**Other Criteria:**For Baxdela injection formulation: documentation of reason why the oral formulation cannot be tried or is not appropriate.

### **BECONASE AQ**

## Affected Drugs:

Beconase AQ

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of allergic or vasomotor rhinitis OR documentation of use for the prevention of nasal polyps.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

#### Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**For rhinitis: documentation of failure on, intolerance to, or contraindication to two formulary agents (flunisolide, fluticasone propionate, mometasone, budesonide). For prevention of nasal polyps: documentation of failure on, intolerance to, or contraindication to mometasone.

#### BELEODAQ

Affected Drugs: Beleodaq

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF RELAPSED OR REFRACTORY PERIPHERAL T-CELL LYMPHOMA

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression

GHP Medicare Formulary - Prior Authorization Criteria

## Affected Drugs:

Nexletol Nexlizet

## Off-Label Uses:N/A

## Exclusion Criteria:N/A

Required Medical Information: Documentation of either clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin OR Heterozygous familial hypercholesterolemia (HeFH). For HeFH one of the following: Genetic testing to confirm mutation in the LDL receptor, PCSK9, or ApoB gene OR documentation of definite HeFH (score greater than 8) on the diagnostic criteria scoring system as defined by the ESC/EAS guidelines and the WHO. Documentation of a baseline LDL drawn within 3 months of the start of therapy showing an LDL greater than 100 if using for HeFH and using for primary prevention OR an LDL greater than 70 if using for secondary prevention. For statin tolerant patients, documentation of an inability to achieve and maintain LDL goal with one of the following (1) maximum tolerated dose of a high intensity statin (atorvastatin 40 mg or higher or rosuvastatin 20 mg or higher) or (2) a maximally tolerated dose of any statin given that the patient has had a previous trial of either atorvastatin or rosuvastatin, with prescribers documentation regarding length of previous trials of statins. Patient must intend to continue on maximal statin therapy once bempedoic acid therapy is started. For statin intolerant patients, documentation of reason for statin intolerance.

## Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

## Prescription Order Restrictions: Cardiologist, lipidologist or endocrinologist

## Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria**:Documentation of therapeutic failure of a trial of ezetemibe alone. Therapeutic failure is defined as an inability to reach target LDL goals (less than 100 mg/dL for patients with HeFH in primary prevention or less than 70 mg/dL for ASCVD or for patients with HeFH using Praluent as secondary prevention) despite at least a 3 month trial. Intolerance to statins is defined as increased LFTs, intolerable myalgia (muscle symptoms without creatinine kinase (CK) elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms), which persist after two retrials with a different dose or different dosing strategy (every other day) of alternative moderate- or high-intensity statin. Contraindications to statins are defined as active liver disease, previous history of rhabdomyolysis, or hypersensitivity.

Affected Drugs: Benlysta

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS AND DOCUMENTATION OF A POSITIVE ANA/ANTI-DSDNA ANTIBODY AND DOCUMENTATION OF BEING ON A STABLE TREATMENT REGIMEN WITH PREDNISONE, NSAID, ANTI-MALARIAL OR IMMUNOSUPPRESSANT AND NO DOCUMENTATION OF CNS INVOLVEMENT. DOCUMENTATION OF A DIAGNOSIS OF ACTIVE LUPUS NEPHRITIS, CLASS III, IV, V ALONE OR IN COMBINATION, CONFIRMED BY A KIDNEY BIOPSY.

#### Age Restrictions:N/A

Prescription Order Restrictions: RHEUMATOLOGIST OR NEPHROLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR LUPUS NEPHRITIS: DOCUMENTATION THAT MEDICATION WILL BE PRESCRIBED IN COMBINATION WITH STANDARD THERAPY (SUCH AS MYCOPHENOLATE MOFETIL (MMF), CORTICOSTEROIDS, CYCLOPHOSPHAMIDE, OR AZATHIOPRINE). REAUTHORIZTION FOR LUPUS NEPHRITIS WILL REQUIRE DOCUMENTATION OF A POSITIVE CLINICAL RESPONSE TO THERAPY (SUCH AS IMPROVEMENT OR STABILIZATION IN UPCR, eGFR, OR RENAL RELATED EVENTS) and DOCUMENTATION OF CONTINUED USE IN COMBINATION WITH STANDARD THERAPY. REAUTHORIZATION FOR SLE WILL REQUIRE DOCUMENTATION SHOWING CLINICAL BENEIFT OF ONE OF THE FOLLOWING: IMPROVEMENT IN FUNCTIONAL IMPAIRMENT, DECREASE IN THE NUMBER OF EXACERBATIONS SINCE STARTING THERAPY, OR DECREASE IN THE DAILY REQUIRED DOSE OF ORAL CORTICOSTEROIDS

#### **BESPONSA**

Affected Drugs: Besponsa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

#### **Coverage Duration:3 MONTHS**

**Other Criteria:**One time reauthorization will require documentation of the following: patient is not receiving hematopoietic stem cell transplant (HSCT) AND has achieved complete remission or complete remission with incomplete hematologic recovery and minimal residual disease (MRD) AND is not experiencing toxicity or worsening of disease.

## **BETHKIS**

Affected Drugs: Bethkis Fobramycin
Off-Label Uses:N/A
Exclusion Criteria:N/A
Required Medical Information:DX OF CYSTIC FIBROSIS
Age Restrictions:N/A
Prescription Order Restrictions: PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST
Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

## **BEXAROTENE GEL**

Affected Drugs: Targretin

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of cutaneous lesions of stage IA or IB Cutaneous Tcell lymphoma (CTCL) in patients who have refractory or persistent disease after other therapies or who have not tolerated other therapies.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: Prescribed by or in consultation with oncologist

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION and DOCUMENTATION THAT MEMBER CONTINUES TO BE FOLLOWED BY AN ONCOLOGIST.

Affected Drugs: Blenrep

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of relapsed or refractory multiple myeloma AND documentation of treatmeant with at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

**Coverage Duration:**6 MONTHS

**Other Criteria**: REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## Affected Drugs:

Blincyto

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

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF RELAPSED OR REFRACTORY CD19-POSITIVE B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) or DIAGNOSIS OF CD19-POSITIVE B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN FIRST OR SECOND REMISSION WITH MINIMAL RESIDUAL DISEASE (MRD) GREATER THAN OR EQUAL TO 0.1%

Age Restrictions:N/A

#### Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration: Relapsed or refractory disease: 20 months, MRD B Cell ALL: 6 months

**Other Criteria:**Reauthorizations will require documentation of well-controlled peer-reviewed literature with evidence supporting the request.

#### **BONIVA IV**

#### Affected Drugs:

Ibandronate Sodium

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DX OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN

Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:INTOLERANCE TO ORAL BIPHOSPHONATES OR INABILITY TO REMAIN IN AN UPRIGHT POSITION FOR A MINIMUM OF 30-60 MINUTES AFTER INGESTION OR DISRUPTION OF THE ALIMENTARY TRACT DUE TO ANY OF THE FOLLOWING REASONS WHICH PRECLUDES THE USE OF ORAL BISPHOSPHONATES: OBSTRUCTING STRICTURE OR NEOPLASM OF THE ESOPHAGUS, STOMACH OR INTESTINE OR SHORT BOWEL SYNDROME SECONDARY TO EXTENSIVE SMALL BOWEL RESECTION OR MOTILITY DISORDER OR MALABSORPTION SECONDARY TO ENTEROVESICAL, ENTEROCUTANEOUS OR ENTEROCOLIC FISTULAS OR PROLONGED PARALYTIC ILEUS FOLLOWING SURGERY OR INJURY AND FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ZOLEDRONIC ACID. THIS DRUG MAY BE COVERED UNDER MEDICARE PART B, BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES (PART B) OR COVERED UNDER MEDICARE PART D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION.

## BONJESTA

Affected Drugs: Bonjesta

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF NAUSEA AND VOMITING OF PREGNANCY IN ADULT WOMEN

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

**Coverage Duration:**9 MONTHS

**Other Criteria:**N/A

# Affected Drugs:

Bosulif

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF CHRONIC, ACCELERATED, OR BLAST PHASE PH POSITIVE CHRONIC MYELOGENOUS LEUKEMIA (CML) or DOCUMENTATION OF NEWLY DIAGNOSED CHRONIC PHASE PHILADELPHIA CHROMOSOME-POSITIVE CHRONIC MYELOID LEUKEMIA.

Age Restrictions:N/A

## Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

## Coverage Duration:12 MONTHS

Other Criteria:FOR ALL INDICATIONS EXCEPT NEWLY DIAGNOSED CHRONIC PHASE PHILADELPHIA CHROMOSOME POSITIVE CML: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE OF THE FOLLOWING PRIOR THERAPIES IMATINIB, SPRYCEL, OR TASIGNA. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

#### Affected Drugs: Braftovi

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of unresectable or metastatic melanoma AND documentation that medication is being prescribed in combination with Mektovi AND documentation of BRAF V600E OR V600K mutation as detected by an FDA approved test. Documentation of metastatic colorectal cancer with progression on at least one prior therapy AND documentation that medication is being prescribed in combination with cetuximab AND documentation of a BRAF V600E mutation as detected by an FDA approved test.

## Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST OR HEMATOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

## BRINTELLIX

#### Affected Drugs:

Trintellix

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER

Age Restrictions: MUST BE AT LEAST 18 YEARS OF AGE

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST TWO ANTIDEPRESSANT CLASSES.

## BRIVIACT

Affected Drugs: Briviact

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of a diagnosis of partial-onset seizures AND Documentation that Briviact is not being used in combination with levetiracetam

Age Restrictions: Must be 4 years of age or older

Prescription Order Restrictions:N/A

Coverage Duration: Remainder of contract year

**Other Criteria:**Failure on, intolerance to, or contraindication to at least two formulary alternatives, one of which must be levetiracetam.

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#### BROVANA

#### Affected Drugs:

Arformoterol Tartrate Brovana

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information:DX OF COPD

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SEREVENT OR DOCUMENTATION OF INABILITY TO USE AN INHALER.

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#### BRUKINSA

Affected Drugs: Brukinsa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of mantle cell lymphoma (MCL) AND documentation of therapeutic failure on or intolerance to one prior therapy.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

## **BUDESONIDE ER**

#### Affected Drugs:

Budesonide ER

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of ulcerative colitis

Age Restrictions:N/A

Prescription Order Restrictions:N/A

**Coverage Duration:8 WEEKS** 

**Other Criteria:**Documentation of failure on, intolerance to, or contraindication to sulfasalazine, balsalazide, or an oral mesalamine product

Affected Drugs: Cablivi

Off-Label Uses:N/A

# Exclusion Criteria:N/A

**Required Medical Information**:Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP). Documentation of (1) use in combination with daily plasma exchange and immunosuppressive therapy (such as glucocorticoids or rituximab) AND documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi OR (2) documentation that the member previously received daily plasma exchange, immunosuppresive therapy and Cablivi within the inpatient settings AND known date of the last plasma exchange AND documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi AND documentation of either the date of plasma exchange is within 30 days of the request date OR if the date of plasma exchange is greater than 30 days of the request date, documentation of persistent underlying disease (such as suppressed ADAMTS 13 activity levels remain present) and documentation of not exceeding the maximum treatment duration of Cablivi (30 days post plasma exchange and up to 28 days of extended treatment).

# Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: by or in consultation with a hematologist

Coverage Duration: 2 MONTHS INITIAL, 2 MONTHS REAUTH

**Other Criteria**:Reauthorization will be based on plasma exchange status and that member has not experienced more than two recurrences of aTTP while on Cablivi. If currently receiving plasma exchange, documentation that medication is currently being used with plasma exchange and immunosuppressive therapy. If plasma exchange has been completed within 30 days, documentation of previously receiving daily plasma exchange and immunosuppressive therapy, the known date of the last plasma exchange, and that the date of plasma exchange is within 30 days of the request date. If plasma exchange has been completed for more than 30 days, documentation sign(s) of persistent underlying disease (such as suppressed ADAMTS13 activity levels remain present) AND date of last plasma exchange AND documentation of not exceeding the maximum treatment duration of Cablivi (30 days post plasma exchange and up to 28 days of extended treatment).

Cabometyx

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

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of use in combination with nivolumab for previously untreated advanced renal cell carcinoma OR documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma AND if the requested dose is 80 mg daily, documentation that the patient is using in combination with a strong CYP3A4 inducer, including but not limited to, rifampin, phenytoin, carbamazepine, phenobarbital, rifabutin, rifapentine, or St. John's Wort. Documentation of hepatocellular carcinoma AND documentation of a therapeutic failure on, intolerance to or contraindication to sorafenib.

#### Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

Calquence

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

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

**Required Medical Information:**Diagnosis of mantle cell lymphoma (MCL) who have received at least one prior therapy OR diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). If the requested dose is 400 mg daily, need documentation that the patient is using in combination with a strong CYP3A inducer, including but not limited to carbamazepine, enzalutamide, fosphenytoin, lumacaftor, mitotane, phenytoin, rifampin, or St. John's Wort.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

# CAPLYTA

# Affected Drugs:

Caplyta

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of schizophrenia

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of therapeutic failure on, intolerance to, or contraindication to two formulary atypical antipsychotics (olanzapine, risperidone, quetiapine, ziprasidone, aripiprazole)

# CARBAGLU

Affected Drugs: Carbaglu

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF HYPERAMMONEMIA DUE TO THE DEFICIENCY OF THE HEPATIC ENZYME N-ACETYLGLUTAMATE SYNTHASE (NAGS). Diagnosis of propionic acidemia (PA) or methylmalonic acidemia (MMA).

Age Restrictions:N/A

Prescription Order Restrictions: METABOLIC DISORDER SPECIALIST OR GENETICIST

Coverage Duration: For MMA or PA: 7 days. NAGS: 6 MONTHS

**Other Criteria:**For MMA or PA: documentation that medication is being prescribed as adjunctive treatment to standard of care (including but not limited to intravenous glucose, insulin, L-carnitine, protein restriction and dialysis). Documentation that medication is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature. Reauthorizations for NAGS will require documentation of continued disease improvement or lack of disease progression

# CAYSTON

Affected Drugs: Cayston

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**:DOCUMENTATION OF CYSTIC FIBROSIS CONFIRMED BY APPROPRIATE DIAGNOSTIC OR GENETIC TESTING AND DOCUMENTATION THAT PSEUDOMONAS AERUGINOSA IS PRESENT IN THE CULTURES OF THE AIRWAY

Age Restrictions: MUST BE 7 YEARS OF AGE OR OLDER

Prescription Order Restrictions: PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TOBRAMYCIN INHALATION SOLUTION

#### CEREZYME

Affected Drugs:

Cerezyme

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF TYPE 1 GAUCHER DISEASE ALONG WITH AT LEAST ONE OF THE FOLLOWING CONDITIONS: ANEMIA, THROMBOCYTOPENIA, BONE DISEASE, HEPATOMEGALY OR SPLENOMEGALY

Age Restrictions:N/A

**Prescription Order Restrictions:**METABOLIC SPECIALIST, GENETICIST, OR HEMATOLOGIST WITH EXPERIENCE TREATING GAUCHER DISEASE

Coverage Duration:6 MONTHS

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ELELYSO FOR THOSE 4 YEARS OF AGE AND OLDER. Reauthorizations will require documentation of continued disease improvement or lack of disease progression

Cholbam

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**: DIAGNOSIS OF BILE ACID SYNTHESIS DISORDERS DUE TO SINGLE ENZYME DEFECTS (SEDS) OR PEROXISOMAL DISORDERS (PDS) INCLUDING ZELLWEGER SPECTRUM DISORDERS IN PATIENTS WHO EXHIBIT MANIFESTATIONS OF LIVER DISEASE, STEATORRHEA, OR COMPLICATIONS FROM DECREASED FAT SOLUBLE VITAMIN ABSORPTION AND DOCUMENTATION THAT DIAGNOSIS HAS BEEN CONFIRMED WITH AN ABNORMAL URINARY BILE ACID FAST ATOM BOMBARDMENT IONIZATION MASS SPECTROMETRY (FAB-MS) ANALYSIS AND FOR THE TREATMENT OF PEROXISOMAL DISORDERS, DOCUMENTATION THAT MEDICATION WILL BE USED AS ADJUNCTIVE THERAPY AND DOCUMENTATION OF BASELINE ALT, AST, TOTAL BILIRUBIN, AND BODY WEIGHT.

# Age Restrictions:N/A

**Prescription Order Restrictions:**GASTROENTEROLOGIST, HEPATOLOGIST, OR METABOLIC SPECIALIST WITH EXPERIENCE IN THE DIAGNOSIS AND TREATMENT OF BILE ACID SYNTHESIS AND PEROXISOMAL DISORDERS

Coverage Duration: 3 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**REAUTHORIZATION WILL REQUIRE DOCUMENTATION SUPPORTING IMPROVEMENT IN TWO LABORATORY CRITERION (ALT OR AST VALUES REDUCED TO LESS THAN 50 U/L OR BASELINE LEVELS REDUCED BY 80%, TOTAL BILIRUBIN VALUES REDUCED TO LESS THAN OR EQUAL TO 1 MG/DL, NO EVIDENCE OF CHOLESTASIS ON LIVER BIOPSY) OR ONE OF THE PRIOR LABORATORY CRITERIA IMPROVEMENTS IN ADDITION TO A BODY WEIGHT INCREASE OF 10% OR BODY WEIGHT STABLE AT GREATER THAN THE 50TH PERCENTILE.

#### Affected Drugs: Chorionic Gonadotropin

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Diagnosis of prepubertal cryptorchidism not caused by anatomical obstruction in male infants and children OR Diagnosis of hypogonadotropic hypogonadism

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**For hypogonadism: failure on, intolerance to, or contraindication to transdermal testosterone

# CIALIS

# Affected Drugs:

Tadalafil

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF BENIGN PROSTATIC HYPERPLASIA (BPH)

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE FORMULARY 5-ALPHA REDUCTASE INHIBITOR (FINASTERIDE OR DUTASTERIDE) AND ONE FORMULARY ALPHA-1 ADRENERIGIC BLOCKER (ALFUZOSIN, TAMSULOSIN, DOXAZOSIN, TERAZOSIN)

Cimzia Cimzia Prefilled Cimzia Starter Kit

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**ADULT RA: DIAGNOSIS OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS. CROHN'S DISEASE -DIAGNOSIS OF CROHN'S DISEASE. ANKYLOSING SPONDYLITIS - DIAGNOSIS OF ANKYLOSING SPONDYLITIS. PSORIATIC ARTHRITIS - DIAGNOSIS OF PSORIATIC ARTHRITIS AND DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS OR A DOCUMENTED HISTORY OF PSORIASIS. DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS CHARACTERIZED BY GREATER THAN OR EQUAL TO 5% OF BODY SURFACE AREA INVOLVED OR DISEASE INVOLVING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE OR GENITALS. Diagnosis of non-radiographic axial spondylarthritis with documentation of either Creactive protein (CRP) level above the upper limit of normal or Sacroiliitis on magnetic resonance imaging (MRI).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**RHEUMATOLOGIST, GASTROENTEROLOGIST OR DERMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF (1) HUMIRA AND (2) RINVOQ ER OR XELJANZ. FOR PSORIATIC ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX OR XELJANZ. FOR PLAQUE PSORIASIS: FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX OR XELJANZ. FOR PLAQUE PSORIASIS: FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX OR SKYRIZI. FOR ANKYLOSING SPONDYLITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA AND COSENTYX. FOR CROHN'S: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO HUMIRA. For nonradiographic axial spondylarthritis: failure on, intolerance to, or contraindication to two nonsteroidal

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anti-inflammatory drugs (NSAIDs). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

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Cinryze

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DIAGNOSIS OF HEREDITARY ANGIOEDEMA and FOR HAE TYPE I AND TYPE II: THE PRESENCE OF SPECIFIC ABNORMALITIES IN COMPLEMENT PROTEINS IN THE SETTING OF A SUGGESTIVE CLINICAL HISTORY OF EPISODIC ANGIOEDEMA WITHOUT URTICARIA SUPPORTED BY DOCUMENTATION OF TWO OR MORE SETS OF COMPLEMENT STUDIES, SEPARATED BY ONE MONTH OR MORE SHOWING LOW C4 LEVELS AND LESS THAN 50 PERCENT OF THE LOWER LIMIT OF NORMAL C1 INH ANTIGENIC PROTEIN LEVELS OR FUNCTION LEVELS.

Age Restrictions: MUST BE 6 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR DERMATOLOGIST

Coverage Duration:6 MONTHS

**Other Criteria**: Documentation that medication is used as prophylactic therapy.

# CLOLAR

# Affected Drugs:

Clofarabine

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF RELAPSED OR REFRACTORY ACUTE LYMPHOBLASTIC LEUKEMIA

Age Restrictions:1 TO 21 YEARS OF AGE

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

**Coverage Duration:**6 MONTHS

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO PRIOR TREATMENT REGIMENS. Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

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clomiPRAMINE HCI

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**PRIOR AUTHORIZATION APPLIES ONLY TO MEMBERS 65 YEARS OF AGE AND OLDER WHO WILL BE EVALUATED FOR APPROPRIATE USE OF HIGH RISK MEDICATION AND WILL FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: FLUOXETINE, FLUVOXAMINE, SERTRALINE

# COMETRIQ

#### Affected Drugs:

Cometriq (100 MG Daily Dose) Cometriq (140 MG Daily Dose) Cometriq (60 MG Daily Dose)

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF PROGRESSIVE METASTATIC MEDULLARY THYROID CANCER

Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria**: REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

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# COPIKTRA

Affected Drugs: Copiktra

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of one of the following: Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) OR relapsed or refractory follicular lymphoma (FL).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria**:Documentation of a therapeutic failure on, intolerance to, or contraindication to at least two prior therapies. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

Affected Drugs: Corlanor

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**:DOCUMENTATION OF STABLE, SYMPTOMATIC HEART FAILURE WITH A LEFT VENTRICULAR EJECTION FRACTION LESS THAN OR EQUAL TO 35% AND DOCUMENTATION OF BEING IN SINUS RHYTHM WITH RESTING HEART RATE GREATER THAN OR EQUAL TO 70 BEATS PER MINUTE AND DOCUMENTATION OF HOSPITALIZATION FOR WORSENING HEART FAILURE WITHIN THE PREVIOUS 12 MONTHS. DOCUMENTATION OF STABLE, SYMPTOMATIC HEART FAILURE DUE TO DILATED CARDIOMYOPATHY and DOCUMENTATION OF CLASS II TO IV HEART FAILURE ACCORDING TO NYHA FUNCTIONAL CLASS OR ROSS CLASSIFICATIONS and DOCUMENTATION OF A LEFT VENTRICULAR EJECTION FRACTION LESS THAN OR EQUAL TO 45% and DOCUMENTATION OF BEING IN SINUS RHYTHM WITH RESTING HEART RATE GREATER THAN OR EQUAL TO THE LOWER LIMIT OF THE NORMAL RANGE BASED ON AGE

**Age Restrictions:**HF with EF less than 35%: 18 years of age or older. HF due to cardiomyopathy: 6 months of age or older

Prescription Order Restrictions: CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO THE MAXIMUM TOLERATED DOSES OF TWO FORMULARY BETA-BLOCKERS ONE OF WHICH MUST BE CARVEDILOL

# COSENTYX

# Affected Drugs:

Cosentyx Cosentyx (300 MG Dose) Cosentyx Sensoready (300 MG) Cosentyx Sensoready Pen

# Off-Label Uses:N/A

# **Exclusion Criteria:**N/A

Required Medical Information: PSORIATIC ARTHRITIS: DX of moderate to severe psoriatic arthritis and documentation of either active psoriatic lesions or a documented history of psoriasis. For peripheral PSA: Intolerance to, contraindication to, or therapeutic failure on methotrexate AND one formulary NSAID OR documentation of a therapeutic failure on or intolerance to prior biologic therapy. For axial PSA: Intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two formulary NSAIDS OR documentation of a therapeutic failure on or intolerance to prior biologic therapy. For Nonradiographic Axial Spondyloarthritis: documentation of objective signs of inflammation, including but not limited to elevated C-reactive protein (CRP), elevated Erythrocyte sedimentation rate (ESR) or presence of sacroilitis on MRI. PLAQUE PSORIASIS: DX of moderate to severe plaque psoriasis with at least 5% BSA or disease affecting crucial body areas such as hands, feet, face or genitals AND therapeutic failure on, intolerance to, or contraindication to one formulary topical corticosteroid AND at least 3 months of one systemic therapy including but not limited to MTX or Cyclosporine or phototherapy OR documentation of a therapeutic failure on or intolerance to prior biologic therapy. ANKYLOSING SPONDYLITIS: DX of A.S. and failure on, intolerance to, or contraindication to 2 formulary NSAIDS OR documentation of a therapeutic failure on or intolerance to prior biologic therapy.

**Age Restrictions:** Psoriasis:must be 6 years of age or older. All other Dx: must be 18 years of age or older.

Prescription Order Restrictions: RHEUMATOLOGIST OR DERMATOLOGIST

#### Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR NONRADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: Documentation of an FDA approved dosing regimen (150 MG every 4 weeks with or without a loading dose) AND documentation of intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two formulary NSAIDS. FOR CONTINUED

THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

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# COTELLIC

# Affected Drugs:

Cotellic

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF UNRESECTABLE OR METASTATIC MELANOMA AND DOCUMENTATION OF BRAF V600E OR V600K MUTATION AS DETECTED BY AN FDA APPROVED TEST. DOCUMENTATION OF CONCOMITANT USE WITH VEMURAFENIB.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST, ONCOLOGIST, or DERMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

# CRINONE

Affected Drugs: Crinone

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of secondary amenorrhea

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria: Failure on, intolerance to, or contraindication to medroxyprogesterone

Xalkori

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) THAT IS ANAPLASTIC LYMPHOMA KINASE (ALK) POSITIVE AS DETECTED BY AN FDA APPROVED TEST or DIAGNOSIS OF METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) THAT IS ROS 1-POSITIVE. Diagnosis of relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is anaplastic lymphoma kinase (ALK) positive AND documentation of at least one prior systemic treatment.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**FOR ALK-POSITIVE, METASTATIC NON-SMALL CELL LUNG CANCER: DOCUMENTATION OF RATIONALE FOR NOT TREATING WITH ALECENSA IF CLINICALLY APPROPRIATE. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Crysvita

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

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

**Required Medical Information:**Diagnosis of X-linked hypophosphatemia as evidenced by one of the following: Reduced TmP/GFR ratio with either reduced plasma concentration of 1,25dihydroxycholecalciferol (1,25-DHCC) or 25-hydroxyvitamin D (25(OH)D) OR genetic testing confirming a mutation in the PHEX (PHosphate regulating Endopeptidase on the X chromosome) gene. Diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors AND documentation of an elevated serum level of FGF23 AND documentation that the tumor cannot be curatively resected or localized.

Age Restrictions:TIO:2 years or older. X-linked:6 months or older

**Prescription Order Restrictions:**BY OR IN CONSULTATION WITH AN ENDOCRINOLOGIST, GENETICIST, NEPHROLOGIST OR ONCOLOGIST

#### Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS REAUTH

**Other Criteria:**Documentation that the member is not currently using vitamin D analogs or phosphate supplements. Subsequent approvals will require documentation of continued follow up and determination of medical necessity from an endocrinologist , nephrologist or oncologist AND documentation of improving patient's disease as evidenced by normalized or improved serum phosphorus levels AND documentation that patient is not using vitamin D analogs or phosphate supplements

# CYCLOSET

#### Affected Drugs:

Cycloset

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DIAGNOSIS OF TYPE 2 DIABETES MELLITUS.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO ORAL FORMULARY ANTIDIABETIC AGENTS.

Cyproheptadine HCI

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**PRIOR AUTHORIZATION APPLIES ONLY TO MEMBERS 65 YEARS OF AGE AND OLDER WHO WILL BE EVALUATED FOR APPROPRIATE USE OF HIGH RISK MEDICATION. DIAGNOSIS OF ALLERGIC CONDITIONS PRURITUS, URTICARIA, SEASONAL OR PERENNIAL ALLERGIES) WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO DESLORATADINE AND LEVOCETIRIZINE. Affected Drugs: Cyramza

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DOCUMENTATION OF ADVANCED OR METASTATIC, GASTRIC, OR GASTRO-ESOPHAGEAL JUNCTION ADENOCARCINOMA WITH DISEASE PROGRESSION ON OR AFTER PRIOR FLUOROPYRIMIDINE OR PLATINUM CONTAINING CHEMOTHERAPY. DOCUMENTATION OF USE IN COMBINATION WITH PACLITAXEL OR CLINICAL JUSTIFICATION FOR USE AS MONOTHERAPY. DIAGNOSIS OF METASTATIC NON SMALL CELL LUNG CANCER WITH EITHER 1)IN COMBINATION WITH DOCETAXEL IN THOSE WITH DISEASE PROGRESSION ON OR AFTER PLATINUM BASED CHEMOTHERAPY AND PATIENTS WITH EGFR OR ALK GENOMIC TUMOR ABERRATIONS MUST PROVIDE DOCUMENTATION OF DISEASE PROGRESSION ON FDA APPROVED THERAPIES FOR THESE ABERRATIONS PRIOR TO RECEIVING CYRAMZA OR 2) USED IN COMBINATION WITH ERLOTINIB AS FIRST LINE TREATMENT WITH EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETIONS OR EXON 21 (L858R) MUTATIONS. DOCUMENTATION OF METASTATIC COLON OR RECTAL CANCER WITH DISEASE PROGRESSION ON OR AFTER FOLFOX, CapeOX OR A REGIMEN NOT PREVIOUSLY CONTAINING IRINOTECAN AND DOCUMENTATION OF USE IN COMBINATION WITH IRINOTECAN OR FOLFIRI (FLUOROURACIL, LEUCOVORIN, AND IRINOTECAN). DOCUMENTATION OF HEPATOCELLULAR CARCINOMA and DOCUMENTATION OF AN ALPHA FETOPROTEIN (AFP) LEVEL OF 400 NG/ML OR GREATER and DOCUMENTATION OF DISEASE PROGRESSION ON OR AFTER TREATMENT WITH SORAFENIB OR AN INTOLERANCE TO SORAFENIB.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria**: REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Decitabine

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

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF MYELODYSPLASTIC SYNDROME (MDS) INCLUDING PREVIOUSLY TREATED AND UNTREATED, DE NOVO AND SECONDARY MDS OF ALL FRENCH-AMERICAN-BRITISH SUBTYPES (REFRACTORY ANEMIA, REFRACTORY ANEMIA WITH RINGED SIDEROBLASTS, REFRACTORY ANEMIA WITH EXCESS BLASTS, REFRACTORY ANEMIA WITH EXCESS BLASTS IN TRANSFORMATION, AND CHRONIC MYELOMONOCYTIC LEUKEMIA) AND INTERMEDIATE-1, INTERMEDIATE-2, AND HIGH RISK INTERNATIONAL PROGNOSTIC SCORING SYSTEM GROUPS

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

# DALIRESP

#### Affected Drugs:

Daliresp

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF COPD ASSOCIATED WITH CHRONIC BRONCHITIS

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**CONCOMITANT USE OF, FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO 1) SPIRIVA or INCRUSE ELLIPTA AND 2) ONE LONG ACTING BETA AGONISTS. Affected Drugs: Danyelza

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response or stable disease to prior therapy AND documentation that medication will be used in combination with granulocyte-macrophage colony stimulating factor (GM-CSF).

Age Restrictions: MUST BE 1 YEAR OF AGE OR OLDER

# Prescription Order Restrictions:N/A

Coverage Duration:6 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## DARAPRIM

#### Affected Drugs:

Pyrimethamine

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of toxoplasmosis

Age Restrictions:N/A

**Prescription Order Restrictions:**BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST

#### Coverage Duration: 3 MONTHS INITIAL, 6 MONTHS CONTINUATION

**Other Criteria:**Documentation of use in combination with leucovorin and a sulfonamide OR therapeutic failure on, intolerance to or contraindication to a sulfonamide. Reauthorization will require documentation of clinical syndrome (such as headache or other neurological symptom) OR documentation of persistent radiographic disease.

# DARZALEX

Affected Drugs: Darzalex

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

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

Required Medical Information: Diagnosis of Multiple Myeloma (MM). For newly diagnosed MM: documentation of either 1)not being eligible for stem cell transplantation (i.e. coexisting conditions, age greater than 65, etc) AND documentation that medication will be given in combination with one of the following: bortezomib, melphalan and prednisone (VMP) OR lenalidomide and dexamethasone OR 2) documentation that member is eligible for stem-cell transplantation AND documentation that medication will be given in combination with bortezomib, thalidomide, and dexamethasone (DVTd). For relapsed or refractory MM: Documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited to Velcade, Kyprolis or Ninlaro) and an immunomodulatory agent (including but not limited to Pomalyst, Revlimid or Thalomid) OR documentation that the member is double-refractory to a proteasome inhibitor and an immunomodulatory agent OR documentation of use in combination with pomalidomide and dexamethasone following a therapeutic failure on, intolerance to, or contraindication to at least 2 prior lines of therapy including lenalidomide and a proteasome inhibitor OR documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor or an immunomodulatory agent AND one of the following: documentation of use in combination with lenalidomide and dexamethasone, OR in combination with bortezomib and dexamethasone OR in combination with carfilzomib and dexamethasone.

#### Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

**Darzalex Faspro** 

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

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

Required Medical Information: Diagnosis of Multiple Myeloma (MM). For newly diagnosed MM: documentation of either 1)not being eligible for stem cell transplantation (i.e. coexisting conditions, age greater than 65, etc) AND documentation that medication will be given in combination with one of the following: bortezomib, melphalan and prednisone (VMP) OR lenalidomide and dexamethasone OR 2) documentation that member is eligible for stem-cell transplantation AND documentation that medication will be given in combination with bortezomib, thalidomide, and dexamethasone (DVTd). For relapsed or refractory MM: Documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited to Velcade, Kyprolis or Ninlaro) and an immunomodulatory agent (including but not limited to Pomalyst, Revlimid or Thalomid) OR documentation that the member is double-refractory to a proteasome inhibitor and an immunomodulatory agent OR documentation of use in combination with pomalidomide and dexamethasone with documentation of a therapeutic failure on, intolerance to or contraindication to at least one prior line of therapy including lenalidomide and a proteosome inhibitor OR documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor or an immunomodulatory agent AND one of the following: documentation of use in combination with lenalidomide and dexamethasone, OR in combination with bortezomib and dexamethasone. Documentation of light-chain amyloidosis used in combination with bortezomib, cyclophosphamide and dexamethasone.

#### Age Restrictions:N/A

#### Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**For light-chain amyloidosis: documentation that member does not have New York Heart Association (NYHA) class IIIB or Class IV heart failure or Mayo cardiac stage IIIB. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## DAURISMO

Affected Drugs: Daurismo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of newly diagnosed acute myeloid leukemia (AML) AND documentation of age greater than or equal to 75 years or documentation of a comorbidity that precludes use of intensive induction chemotherapy AND documentation of use in combination with low-dose cytarabine.

Age Restrictions:N/A

#### Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**Subsequent approval after 12 months will require documentation of continued disease improvement or lack of disease progression.

### DEMSER

# Affected Drugs:

Demser metyroSINE

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**TREATMENT OF PHEOCHROMOCYTOMA PREOPERATIVELY. TREATMENT OF PHEOCHROMOCYTOMA IN MANAGEMENT OF PATIENTS WHEN SURGERY IS CONTRAINDICATED. CHRONIC TREATMENT OF MALIGNANT PHEOCHROMOCYTOMA.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**N/A

GHP Medicare Formulary - Prior Authorization Criteria

# DIACOMIT

Affected Drugs: Diacomit

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of Dravet syndrome AND documentation that medication is to be used in combination with clobazam.

Age Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: by or in consultation wih a neurologist

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

### DICLEGIS

Affected Drugs: Doxylamine-Pyridoxine

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF NAUSEA AND VOMITING OF PREGNANCY IN ADULT WOMEN

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

**Coverage Duration:9 MONTHS** 

Other Criteria:N/A

Dojolvi

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD) confirmed by at least two of the following, (1) Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma, (2) Low enzyme activity in cultured fibroblasts, (3) One or more known pathogenic mutations in a gene associated with a long-chain fatty acid oxidation disorder (e.g., CPT2, ACADVL, HADHA, or HADHB)

### Age Restrictions:N/A

**Prescription Order Restrictions:**by or in consultation with a metabolic specialist or a physician who specializes in the management of long-chain fatty acid oxidation disorders

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs: Doptelet

Off-Label Uses:N/A

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

**Required Medical Information:**Documentation of thrombocytopenia in adult patients with chronic liver disease AND documentation of a platelet count less than 50 x 1000000000 (10 TO THE 9TH POWER)/L measured within the past 30 days. Documentation of a planned invasive procedure to be performed 10 to 13 days after initiation of treatment. Diagnosis of chronic immune thrombocytopenia AND documentation of a platelet count less than 30,000/microL.

### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, transplant specialist, interventional radiologist or endocrinologist

Coverage Duration: pre-procedure: 30 DAYS. Chronic ITP 3 months initial, 12 months reauth

**Other Criteria:**Documentation that the member is not receiving other TPO-Ras (i.e. romiplostin, eltrombopag). For pre-procedure of thrombocytopenia with chronic liver disease: Documentation that the correct dose of medication is being used based on the platelet count (platelet count 40-50 x 100000000 (10 TO THE 9TH POWER)/L: 40 mg once daily for 5 consecutive days, platelet count less than 40 x 100000000 (10 TO THE 9TH POWER)/L: 000: 60 mg once daily for 5 consecutive days). For chronic ITP: documentation of a therapeutic failure on one previous treatment, including, but not limited to: corticosteroids, IVIG, Rhogam (if RhD-positive and spleen intact), Rituximab, splenectomy, eltrombopag or romiplostim. Subsequent approval after 3 months will require documentation of medical necessity such as a platelet count necessary to reduce the risk for bleeding OR a hematological response.

Drizalma Sprinkle

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Dx of one of the following: major depressive disorder, diabetic peripheral neuropathic pain, chronic musculoskeletal pain, fibromyalgia, or generalized anxiety disorder

Age Restrictions: For GAD: 7 years of age or older. All others: 18 years or older

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of difficulty swallowing OR documentation of administration of medication through a nasogastric tube OR documentation of therapeutic failure on, intolerance to, or contraindication to duloxetine capsules.

### DRONABINOL

### Affected Drugs:

Dronabinol

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF CHEMOTHERAPY INDUCED NAUSEA AND VOMITING or DIAGNOSIS OF ANOREXIA ASSOCIATED WITH WEIGHT LOSS IN PATIENTS WITH AIDS

Age Restrictions:N/A

### Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

**Other Criteria:**FOR CHEMOTHERAPY INDUCED NAUSEA AND VOMITING: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO ANTIEMETIC THERAPIES, ONE OF WHICH MUST BE A 5HT3 ANTAGONIST. FOR ANOREXIA: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO MEGESTEROL ACETATE.

### DUAVEE

### Affected Drugs:

Duavee

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF AN INTACT UTERUS. DOCUMENTATION OF USE FOR ABNORMAL VASOMOTOR FUNCTION OR PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS

Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FOR ABNORMAL VASOMOTOR FUNCTION: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO FEMRING. FOR PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: ALENDRONATE, IBANDRONATE, RALOXIFENE, RISEDRONATE. Affected Drugs: Dupixent

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of moderate to severe atopic dermatitis. Documentation of either oral corticosteroid dependent asthma OR moderate to severe eosinophilic asthma with a blood eosinophilic count greater than or equal to 150 cells/microL. For asthma, documentation that medication will be used as an add-on maintenance treatment. Diagnosis of add-on maintenance treatment of inadequately controlled chronic rhino-sinusitis with nasal polyps (CRwNP).

Age Restrictions: Atopic dermatitis: 6 yrs or older. Asthma and CRwNP: 12 yrs or older

**Prescription Order Restrictions:**MUST BE PRESCRIBED BY OR IN CONSULTATION WITH A PULMONOLOGIST, DERMATOLOGIST, ALLERGIST OR IMMUNOLOGIST, OR OTOLARYNGOLOGIST (ENT provider)

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS RENEWAL

Other Criteria: For atopic dermatitis: contraindication to, intolerance to, or therapeutic failure on at least one systemic therapy (i.e. methotrexate, azathioprine, mycophenolate) AND documentation of failure on either daily treatment with at least medium potency topical corticosteroid OR calcineurin inhibitor (i.e. tacrolimus) if corticosteroids are not advisable. For Asthma, documentation that medication will not be used in combination with Xolair, Fasenra, Nucala or Cingair AND documentation of one of the following: a contraindication, intolerance to, or poorly controlled symptoms despite at least a 3-month trial of maximally tolerated inhaled corticosteroids or oral systemic corticosteroids plus a long-acting beta agonist OR documentation of one exacerbation in the previous 12 months requiring additional medical treatment despite current therapy or intolerance to inhaled corticosteroids plus a long-acting beta agonist. For CRwNP: Chronic rhinosinusitis is defined as nasal mucosal inflammation which persists for 12 weeks or longer. Documentation of a therapeutic failure on, intolerance to, or contraindication to two intranasal corticosteroids. Documentation that medication will be used as add on therapy (i.e. with intranasal corticosteroids or other therapy). Reauthorizations will require documentation of continued disease improvement or lack of disease progression AND (for CRwNP), documentation that medication continues to be used as add on therapy.

Duzallo

Off-Label Uses:N/A

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

**Required Medical Information:**Diagnosis of symptomatic hyperuricemia associated with gout. Documentation of not achieving target serum uric acid levels while taking a stable dose of allopurinol of at least 300 mg (or at least 200 mg if estimated creatinine clearance less than 60 mL/min). Documentation of an estimated creatinine clearance greater than or equal to 45 mL/min. Documentation that medication is not being used in tumor lysis syndrome, Lesch-Nyhan syndrome, or kidney transplant recipients.

### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

### Prescription Order Restrictions:N/A

### Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of a therapeutic failure on, intolerance to, or contraindication to probenecid.

### ELAPRASE

### Affected Drugs:

Elaprase

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information:DX OF HUNTER'S SYNDROME (MPS II)

Age Restrictions:N/A

**Prescription Order Restrictions:**METABOLIC SPECIALIST OR GENETICIST WITH EXPERIENCE TREATING MPS II

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

Elelyso

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF TYPE 1 GAUCHER DISEASE WITH AT LEAST ONE OF THE FOLLOWING - ANEMIA, THROMBOCYTOPENIA, BONE DISEASE, HEPATOMEGALY OR SPLENOMEGALY

Age Restrictions:N/A

**Prescription Order Restrictions:**METABOLIC SPECIALIST, GENETICIST OR HEMATOLOGIST WITH EXPERIENCE TREATING GAUCHER DISEASE

Coverage Duration:6 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

### ELIDEL

### Affected Drugs:

Pimecrolimus

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information:DX OF ATOPIC DERMATITIS

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO TACROLIMUS OINTMENT AND ONE FORMULARY TOPICAL CORTICOSTEROID UNLESS INADVISABLE DUE TO RISKS (SUCH AS USE ON SENSITIVE SKIN AREAS (FACE, AXILLAE, GROIN))

### ELITEK

Affected Drugs: Elitek

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF HYPERURICEMIA IN PATIENTS WITH LEUKEMIA, LYMPHOMA, AND SOLID TUMOR MALIGNANCIES

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

**Coverage Duration:**1 COURSE OF THERAPY (5 DAYS)

Other Criteria:DOCUMENTATION OF A HIGH RISK OF TUMOR LYSIS SYNDROME CHARACTERIZED BY ELEVATED SERUM CREATININE OR LEUKEMIAS WITH VERY HIGH WHITE BLOOD CELL COUNTS OF GREATER THAN OR EQUAL TO 25,000 / MM(3) OR BURKITT'S LYMPHOMA OR T-CELL NON-HODGKIN'S LYMPHOMA OR SERUM URIC ACID LEVEL GREATER THAN OR EQUAL TO 8 MG/DL AND FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ORAL OR INJECTABLE ALLOPURINOL

### **EMEND**

Affected Drugs: Aprepitant

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**CHEMOTHERAPY REGIMEN WITH MODERATE TO HIGH EMETOGENIC POTENTIAL OR INDICATION OF POSTOPERATIVE NAUSEA/VOMITING.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST, ONCOLOGIST, SURGEON

Coverage Duration:12 MONTHS

**Other Criteria:**MUST BE USED IN COMBINATION WITH OTHER ORAL ANTIEMETIC AGENTS WHEN USED FOR THE PREVENTION OF CHEMOTHERAPY INDUCED NAUSEA

### EMFLAZA

Affected Drugs: Emflaza

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF DUCHENNE MUSCULAR DYSTROPHY CONFIRMED BY GENETIC TESTING

Age Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: NEUROLOGIST OR PEDIATRIC NEUROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO PREDNISONE

### EMGALITY

### Affected Drugs:

Emgality Emgality (300 MG Dose)

### Off-Label Uses:N/A

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

**Required Medical Information:**Diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria AND documentation of the number of baseline migraine or headache days per month. Diagnosis of episodic cluster headache, based on the ICHD-III diagnostic criteria AND documentation of the number of baseline cluster headache attack frequency AND documentation that member is currently experiencing a cluster headache period (period of recurrent attacks).

### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

### Prescription Order Restrictions:N/A

# **Coverage Duration:**MIGRAINE:6 MONTHS INITIAL, 1 YEAR CONTINUATION. CLUSTER HA:6 MONTHS

Other Criteria: Migraine: provider attestation of a therapeutic failure on, intolerance to, or contraindication to at least two of the following: one beta blocker (i.e., metoprolol, propranolol, timolol, atenolol, nadolol), topiramate, divalproex or sodium valproate, amitriptyline, or venlafaxine. Attestation that medication is not being used concurrently with botulinum toxin OR if being used in combination, attestation of the following: therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND attestation of a therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist. Reauthorization will require attestation of continued or sustained reduction in migraine or headache frequency or a decrease in severity or duration of migraine AND either attestation that the medication is not being used concurrently with botulinum toxin OR if the request is for combination use with Botox attestation of the following: previous therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND attestation of a previous therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist. Cluster HA: Documentation of a therapeutic failure on, intolerance to, or contraindication to verapamil. Reauthorization for use for cluster headaches will require a diagnosis of episodic cluster headache, based on the ICHD-III diagnostic criteria AND documentation that the member is currently experiencing a cluster headache period (period of recurrent attacks) AND documentation of continued or sustained reduction in cluster headache attack frequency.

### **EMPAVELI**

Affected Drugs:

Empaveli

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

Age Restrictions:N/A

### Prescription Order Restrictions: HEMATOLOGIST

#### Coverage Duration:6 MONTHS

**Other Criteria:**Documentation of diagnosis confirmed by flow cytometry. Documentation that member has received vaccinations against encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenza type B. Documentation of one of the following:1)member is transfusion-depedent prior to starting therapy (i.e., has at least 1 transfusion in the 24 months prior to initiation of medication due to hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 9 g/dL in persons with symptoms from anemia) OR 2) there is significant adverse impact on members health such as end organ damage or thrombosis without other cause. Reauthorization will require documentation of hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal AND reduced need or elimination of transfusion requirements OR stabilization of hemoglobin levels.

Affected Drugs: Empliciti

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF MULTIPLE MYELOMA AND DOCUMENTATION OF ONE OF THE FOLLOWING: 1) documentation that member has previously been treated with at least one prior therapy for multiple myeloma AND that the medication is being used in combination with lenalidomide and dexamethasone OR 2) documentation that the member has previously been treated with at least two prior therapies for multiple myeloma AND that medication is being used in combination combination with pomalidomide and dexamethasone.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

**Coverage Duration:**6 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 6 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

### ENBREL

### Affected Drugs:

Enbrel Enbrel Mini Enbrel SureClick

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**: ADULT RA - DIAGNOSIS OF RA MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS. PJIA - DIAGNOSIS OF POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS. PSORIATIC ARTHRITIS - DIAGNOSIS OF MODERATE TO SEVERE PSA AND DOCUMENTATION OF ACTIVE PSORIATIC LESIONS OR HISTORY OF PSORIASIS. ANKYLOSING SPONDYLITIS - DIAGNOSIS OF ANKYLOSING SPONDYLITIS. PLAQUE PSORIASIS - DIAGNOSIS OF MODERATE TO SEVERE ADULT OR PEDIATRIC PLAQUE PSORIASIS WITH GREATER THAN OR EQUAL TO 5% OF BSA INVOLVED OR DISEASE INVOLVING CRUCIAL BODY AREAS SUCH AS THE HANDS, FEET, FACE OR GENITALS.

Age Restrictions: MUST BE AT LEAST 18 YEARS OF AGE UNLESS TREATING JIA, THEN PATIENT MUST BE AT LEAST 2 YEARS OF AGE, OR IF TREATING PLAQUE PSORIASIS MUST BE AT LEAST 4 YEARS OF AGE.

Prescription Order Restrictions: RHEUMATOLOGIST OR DERMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF (1) HUMIRA AND (2) RINVOQ ER OR XELJANZ. FOR PJIA: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO HUMIRA. FOR PSORIATIC ARTHRITIS: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX OR XELJANZ. FOR ANKYLOSING SPONDYLITIS: THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA AND COSENTYX. FOR ADULT PLAQUE PSORIASIS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO A MINIMUM 3-MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX OR SKYRIZI. FOR PEDIATRIC PLAQUE PSORIASIS: THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO TWO FORMULARY TOPICAL CORTICOSTEROIDS (such as, but not limited to hydrocortisone or

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mometasone). FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

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### ENDARI

#### Affected Drugs: Endari

Endari

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of sickle cell disease AND documentation of being used to reduce the acute complications of sickle cell disease.

Age Restrictions: MUST BE 5 YEARS OF AGE OR OLDER

### Prescription Order Restrictions: WRITTEN BY OR IN CONSULTATION WITH A HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria**:Documentation of a therapeutic failure on, intolerance to, or contraindication to hydroxyurea. Reauthorization will require documentation of continued or sustained improvement in the acute complications of sickle cell disease (i.e. number of sickle cell crises, hospitalizations or number of acute chest syndrome occurrences)

Affected Drugs: Enhertu

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Diagnosis of unresectable or metastatic HER2-positive breast cancer AND documentation of two or more prior anti-HER2 based therapies in the metastatic setting. Diagnosis of locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma AND documentation of one or more prior trastuzumab based therapies.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

### ENSPRYNG

Affected Drugs: Enspryng

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of Neuromyelitis Optica Spectrum Disorder (NMOSD) AND documentation that member is anti-aquaporin-4 (AQP4) antibody positive.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: By or in consultation with a neurologist or ophthalmologist

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Sofosbuvir-Velpatasvir

### Off-Label Uses:N/A

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

**Required Medical Information:**CRITERIA (INDICATION, DOSING, ETC.) WILL BE APPLIED CONSISTENT WITH CURRENT AASLD-IDSA GUIDANCE. MEDICAL RECORD DOCUMENTATION OF A DIAGNOSIS OF HEPATITIS C INFECTION WITH IDENTIFICATION OF GENOTYPE AND SUBTYPE. DOCUMENTATION OF METAVIR LIVER FIBROSIS. DOCUMENTATION OF PREVIOUS TREATMENT AND TREATMENT RESPONSE. DOCUMENTATION OF RECEIVING THE FOLLOWING WITHIN THE PAST 3 MONTHS:HEPATIC FUNCTION PANEL, COMPLETE BLOOD COUNT INCLUDING DIFFERENTIAL, BASIC METABOLIC PANEL, AND BASELINE HCV RNA VIRAL LOAD. DOCUMENTATION OF NO LIMITED LIFE EXPECTANCY OF LESS THAN 12 MONTHS DUE TO NON LIVER RELATED COMORBID CONDITIONS.

### Age Restrictions: MUST BE 6 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**BOARD CERTIFIED GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST OR TRANSPLANT SPECIALIST

### Coverage Duration: PER AASLD/IDSA GUIDELINES

**Other Criteria**:Documentation of any potential drug interactions that may impact drug therapy addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the risks associated with the use of both medications when they interact). Documentation of either 1) completed hepatitis B series OR 2) Hepatitis B screening (sAb/sAg and cAb/cAg) and quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg AND either documentation of treatment for Hepatitis B if there is detectable hepatits B virus OR documentation of being vaccinated against Hepatitis B if negative for hepatitis B sAb. Documentation of intolerance to, contraindication to, or therapeutic failure of Mavyret, if appropriate.

### **EPIDIOLEX**

Affected Drugs: Epidiolex

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of a diagnosis of Lennox-Gastaut syndrome, Dravet syndrome or seizures associated with tuberous sclerosis complex.

Age Restrictions:N/A

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**For Lennox-Gastaut Syndrome: documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary alternatives.

### **EPOETIN**

### Affected Drugs:

Epogen Procrit Retacrit

### Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: TX OF ANEMIA OF CHRONIC KIDNEY DISEASE. TX OF ANEMIA IN NON-MYELOID MALIGNANCY - MUST BE ON ANEMIA CAUSING CHEMO AND THERE IS A MINIMUM OF TWO ADDITIONAL MONTHS OF PLANNED CHEMO. TX OF ANEMIA IN ZIDOVUDINE TREATED HIV INFECTED INDIVIDUAL AND ENDOGENOUS EPO LEVELS OF 500 MU/ML OR LESS and ZIDOVUDINE DOSES OF 4200 MG OR LESS PER WEEK. REDUCTION OF ALLOGENEIC BLOOD TRANSFUSION IN ANEMIC INDIVIDUAL UNDERGOING ELECTIVE. NONCARDIAC, NONVASCULAR SURGERY IN WHICH ANTICIPATED BLOOD LOSS IS GREATER THAN 2 UNITS AND THE NEED FOR ALLOGENEIC BLOOD TRANSFUSION IS ANTICIPATED. FOR CRF NOT ON DIALYSIS AND CANCER: HEMOGLOBIN (HGB) MUST BE LESS THAN OR EQUAL TO 10GM/DL FOR NEW STARTS or LESS THAN 10 GM/DL FOR CONTINUATION OF THERAPY OR DOCUMENTATON THAT THE DOSE WILL BE REDUCED OR INTERRUPTED FOR CKD ON DIALYSIS HEMOGLOBIN (HGB) MUST BE LESS THAN OR EQUAL TO 10GM/DL FOR NEW STARTS or LESS THAN 11 GM/DL FOR CONTINUATION OF THERAPY OR DOCUMENTATON THAT THE DOSE WILL BE REDUCED OR INTERRUPTED FOR SURGERY INDICATION: HGB MUST BE LESS THAN 13 G/DL. FOR ALL OTHER INDICATIONS: HGB MUST BE LESS THAN OR EQUAL TO 10GM/DL FOR NEW STARTS or LESS THAN 12 GM/DL FOR CONTINUATION OF THERAPY. FOR ALL INDICATIONS: DOCUMENTATION OF ADEQUATE IRON STORES W/ SERUM FERRITIN GREATER THAN 100 NG/ML OR TRANSFERRIN LEVEL SATURATION GREATER THAN 20% OR A HISTORY OF CHELATION THERAPY FOR IRON.

### Age Restrictions:N/A

### Prescription Order Restrictions:N/A

**Coverage Duration:**FOR SURGICAL INDICATION: 3 MONTHS. ALL OTHER INDICATIONS 12 MONTHS

**Other Criteria:**NON MYELOID MALIGNANCIES INCLUDE ALL TYPES OF CARCINOMA, SARCOMA, MELANOMA, MULTIPLE MYELOMA, LYMPHOMA, AND LYMPHOCYTIC LEUKEMIA. REAUTHORIZATION WILL REQUIRE REPEAT HGB (WITHIN 3 MONTHS OF REAUTH) AND FERRITIN OR TSAT LEVELS (WITHIN 6 MONTHS OF REAUTH). THIS DRUG MAY BE EITHER

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BUNDLED WITH AND COVERED UNDER END STAGE RENAL DISEASE DIALYSIS RELATED SERVICES OR COVERED UNDER MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION.

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### **EPOPROSTENOL**

### Affected Drugs:

Epoprostenol Sodium

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**MEDICAL RECORD DOCUMENTATION OF A DIAGNOSIS OF CLASS II OR HIGHER PULMONARY ARTERIAL HYPERTENSION

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**FOR CLASS 2 OR 3 PAH: MEDICAL RECORD DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL

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### ERAXIS

### Affected Drugs:

Eraxis

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**NON-NEUTROPENIC PATIENT WITH DX OF CANDIDEMIA OR OTHER CANDIDA INFECTION (OTHER THAN ENDOCARDITIS, OSTEOMYELITIS OR MENINGITIS).

Age Restrictions:1 MONTH OF AGE OR OLDER

Prescription Order Restrictions: INFECTIOUS DISEASE SPECIALIST

Coverage Duration:8 WEEKS (TWO COURSES OF THERAPY)

**Other Criteria:**FOR A DIAGNOSIS OF ESOPHAGEAL CANDIDIASIS - FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO FLUCONAZOLE THERARPY

Affected Drugs: Erivedge

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF METASTATIC BASAL CELL CARCINOMA, OR LOCALLY ADVANCED BASAL CELL CARCINOMA THAT HAS RECURRED FOLLOWING SURGERY OR FOR PATIENTS WHO ARE NOT CANDIDATES FOR SURGERY, AND WHO ARE NOT CANDIDATES FOR RADIATION.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**PER NCCN GUIDELINES, TREATMENT SUPPORTED BY MULTIDISCIPLINARY BOARD CONSULTATION OR A SECOND DERMATOLOGIST OR ONCOLOGIST. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### Affected Drugs: Erleada

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of prostate cancer with evidence of metastatic castrationsensitive disease OR diagnosis of non-metastatic prostate cancer AND documentation that member is no longer responding to castration or is hormone resistant

Age Restrictions:N/A

### Prescription Order Restrictions:ONCOLOGIST OR UROLOGIST

### Coverage Duration:12 MONTHS

**Other Criteria:**Documentation that medication will be used concurrently with a gonadotropinreleasing hormone (GnRH) analog OR documentation of bilateral orchiectomy. Reauthorizations will require documentation of continued disease improvement or lack of disease progression.n.

Esbriet

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DOCUMENTATION OF IDIOPATHIC PULMONARY FIBROSIS (IPF) CONFIRMED BY EITHER A USUAL INTERSTITIAL PNEUMONIA PATTERN ON HIGH RESOLUTION CT SCAN OR BOTH HRCT AND SURGICAL LUNG BIOPSY PATTERN SUGGESTIVE OF IPF OR PROBABLE IPF MADE BY AN INTERDISCIPLINARY TEAM INCLUDING, BUT NOT LIMITED TO SPECIALISTS FROM PULMONARY MEDICINE, RADIOLOGY, THORACIC SURGERY, PATHOLOGY OR RHEUMATOLOGY AND DOCUMENTATION THAT THERE ARE NO OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE SUCH AS DOMESTIC AND OCCUPATIONAL ENVIRONMENTAL EXPOSURES, CONNECTIVE TISSUE DISEASE OR DRUG TOXICITY AND DOCUMENTATION THAT THE PATIENT WAS TAUGHT PULMONARY REHABILITATION TECHNIQUES

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: PULMONOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**N/A

### EUCRISA

### Affected Drugs:

Eucrisa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of mild to moderate atopic dermatitis

Age Restrictions:N/A

**Prescription Order Restrictions:**MUST BE PRESCRIBED BY OR IN CONSULTATION WITH A DERMATOLOGIST, ALLERGIST OR IMMUNOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of contraindication to, intolerance to, or therapeutic failure on tacrolimus ointment AND at least one formulary topical corticosteroid unless deemed inadvisable due to potential risks such as use on sensitive skin areas (face, axillae, or groin)

Evenity

### Off-Label Uses:N/A

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

**Required Medical Information**:Diagnosis of postmenopausal osteoporosis AND documentation that member has not previously received greater than or equal to 12 monthly doses of Evenity. Documentation that the patient is at high-risk of a fracture, determined by the presence of one or more of the following: 1) previous osteoporotic fracture, 2)spine or hip DXA T-Score of -2.5 or below, 3)FRAX calculation of the 10-year hip fracture risk of 3% or greater, 4)FRAX calculation of the 10-year risk of major osteoporotic fractures of 20% or greater or 5) documentation that the patient has failed or is intolerant to at least one prior osteoporosis therapy.

### Age Restrictions:N/A

**Prescription Order Restrictions:**RHEUMATOLOGIST, ENDOCRINOLOGIST, INTERNIST AND ORTHOPEDIST

### Coverage Duration:12 MONTHS

**Other Criteria:**Documentation that the patient has not had a myocardial infarction or stroke within the past 12 months.

**Affected Drugs:** Evkeeza

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of homozygous familial hypercholesterolemia that is caused by mutations of the low-density lipoprotein (LDL) receptor (LDLr) gene AND documenation of use as adjunctive therapy with other low-density lipoprotein-cholesterol (LDL-C) lowering therapies.

Age Restrictions: MUST BE AT LEAST 12 YEARS OF AGE

Prescription Order Restrictions: LIDIPOLOGIST OR CARDIOLOGIST

### Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria**:Documentation of failure to adequately control LDL levels with a maximum tolerated statin therapy (if statin tolerant) to less than 130 mg/dL in pediatric patients 12 to 18 years of age OR less than 100 mg/dL in adults without CVD OR less than 70 mg/dL in adults with established CVD. For patients 13 years and older: documentation of therapeutic failure on, intolerance to, or contraindication to evolocumab (Repatha). For patients 18 years and older: documentation of therapeutic failure on, intolerance to, or contraindication to evolocumab (Repatha) OR alirocumab (Praulent). For requests for use in combination with Juxtapid: documentation of failure to adequately control LDL levels with a minimum 6-month trial of maximum tolerated Juxtapid dose without concomiitant use of Evkeeza. Reauthorization will require documentation of medical necessity and that therapy with Evkeeza is effective.

### Affected Drugs: Evrysdi

Off-Label Uses:N/A

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

**Required Medical Information:**Diagnosis of 5q Spinal Muscular Atrophy (SMA) confirmed by genetic testing with either one of the following: 1)Homozygous exon 7 gene deletion, 2) Homozygous exon 7 conversion mutation OR 3) compound heterozygous exon 7 mutation OR documentation of diagnostic testing confirming zero SMN1 copies

Age Restrictions: MUST BE 2 MONTHS OF AGE OR OLDER

### Prescription Order Restrictions: NEUROLOGIST OR PEDIATRIC NEUROLOGIST

### Coverage Duration:12 MONTHS

**Other Criteria**:Documentation that patient has not received prior treatment with gene therapy (such as, but not limited to Zolgensma) AND documentation that member will not receive routine concomitant SMN modifying therapy (such as, but not limited to Spinraza). Reauthorization will require documentation of medical necessity AND documentation that member has not received prior treatment with gene therapy AND documentation that memer will not receive routine concomitant SMN modifying therapy.

Deferasirox

Off-Label Uses:N/A

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

**Required Medical Information:**Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis) OR diagnosis of chronic iron overload caused by non-transfusion dependent thalassemia

**Age Restrictions:** for transfusional hemosiderosis: must be 2 years of age or older. For non-transfusional dependent thalassemia: must be 10 years of age or older

### Prescription Order Restrictions:N/A

### Coverage Duration:6 MONTHS

**Other Criteria:**For transfusional hemosiderosis: documentation of a serum ferritin level greater than 1000 MCG/L. Continuation of coverage requires documentation of a serum ferritin greater than 500 MCG/L, but decreased from baseline. For non-transfusion dependent thalassemia: documentation of LIC (liver iron concentration) greater than 5 milligrams of iron per gram of dry liver tissue weight (FE/Gdw) AND serum ferritin greater than 300 MCG/L. Continuation of coverage requires documentation of a serum ferritin greater than 300 MCG/L.

Exondys 51

# Off-Label Uses:N/A

# **Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of Duchenne's Muscular Dystrophy confirmed by genetic testing with mutation of the DMD gene that is amenable by exon 51 skipping AND documentation that medication is being given concurrently with oral corticosteroids AND documentation that the patient is ambulatory (able to walk with assistance, not wheelchair bound) as proven by documentation of a 6-minute walk test distance within the past 3 months of initiation of Exondys

#### Age Restrictions:N/A

# Prescription Order Restrictions: NEUROLOGIST OR GENETIC SPECIALIST

#### Coverage Duration:6 MONTHS

**Other Criteria:**Reauthorization will require continued concurrent use with oral corticosteroids and documentation that the patient remains ambulatory as proven by documentation of a follow up 6 minute walk test distance within the past 6 months

# FABIOR

#### Affected Drugs:

Fabior

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DX OF ACNE, ACNE VULGARIS, OR ADULT ONSET ACNE

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY TOPICAL RETINOIDS, INCLUDING BUT NOT LIMITED TO ADAPALENE AND TRETINOIN.

# FABRAZYME

#### Affected Drugs:

Fabrazyme

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information:DX OF FABRY DISEASE

Age Restrictions:N/A

**Prescription Order Restrictions:**METABOLIC SPECIALIST WITH EXPERIENCE TREATING FABRY DISEASE

**Coverage Duration:**6 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

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# FARYDAK

Affected Drugs: Farydak

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF MULTIPLE MYELOMA AND DOCUMENTATION OF BEING USED IN COMBINATION WITH VELCADE AND DEXAMETHASONE

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND CONTINUATION. MAXIMUM OF 12 MONTHS

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO BORTEZOMIB AND AN IMMUNOMODULATORY AGENT (INCLUDING, BUT NOT LIMITED TO POMALYST, REVLIMID, THALOMID)

# FASENRA

# Affected Drugs:

Fasenra Fasenra Pen

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

#### Exclusion Criteria:N/A

**Required Medical Information:**Diagnosis of severe eosinophilic asthma AND documentation that medication is being used as add-on maintenance treatment. Documentation of a blood eosinophil count of 150 cell/mcL or greater within 3 months of starting therapy.

Age Restrictions: Must be 12 years of age or older

#### Prescription Order Restrictions: ALLERGIST, IMMUNOLOGIST OR PULMONOLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**Documentation of contraindication, intolerance to, or poorly controlled symptoms despite at least a 3-month trial of maximally tolerated inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist OR one exacerbation in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care vistis, or hospitalization) despite current therapy or intolerance to inhaled corticosteroids plus a long-acting beta agonist AND documentation that Fasenra is not being used in combination with omalizumab, mepolizumab, or reslizumab. Documentation of a therapeutic failure on, intolerance to, or contraindication to Nucala. Subsequent approval after 12 months will require documentation of continued disease improvement or lack of disease progression.

# FENSOLVI

#### Affected Drugs:

Fensolvi (6 Month)

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DIAGNOSIS OF CENTRAL PRECOCIOUS PUBERTY

Age Restrictions:2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: PEDIATRIC ENDOCRINOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO , OR CONTRAINDICATION TO TWO OF THE FOLLOWING: LUPRON DEPOT-PED, TRIPTODUR, OR SUPPRELIN LA.

# FERRIC CITRATE

Affected Drugs:

Auryxia

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**N/A

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria: This medication requires payment determination

# FERRIPROX

#### Affected Drugs:

Deferiprone Ferriprox Ferriprox Twice-A-Day

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMIA SYNDROME

Age Restrictions:N/A

Prescription Order Restrictions:HEMATOLOGIST

**Coverage Duration:**6 MONTHS

**Other Criteria:**THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO EXJADE. DOCUMENTATION OF ANC GREATER THAN 1.5 X 100000000 (10 TO THE 9TH POWER)/L. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF SERUM FERRITIN LEVEL GREATER THAN 300 MCG/L.

Affected Drugs: Fetroja

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of complicated urinary tract infection, including pyelonephritis caused by the following suceptible gram negative microorganisms: Escherichia coli, Klebsiella penumoniae, Proteus mirabilis, Pseudomonas aeruginosa, or Enterobacter cloacae complex. Documentation of hospital acquired bacterial pneumonia (HABP) or Ventilator associated bacterial pneumonia (VABP) caused by the following susceptible gram negative microorganisms: Acinetobacter baumannii complex, Escherichia coli, Klebsiella penumoniae, Pseudomonas aeruginosa, Serratia marcescens, or Enterobacter cloacae complex.

# Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**WRITTEN BY OR IN CONSULTATION WITH A INFECTIOUS DISEASE PROVIDER

# Coverage Duration:2 WEEKS

Other Criteria:DOCUMENTATION OF A CULTURE AND SENSITIVITY SHOWING THE PATIENT'S INFECTION IS NOT SUSCEPTIBLE TO PREFERRED ALTERNATIVE ANTIBIOTICS TREATMENTS OR A DOCUMENTED HISTORY OF PREVIOUS INTOLERANCE TO OR CONTRAINDICATION TO TWO OTHER ANTIBIOTICS SHOWN TO BE SUSCEPTIBLE ON THE CULTURE AND SENSITIVITY.

# FETZIMA

#### Affected Drugs:

Fetzima Fetzima Titration

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST TWO ANTIDEPRESSANT CLASSES.

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# **FINTEPLA**

# Affected Drugs:

Fintepla

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of Dravet syndrome

Age Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of a therapeutic failure on, intolerance to or contraindication to two formulary alternatives used for the treatment of Dravet syndrome, including but not limited to cannabidiol, clobazam, valproate and topiramate.

Icatibant Acetate

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**:DIAGNOSIS OF HEREDITARY ANGIOEDEMA AND DOCUMENATION OF THE PRESENCE OF SPECIFIC ABNORMALITIES IN COMPLEMENT PROTEINS IN THE SETTING OF A SUGGESTIVE CLINICAL HISTORY OF EPISODIC ANGIOEDEMA WITHOUT URTICARIA SUPPORTED BY DOCUMENTATION OF TWO OR MORE SETS OF COMPLEMENT STUDIES, SEPARATED BY ONE MONTH OR MORE SHOWING LOW C4 LEVELS AND LESS THAN 50 PERCENT OF THE LOWER LIMIT OF NORMAL C1 INH ANTIGENIC PROTEIN LEVELS OR FUNCTION LEVELS.

Age Restrictions: MUST BE AT LEAST 18 YEARS OF AGE

**Prescription Order Restrictions:**ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST, OR DERMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS REAUTH

**Other Criteria**:DOCUMENTATION THAT ICATIBANT IS BEING USED FOR TREATMENT OF ACUTE HEREDITARY ANGIOEDEMA ATTACK. DOCUMENTATION THAT ICATIBANT IS NOT BEING USED IN COMBINATION WITH OTHER APPROVED TREATMENTS FOR ACUTE HAE ATTACKS. Reauthorization will require documentation of medical necessity. Affected Drugs: Firdapse

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of Lambert-Eaton Myasthenic Syndrome confirmed by one of the following: post-exercise facilitation test showing increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared to pre-exercise baseline value OR high-frequency Repetitive Nerve Stimulation (RNS) showing increase in compound muscle action potential (CMAP) of at least 60 percent OR positive anti-P/Q type voltage-gated calcium channel antibody test.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria**:REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION or PRESCRIBER ATTESTATION OF MEDICAL NECESSITY AND THAT THE MEMBER WILL BENEFIT FROM CONTINUED THERAPY.

# FLECTOR

Affected Drugs:

Diclofenac Epolamine

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DIAGNOSIS OF USE FOR THE TREATMENT OF ACUTE PAIN DUE TO MINOR STRAINS, SPRAINS, CONTUSIONS.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:12 WEEKS

Other Criteria:N/A

# FORTEO

#### Affected Drugs:

Forteo Teriparatide (Recombinant)

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DIAGNOSIS OF PRIMARY, HYPOGONADAL, OR GLUCOCORTICOID INDUCED OSTEOPOROSIS IN MALES or POSTMENOPAUSAL or GLUCOCORTICOID INDUCED OSTEOPOROSIS IN FEMALES. DOCUMENTATION THAT MEMBER HAS NOT PREVIOUSLY BEEN ON A PARATHYROID HORMONE ANALOG FOR GREATER THAN 2 YEARS.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:24 MONTHS

**Other Criteria:**DOCUMENTATION OF AN ATTEMPT OF THERAPY WITH OR CONTRAINDICATION TO BISPHOSPHONATES or EITHER A PREVIOUS OSTEOPOROTIC FRACTURE OR HIGH RISK OF FRACTURE (T-SCORE LESS THAN -2.5 WITH DOCUMENTED RISK FACTORS).

# FOTIVDA

**Affected Drugs:** Fotivda

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of relapsed or refractory advanced renal cell cancer following two or more prior systemic therapies.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

Fulphila

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

**Exclusion Criteria:**PROPHYLAXIS DURING CHEMO REGIMENS WITH A FEBRILE NEUTROPENIA RISK LESS THAN 20% AND NO HIGH RISK FOR COMPLICATIONS, THOSE WHO ARE NEUTROPENIC BUT AFEBRILE, TO ALLOW AN INCREASE IN THE DOSE-INTENSITY OF CYTOTOXIC CHEMO BEYOND ESTABLISHED DOSE RANGES

**Required Medical Information:**PREVENTION OF FEBRILE NEUTROPENIA WHEN RISK DUE TO MYELOSUPPRESIVE CHEMO REGIMEN IS 20% OR GREATER OR TO PREVENT FEBRILE NEUTROPENIA WHEN THE RISK OF DEVELOPING FEBRILE NEUTROPENIA IS LESS THAN 20% WITH ONE ADDITIONAL RISK FACTOR. PREVENTION OF FEBRILE NEUTROPENIA WHEN A PREVIOUS CYCLE RESULTED IN A NEUTROPENIC COMPLICATION AND DOSE REDUCTION WILL COMPROMISE DISEASE FREE OR OVERALL SURVIVAL OR TREATMENT OUTCOME.

#### Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

#### Coverage Duration:6 MONTHS

Other Criteria: ADDITIONAL RISK FACTORS FOR THE PREVENTION OF FEBRILE NEUTROPENIA INCLUDE, BUT ARE NOT LIMITED TO: 65 YRS OR OLDER, POOR PERFORMANCE STATUS, PREVIOUS HISTORY OF FEBRILE NEUTROPENIA, EXTENSIVE PRIOR RADIATION OR CHEMOTHERAPY TREATMENT, POOR NUTRITIONAL STATUS, RECENT SURGERY OR OPEN WOUNDS OR ACTIVE INFECTION, ADVANCED CANCER, PERSISTENT NEUTROPENIA, BONE MARROW INVOLVEMENT BY TUMOR, LIVER DYSFUNCTION (BILIRUBIN GREATER THAN 2), OR RENAL DYSFUNCTION (CrcL LESS THAN 50 ML/MIN).

# **FYCOMPA**

Affected Drugs:

Fycompa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF PARTIAL ONSET SEIZURES OR PRIMARY GENERALIZED TONIC-CLONIC SEIZURES.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: carbamazepine, divalproex, valproic acid, felbamate, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, tiagabine, topiramate, zonisamide, Lyrica, Sabril, Aptiom, Vimpat

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Affected Drugs: Galafold

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of Fabry disease as confirmed by one of the following: Enzyme assay indicating deficiency of Alpha Gal-A (if male) OR genetic test documenting galactosidase alpha gene mutation. Documentation of in vitro assay data confirming the presence of an amenable galactosidase alpha gene (GLA) variant, in accordance with the FDA-approved prescribing information.

# Age Restrictions: MUST BE 16 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**By or in consultation with a geneticist, nephrologist, cardiologist or a specialist with experience treating Fabry disease

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria**:Documentation that medication is not being used concurrently with enzyme replacement therapy intended for the treatment of Fabry disease, such as agalsidase beta. Reauthorization will require medical record documentation of clinical improvement or lack of progression in signs and symptoms of Fabry disease while on therapy.

# GATTEX

# Affected Drugs:

Gattex

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DIAGNOSIS OF SHORT BOWEL SYNDROME

Age Restrictions: MUST BE AT LEAST 1 YEAR OF AGE

Prescription Order Restrictions: GASTROENTEROLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**FOR PATIENTS 1 THROUGH 17 YEARS OF AGE: DOCUMENTATION THAT THE MEMBER IS DEPENDENT ON PARENTERAL NUTRITION/INTRAVENOUS SUPPORT. FOR PATIENTS 18 YEARS AND OLDER: DOCUMENTATION THAT THE MEMBER HAS BEEN DEPENDENT ON PARENTERAL NUTRITION/INTRAVENOUS SUPPORT FOR A MINIMUM OF 12 MONTHS CONTINUOUSLY AND THAT THE MEMBER REQUIRES PARENTERAL NUTRITION AT LEAST 3 TIMES PER WEEK. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF A DECREASE OF PARENTERAL NUTRITION/INTRAVENOUS SUPPORT OF AT LEAST 20% COMPARED TO BASELINE, ENTERAL AUTONOMY, OR REDUCTION IN PARENTERAL SUPPORT INFUSION OF 1 OR MORE DAYS PER WEEK.

Affected Drugs: Gavreto

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Documentation of metastatic non-small cell lung cancer (NSCLC) AND documentation of a rearranged during transfection (RET)-fusion positive tumor as detected by an FDA approved test. Documentation of either 1)advanced metastatic RET-mutant medullary thyroid cancer (MTC) AND documentation that sytemic therapy is required OR 2)documentation of advanced metastatic RET fusion-positive thryoid cancer AND documentation that systemic therapy is required AND documentation that patient is radioactive-iodine refractory when radioactive iodine is appropriate.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# GAZYVA

Affected Drugs:

Gazyva

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**: DIAGNOSIS OF CHRONIC LYMPHOCYTIC LEUKEMIA WHICH IS PREVIOUSLY UNTREATED or DIAGNOSIS OF FOLLICULAR LYMPHOMA.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

**Coverage Duration:**CLL: 12 MONTHS. FOLLICULAR LYMPHOMA: 6 MONTHS INITIAL, 24 MONTHS REAUTH

Other Criteria:FOR CLL: DOCUMENTATION OF BEING USED IN COMBINATION WITH CHLORAMBUCIL. FOR FOLLICULAR LYMPHOMA: DOCUMENTATION OF PREVIOUSLY UNTREATED STAGE II BULKY, III OR IV DISEASE USED IN COMBINATION WITH CHEMOTHERAPY, or AS MONOTHERAPY FOLLOWING AT LEAST A PARTIAL REMISSION IF PREVIOUSLY TREATED WITH AT LEAST 6 CYCLES OF GAZYVA IN COMBINATION WITH CHEMOTHERAPY. FOR SECOND LINE FOLLICULAR LYMPHOMA: DOCUMENTATION OF BEING USED IN COMBINATION WITH BENDAMUSTINE, OR AS MONOTHERAPY IF PREVIOUSLY TREATED WITH 6 CYCLES IN COMBINATION WITH BENDAMUSTINE and DOCUMENTATION THAT PATIENT RELAPSED AFTER, OR IS REFRACTORY TO A RITUXIMAB CONTAINING REGIMEN. REAUTH FOR FOLLICULAR LYMPHOMA AFTER INITIAL 6 MONTHS WILL REQUIRE DOCUMENTATION OF A COMPLETE RESPONSE, PARTIAL RESPONSE, OR HAS STABLE DISEASE AND THAT MEDICATION IS BEING USED AS MONOTHERAPY. SUBSEQUENT APPROVAL FOR CLL WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

Gilotrif

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF FIRST LINE TREATMENT FOR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE NON-RESISTANT EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST or DOCUMENTATION OF A DIAGNOSIS OF METASTATIC, SQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC) WHICH HAS PROGRESSED AFTER PLATINUM BASED CHEMOTHERAPY.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs: Givlaari

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of acute hepatic porphyria (AHP), including acute intermittent porphyria (AIP), hereditary coproporphyria (HCP), variegate porphyria (VP), and aminolevulinic acid dehydratase (ALAD) porphyria (ADP) confirmed my at least one of the following: 1)elevated urinary or plasma aminolevulinic acid (ALA) OR 2)elevated urinary or plasma porphobilinogen (PBG) OR 3) genetic testing confirming a mutation associated with acute hepatic porphyria (AHP).

# Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**Specialist with experience managing porphyrias (i.e., hematologist, hepatologist or gastroenterologist)

# Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS REAUTH

**Other Criteria**:Documentation of the baseline number of porphyria attacks requiring hospitalization, urgent healthcare visit, or IV hemin treatment within the previous 6 months AND documentation of active disease with at least two documented porphyria attacks with the previous 6 months. Reuathorization will require documentation of a clinically significant response to treatment as evidenced by: 1) a reduction in the number of porphyria attacks requiring hospitalization, urgent healthcare visit, or IV hemin treatment within the previous 6 months from baseline OR 2) decreased severity in the symptoms of acute hepatic porphyria, OR 3) a reduction in the levels of urinary or plasma aminolevulinic acid (ALA) OR urinary or plasma porphobilinogen (PBG).

Granix

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**PREVENTION OF FEBRILE NEUTROPENIA WHEN RISK DUE TO MYELOSUPPRESIVE CHEMO REGIMEN IS 20% OR GREATER. TO PREVENT FEBRILE NEUTROPENIA WHEN THE RISK OF DEVELOPING FEBRILE NEUTROPENIA IS LESS THAN 20% WITH ONE OF THE FOLLOWING RISK FACTORS: 65 YRS OR OLDER, POOR PERFORMANCE STATUS, PREVIOUS HISTORY OF FEBRILE NEUTROPENIA, EXTENSIVE PRIOR RADIATION OR CHEMO TREATMENT, POOR NUTRITIONAL STATUS, RECENT SURGERY OR OPEN WOUNDS OR ACTIVE INFECTION, ADVANCED CANCER, PERSISTENT NEUTROPENIA, BONE MARROW INVOLVEMENT BY TUMOR, LIVER DYSFUNCTION (BILIRUBIN GREATER THAN 2), OR RENAL DYSFUNCTION (CrCI LESS THAN 50 ML/MIN)

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:6 MONTHS

Other Criteria:N/A

# **GROWTH HORMONE**

# Affected Drugs:

Norditropin FlexPro

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**GROWTH HORMONE STIMULATION TESTS, IGF-I LEVELS, GROWTH VELOCITY CURVES

Age Restrictions:N/A

Prescription Order Restrictions: ENDOCRINOLOGIST OR NEPHROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

Affected Drugs: Haegarda

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF HEREDITARY ANGIOEDEMA and FOR HAE TYPE I AND TYPE II: THE PRESENCE OF SPECIFIC ABNORMALITIES IN COMPLEMENT PROTEINS IN THE SETTING OF A SUGGESTIVE CLINICAL HISTORY OF EPISODIC ANGIOEDMEA WITHOUT URTICARIA SUPPORTED BY DOCUMENTATION OF LOW C4 LEVELS AND LESS THAN 50 PERCENT OF THE LOWER LIMIT OF NORMAL C1 INH ANTIGENIC PROTEIN LEVELS OR FUNCTION LEVELS

Age Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR DERMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS REAUTH

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS USED AS PROPHYLACTIC THERAPY. Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

### HALAVEN

# Affected Drugs:

Halaven

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF METASTATIC BREAST CANCER or DIAGNOSIS OF UNRESECTABLE OR METASTATIC LIPOSARCOMA

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**FOR BREAST CA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST 2 PRIOR CHEMOTHERAPEUTIC REGIMENS. PRIOR THERAPY SHOULD HAVE INCLUDED AN ANTHRACYCLINE AND A TAXANE IN THE ADJUVANT OR METASTATIC SETTING. FOR LIPOSARCOMA: DOCUMENTATION OF A PREVIOUS TRIAL OF AN ANTHRACYCLINE CONTAINING REGIMEN. Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

Ledipasvir-Sofosbuvir

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

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

**Required Medical Information:**CRITERIA (INDICATION, DOSING, ETC.) WILL BE APPLIED CONSISTENT WITH CURRENT AASLD-IDSA GUIDANCE. MEDICAL RECORD DOCUMENTATION OF A DIAGNOSIS OF HEPATITIS C INFECTION WITH IDENTIFICATION OF GENOTYPE AND SUBTYPE. DOCUMENTATION OF METAVIR LIVER FIBROSIS. DOCUMENTATION OF PREVIOUS TREATMENT AND TREATMENT RESPONSE. DOCUMENTATION OF RECEIVING THE FOLLOWING WITHIN THE PAST 3 MONTHS:HEPATIC FUNCTION PANEL, COMPLETE BLOOD COUNT INCLUDING DIFFERENTIAL, BASIC METABOLIC PANEL, AND BASELINE HCV RNA VIRAL LOAD. DOCUMENTATION OF NO LIMITED LIFE EXPECTANCY OF LESS THAN 12 MONTHS DUE TO NON LIVER RELATED COMORBID CONDITIONS.

# Age Restrictions: MUST BE 3 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**BOARD CERTIFIED GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST OR TRANSPLANT SPECIALIST

## Coverage Duration: PER AASLD/IDSA GUIDELINES

**Other Criteria**:Documentation of any potential drug interactions that may impact drug therapy addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the risks associated with the use of both medications when they interact). Documentation of either 1) completed hepatitis B series OR 2) Hepatitis B screening (sAb/sAg and cAb/cAg) and quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg AND either documentation of treatment for Hepatitis B if there is detectable hepatits B virus OR documentation of being vaccinated against Hepatitis B if negative for hepatitis B sAb. Documentation of intolerance to, contraindication to, or therapeutic failure of Mavyret, if appropriate

# HETLIOZ

# Affected Drugs:

Hetlioz Hetlioz LQ

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

Exclusion Criteria:N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF NON-24-HOUR SLEEP-WAKE DISORDER (FREE-RUNNING DISORDER) AND DOCUMENTATION THAT THE MEMBER IS TOTALLY BLIND WITH NO PERCEPTION OF LIGHT. DOCUMENTATION OF A DIAGNOSIS OF NIGHTTIME SLEEP DISTURBANCES IN SMITH-MAGENIS SYNDROME (SMS).

Age Restrictions: SLEEP WAKE DISORDER: 18 YRS OF AGE OR OLDER. SMS: 3 YRS OF AGE OR OLDER

Prescription Order Restrictions:N/A

#### **Coverage Duration:**6 MONTHS

Other Criteria: REAUTHORIZATION FOR NON-24-HOUR SLEEP WAKE DISORDER WILL REQUIRE DOCUMENTATION OF A CLINICALLY SIGNIFICANT INCREASE IN NIGHTTIME SLEEP OR A CLINICALLY SIGNIFICANT DECREASE IN DAYTIME SLEEP. REAUTHORIZATION FOR SMS WILL REQUIRE DOCUMENTATION OF A CLINICALLY SIGNIFICANT INCREASE IN NIGHTTIME SLEEP OR A CLINCIALLY SIGNIFICANT DECREASE IN NIGHTTIME SLEEP DISTRUBANCES.

# **HUMIRA**

#### Affected Drugs:

Humira Humira Pediatric Crohns Start Humira Pen Humira Pen-CD/UC/HS Starter Humira Pen-Pediatric UC Start Humira Pen-Ps/UV/Adol HS Start Humira Pen-Psor/Uveit Starter

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

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

Required Medical Information: ADULT RA - DX OF RA MADE IN ACCORDANCE WITH THE ACR CRITERIA AND A 3 MONTH TRIAL OF MTX OR OTHER DMARD IF MTX NOT TOLERATED OR CONTRAINDICATED. JIA - DX OF MODERATE TO SEVERE JIA AND A MINIMUM 3 MONTH TRIAL OF ONE NSAID AND MTX THERAPY OR OTHER DMARD IF MTX IS CONTRAINDICATED. PSORIATIC ARTHRITIS - DX OF MODERATE TO SEVERE PSA AND ACTIVE PSORIATIC LESIONS OR HISTORY OF PSORIASIS. FOR PERIPHERAL PSA: INTOLERANCE OR FAILURE TO MTX AND ONE FORMULARY NSAID. FOR AXIAL PSA: INTOLERANCE, CONTRAINDICATION OR FAILURE TO TWO FORMULARY NSAIDS. PLAQUE PSORIASIS - DX OF MODERATE TO SEVERE PLAQUE PSORIASIS WITH AT LEAST 5% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE OR GENITALS AND FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO ONE FORMULARY TOPICAL CORTICOSTEROID AND AT LEAST 3 MONTHS OF ONE SYSTEMIC THERAPY INCLUDING BUT NOT LIMITED TO MTX OR CYCLOSPORINE OR PHOTOTHERAPY. CROHN'S -DOCUMENTATION OF MODERATE OR HIGH RISK PATIENT OR A DX OF CROHNS DISEASE WITH FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE CORTICOSTEROID and ONE IMMUNOMODULATOR. ANKYLOSING SPONDYLITIS - DX OF A.S. AND FAILURE ON. INTOLERANCE TO, OR CONTRAINDICATION TO 2 FORMULARY NSAIDS. ULCERATIVE COLITIS - DX OF MODERATE TO SEVERE UC WITH FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AZATHIOPRINE OR 6-MP. FOR HIDRADENITIS SUPPURATIVA (HS)-DX OF MODERATE TO SEVERE HS, DEFINED AS STAGE II OR III ON THE HURLEY STAGING SYSTEM and DOCUMENTATION OF AT LEAST 3 ABSCESSES OR INFLAMMATORY NODULES. UVEITIS - DX OF NON-INFECTIOUS ITERMEDIATE. POSTERIOR OR PANUVEITIS WITH FAILURE ON. INTOLERANCE TO. OR CONTRAINDICATION TO ONE LOCAL OR SYSTEMIC CORTICOSTEROID AND EITHER ONE IMMUNUOSUPPRESSANT or IF UNDER 18 YEARS OF AGE, METHOTREXATE.

**Age Restrictions:**MUST BE AT LEAST 18 YEARS FOR: PSORIASIS, PSA, RA, AND ANKYLOSING SPONDYLITIS. MUST BE AT LEAST 2 YEARS OF AGE FOR PJIA OR UVEITIS. MUST BE AT LEAST 5 YEARS OF AGE FOR UC. MUST BE AT LEAST 6 YEARS OF AGE FOR CROHNS. MUST BE AT LEAST 12 YEARS OF AGE FOR HS.

**Prescription Order Restrictions:**RHEUMATOLOGIST, GASTROENTEROLOGIST, DERMATOLOGIST OR OPHTHALMOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. IF UNDER 18 AND USING FOR UVEITIS, MUST SHOW DOCUMENTATION OF USE IN COMBINATION WITH METHOTREXATE OR A DOCUMENTED REASON WHY IT ISN'T BEING USED IN COMBINATION WITH METHOTREXATE. FOR CONTINUED THERAPY MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION. IN ORDER TO RECEIVE WEEKLY DOSING OF HUMIRA FOR RHEUMATOID ARTHRITIS, MUST SHOW DOCUMENTATION OF THERAPEUTIC FAILURE ON EVERY OTHER WEEK DOSING SCHEDULE. IN ORDER TO RECEIVE WEEKLY DOSING OF HUMIRA FOR UC OR CROHN'S, MUST SHOW DOCUMENTATION OF INADEQUATE DRUG TROUGH LEVEL (LESS THAN OR EQUAL TO 7.5 MCG/ML) TO SUPPORT WEEKLY DOSING, PER AGA GUIDELINES.

Ibrance

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF HORMONE RECEPTOR POSITIVE, HER2 NEGATIVE ADVANCED OR METASTATIC BREAST CANCER and ONE OF THE FOLLOWING: PRESCRIBED FOR INITIAL ENDOCRINE BASED THERAPY IN COMBINATION WITH AN AROMATASE INHIBITOR (i.e. LETROZOLE) or AFTER DISEASE PROGRESSION FOLLOWING ENDOCRINE THERAPY, USED IN COMBINATION WITH FULVESTRANT.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Iclusig

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF CHRONIC PHASE, ACCELERATED PHASE, OR BLAST PHASE CHRONIC MYELOID LEUKEMIA (CML) OR PHILADELPHIA CHROMOSOME POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA (PH+ALL)

Age Restrictions:N/A

# Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

# Coverage Duration:12 MONTHS

**Other Criteria:**For chronic phase (CP) chronic myeloid leukemia: documentation of resistance or intolerance to at least two prior kinase inhibitors. For accelerated phase of blase phase CML or Philadelphis chromosome positive acute lymphoblastic leukemia: DOCUMENTATION OF RESISTANCE OR INTOLERANCE TO ONE PRIOR TYROSINE KINASE INHIBITOR THERAPY OR DOCUMENTATION OF CELL MUTATION T3151. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# **IDHIFA**

Affected Drugs: IDHIFA

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

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

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria**:Reauthorizations will require documentation of continued disease improvement or lack of disease progression

llaris

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DOCUMENTATION OF DIAGNOSIS OF CRYOPYRIN-ASSOCIATED PERIODIC SYNDROME (CAPS), INCLUDING FAMILIAL COLD AUTOINFLAMMATORY SYNDROME (FCAS) AND MUCKLE-WELLS SYNDROME (MWS) SUPPORTED BY DOCUMENTATION OF GENETIC TESTING TO IDENTIFY THE CIAS1/NLRP-3 GENE MUTATION. DIAGNOSIS OF SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) AND MEDICAL RECORD DOCUMENTATION OF ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) DIAGNOSED PRIOR TO AGE 16 YEARS, CHARACTERIZED BY GREATER OR EQUAL TO 2 JOINTS WITH ACTIVE ARTHRITIS AND SPIKING. INTERMITTENT FEVER (GREATER THAN 38 DEGREES C) WITHOUT INFECTIOUS CAUSE AND CRP GREATER THAN 30 MG/DL). DIAGNOSIS OF TUMOR NECROSIS FACTOR RECEPTOR ASSOCIATED PERIODIC SYNDROME (TRAPS) SUPPORTED BY DOCUMENTATION OF GENETIC TESTING TO IDENTIFY THE TNFRSF1A GENE MUTATION. DIAGNOSIS OF HYPERIMMUNOGLOBULIN D SYNDROME (HIDS) or MEVALONATE KINASE DEFICIENCY (MKD) WITH DOCUMENTATION OF ELEVATED IGG D LEVEL OR GENETIC TESTING TO IDENTIFY THE MVK GENE MUTATION. DIAGNOSIS OF FAMILIAL MEDITERRANEAN FEVER (FMF) AS CONFIRMED BY GENETIC TESTING TO IDENTIFY THE MEFV GENE MUTATION. Diagnosis of adult onset Still's disease diagnosed after age 16 years with active disease characterized by disease activity based on Disease Activity Score 28 (DAS28) of 3.2 or greater AND documentation of at least 4 painful and 4 swollen joints at screening and baseline.

**Age Restrictions:**FOR CAPS: MUST BE 4 YEARS OF AGE OR OLDER. FOR SJIA: MUST BE 2 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**FOR CAPS, TRAPS, HIDS,MKD OR FMF: PRESCRIBED BY AN IMMUNOLOGIST, RHEUMATOLOGIST, DERMATOLOGIST OR ALLERGIST. FOR SJIA or STILLS: PRESCRIBED BY A RHEUMATOLOGIST.

**Coverage Duration:**FOR CAPS: 12 WEEKS THEN 1 YEAR. FOR ALL OTHER INDICATIONS: 6 MONTHS THEN 1 YEAR.

**Other Criteria:**FOR SJIA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ACTEMRA. FOR FMF: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO COLCHICINE. FOR CAPS: FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO

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KINERET. REAUTHORIZATION WITH REQUIRE CONTINUED IMPROVEMENT IN THE SIGNS AND SYMPTOMS OF THE DISEASE.

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## Affected Drugs:

Imbruvica

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

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

**Required Medical Information:**DIAGNOSIS OF MANTLE CELL LYMPHOMA (MCL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY. DIAGNOSIS OF CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) OR SMALL LYMPHOCYTIC LEUKEMIA (SLL) or CLL/SLL WITH 17P DELETION. DIAGNOSIS OF WALDENSTROM MACROGLOBULINEMIA. DIAGNOSIS OF MARGINAL ZONE LYMPHOMA WHO HAVE RECEIVED AT LEAST ONE PRIOR ANTI CD20-BASED THERAPY. DIAGNOSIS OF CHRONIC GRAFT VERSUS HOST DISEASE AFTER FAILURE OF ONE OR MORE LINES OF SYSTEMIC THERAPY.

### Age Restrictions:N/A

**Prescription Order Restrictions:**HEMATOLOGIST, ONCOLOGIST OR TRANSPLANT SPECIALIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# Affected Drugs:

Imfinzi

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of unresectable Stage III Non-Small Cell Lung Cancer (NSCLC) with documentation that patient has received and has not progressed following a minimum of two cycles of concurrent platinum-based chemotherapy and radiation therapy OR Diagnosis of extensive-stage small cell lung cancer used in combination with etoposide and either carboplatin or cisplatin.

# Age Restrictions:18 YEARS OF AGE OR OLDER

# Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

**Coverage Duration:**6 MONTHS INITIAL. 6 MONTHS RENEWAL FOR (N)SCLC, 12 MONTHS RENEWAL FOR ALL OTHER INDICATIONS

Other Criteria: REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. REAUTHORIZATION FOR NSCLC OR SCLC BEYOND 1 YEAR WILL REQUIRE DOCUMENTATION OF PEER REVIEWED LITERATURE CITING WELL DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBERS HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA APPROVED TREATMENT DURATION. Affected Drugs: Imlygic

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF UNRESECTABLE CUTANEOUS, SUBCUTANEOUS OR NODAL MELANOMA LESIONS AND DOCUMENTATION OF MELANOMA RECURRENCE AFTER INTIAL SURGERY

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR DERMATOLOGIST

**Coverage Duration:**6 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 6 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs: Inflectra

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: CROHN'S DISEASE- DIAGNOSIS OF MODERATE TO SEVERE CROHN'S AND DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO 12 WEEKS OF HUMIRA THERAPY OR DIAGNOSIS OF CROHN'S WITH ACTIVE DRAINING FISTULAS. RA - DIAGNOSIS OF MODERATE TO SEVERE RA MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RA AND BEING USED IN CONJUNCTION WITH METHOTREXATE. ANKYLOSING SPONDYLITIS - DIAGNOSIS OF ANKYLOSING SPONDYLITIS. PLAQUE PSORIASIS - DIAGNOSIS OF CHRONIC, SEVERE PLAQUE PSORIASIS WITH AT LEAST 5% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE OR GENITALS. PSORIATIC ARTHRITIS - DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE PSA AND HISTORY OF PSORIASIS OR ACTIVE PSORIATIC LESIONS. ULCERATIVE COLITIS -DIAGNOSIS OF MODERATE TO SEVERE UC

**Age Restrictions:**MUST BE AT LEAST 18 YEARS OF AGE FOR THE FOLLOWING DIAGNOSES -RA, ANKYLOSING SPONDYLITIS, PLAQUE PSORIASIS, PSORIATIC ARTHRITIS. MUST BE AT LEAST 6 YEARS OF AGE FOR CROHNS DISEASE AND ULCERATIVE COLITIS.

**Prescription Order Restrictions:**RHEUMATOLOGIST, DERMATOLOGIST OR GASTROENTEROLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF (1) HUMIRA AND (2) RINVOQ ER OR XELJANZ. FOR UC: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA AND XELJANZ. FOR PSORIATIC ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX, OR XELJANZ. FOR PLAQUE PSORIASIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX, OR SKYRIZI. FOR ANKYLOSING SPONDYLITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF

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HUMIRA AND COSENTYX. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

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# Affected Drugs:

Avsola Renflexis

## Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: CROHN'S DISEASE- DIAGNOSIS OF MODERATE TO SEVERE CROHN'S AND DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO 12 WEEKS OF HUMIRA THERAPY OR DIAGNOSIS OF CROHN'S WITH ACTIVE DRAINING FISTULAS. RA - DIAGNOSIS OF MODERATE TO SEVERE RA MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RA AND BEING USED IN CONJUNCTION WITH METHOTREXATE. ANKYLOSING SPONDYLITIS - DIAGNOSIS OF ANKYLOSING SPONDYLITIS. PLAQUE PSORIASIS - DIAGNOSIS OF CHRONIC, SEVERE PLAQUE PSORIASIS WITH AT LEAST 5% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE OR GENITALS. PSORIATIC ARTHRITIS - DIAGNOSIS OF MODERATELY TO SEVERELY ACTIVE PSA AND HISTORY OF PSORIASIS OR ACTIVE PSORIATIC LESIONS. ULCERATIVE COLITIS -DIAGNOSIS OF MODERATE TO SEVERE UC

**Age Restrictions:**MUST BE AT LEAST 18 YEARS OF AGE FOR THE FOLLOWING DIAGNOSES -RA, ,ANKYLOSING SPONDYLITIS, PLAQUE PSORIASIS, PSORIATIC ARTHRITIS. MUST BE AT LEAST 6 YEARS OF AGE FOR CROHNS DISEASE AND ULCERATIVE COLITIS.

**Prescription Order Restrictions:**RHEUMATOLOGIST, DERMATOLOGIST OR GASTROENTEROLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF (1) HUMIRA AND (2) RINVOQ ER OR XELJANZ. FOR UC: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA AND XELJANZ OR DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED TO INDUCE DISEASE REMISSION. FOR PSORIATIC ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX, OR XELJANZ. FOR PLAQUE PSORIASIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX, OR SKYRIZI.

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FOR ANKYLOSING SPONDYLITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA AND COSENTYX. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

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Affected Drugs: Ingrezza

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of tardive dyskinesia as evidenced by either moderate to severe abnormal body movements (AIMS score 3 or 4) in at least 1 body area or mild abnormal body movements (AIMS score 1 or 2) in 2 or more body areas AND documentation of no other causes of involuntary movements AND documentation of baseline AIMS score prior to initiating therapy AND if the symptoms are related to use of a first-generation antipsychotic, documentation that a switch to a second generation antipsychotic has been attempted and did not resolve symptoms OR provider rationale as to why a switch to a second generation antipsychotic would not be appropriate.

# Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**BY OR IN CONSULTATION WITH PSYCHIATRIST OR NEUROLOGIST

### Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorization will require documentation of improvement in condition as evidenced by a reduction from baseline AIMS score.

## Affected Drugs:

Abilify Maintena Aristada Invega Sustenna Invega Trinza RisperDAL Consta ZyPREXA Relprevv

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**FOR ABILIFY MAINTENA - DIAGNOSIS OF SCHIZOPHRENIA or BIPOLAR I DISORDER AS MONOTHERAPY. FOR ARISTADA, INVEGA TRINZA AND ZYPREXA RELPREVV - DIAGNOSIS OF SCHIZOPHRENIA. FOR INVEGA SUSTENNA - DIAGNOSIS OF SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDERS AS MONOTHERAPY OR AS AN ADJUNCT TO MOOD STABILIZERS OR ANTIDEPRESSANTS. FOR RISPERDAL CONSTA -SCHIZOPHRENIA OR BIPOLAR I DISORDER AS MONOTHERAPY OR AS ADJUNCTIVE THERAPY TO LITHIUM OR VALPROATE.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:DOCUMENTED HISTORY OF FAILURE ON OR INTOLERANCE TO ORAL EQUIVALENT OF REQUESTED INJECTABLE THERAPY. FOR INVEGA TRINZA -DOCUMENTATION THAT THE PATIENT HAS BEEN ADEQUATELY TREATED WITH INVEGA SUSTENNA FOR AT LEAST 4 MONTHS.

# INLYTA

#### Affected Drugs:

Inlyta

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information:DX OF ADVANCED RENAL CELL CARCINOMA

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**For advanced RCC: documentation of failure on one prior systemic therapy OR use as first line treatment in combination with either pembrolizumab or avelumab. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs: Ingovi

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of a diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# Affected Drugs:

Inrebic

## Off-Label Uses:N/A

# **Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of intermediate (INT-2) or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis AND documentation of platelet count greater than or equal to 50 X 10(9)/L AND documentation of splenomegaly (as measured by CT, MRI or ultrasound) AND documentation of a baseline total symptom score measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF).

# Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

# Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

## Coverage Duration:6 MONTHS

**Other Criteria:**Documentation that member is ineligible for allogeneic hematopoietic cell transplantation. Documentation that medication will not be used in combination with another Janus kinase inhibitor (i.e. ruxolitinib). Reauthorization will require documentation of platelet count greater than or equal to  $50 \times 10(9)/L$  AND either a reduction of at least 35% in spleen volume from pretreatment baseline OR achievement of a 50% or greater reduction in Total Symptom Score from baseline as measured by the MFSAF.

## INTUNIV

## Affected Drugs:

guanFACINE HCI ER

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)

Age Restrictions: MUST BE BETWEEN 6 TO 17 YEARS OF AGE.

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY STIMULANTS

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## IRESSA

# Affected Drugs:

Iressa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF METASTATIC NON-SMALL CELL LUNG CANCER WITH EGFR EXON 19 DELETIONS OR EXON (L858R) SUBSTITUTION MUTATIONS AS DETECTED BY AN FDA APPROVED TEST

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# ISTODAX

#### Affected Drugs:

romiDEPsin

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DX OF CUTANEOUS T-CELL LYMPHOMA

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

**Other Criteria:**DOCUMENTATION OF DISEASE PROGRESSION WHILE ON AT LEAST ONE PRIOR SYSTEMIC THERAPY INCLUDING BUT NOT LIMITED TO CHOP REGIMENS, CHOEP, ICE, IVE, EPOCH, HYPERCVAD.

# ITRACONAZOLE

#### Affected Drugs:

Itraconazole

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: POSITIVE CULTURE SUBSTANTIATING DIAGNOSIS

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FOR ONYCHOMYCOSIS: FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO TERBINAFINE

Affected Drugs: Bivigam Cutaquig Cuvitru Flebogamma DIF GamaSTAN Gammagard Gammagard S/D Less IgA Gammaplex Gamunex-C Hizentra Hyqvia Panzyga Privigen

# Off-Label Uses:N/A

**Exclusion Criteria:**USE OF IVIG FOR THE FOLLOWING INDICATIONS IS CONSIDERED INVESTIGATIONAL AND WILL NOT BE COVERED: ALZHEIMER'S DISEASE, AMYOTROPHIC LATERAL SCLEROSIS, ATOPIC DERMATITIS, AUTISM, CHRONIC FATIGUE SYNDROME, CHRONIC MUCOCUTANEOUS CANDIDIASIS, COMPLEX REGIONAL PAIN SYNDROME, EPILEPSY, INCLUSION BODY MYOSITIS, LYME DISEASE, NEUROMYELITIS OPTICA (DEVIC'S DISEASE), OPTIC NEURITIS, PARAPROTEINEMIC DEMYELINATING NEUROPATHY, POST-POLIO SYNDROME, RECURRENT SPONTANEOUS MISCARRIAGE, RHEUMATIC FEVER, SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS, SYSTEMIC LUPUS ERYTHEMATOSUS.

**Required Medical Information:**PRIMARY IMMUNODEFICIENCY: DOCUMENTATION OF IG DEFICIENCY AND AN INABILITY TO AMOUNT AN IMMUNOLOGIC RESPONSE TO INCITING ANTIGENS AND DOCUMENTATION OF SEVERE INFECTIONS DESPITE TX WITH PROPHYLACTIC ANTIBIOTICS. ACUTE ITP: ACTIVE BLEEDING AND PLATELET COUNT LESS THAN 30,000/MM3 OR PRE-OP TX PRIOR TO SURGICAL PROCEDURE AND DOCUMENTATION OF USE WITH A CORTICOSTEROID OR A CONTRAINDICATION OR FAILURE ON CORTICOSTEROID. CHRONIC ITP: PLATELET COUNT LESS THAN 30,000/MM3 IN CHILDREN OR LESS THAN 20,000/MM3 IN ADULTS OR THOSE WITH ACTIVE BLEEDING AND PRIOR TX W/ HIGH DOSE CORTICOSTEROIDS AND SPLENECTOMY, AND NO CONCURRENT ILLNESS EXPLAINING THROMBOCYTOPENIA. CLL: DX OF CLL, AND IGG LEVEL LESS THAN 500 MG/DL, AND HX OF BACTERIAL INFECTION REQUIRING ORAL OR IV ABX TX W/IN LAST 6 MONTHS. CIDP: DX OF CIDP, DOCUMENTED EVIDENCE OF FOCAL OR SYMMETRIC NEUROLOGIC DEFICITS THAT ARE PROGRESSIVE OR RELAPSING OVER 12 WEEKS OR LONGER, AND

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EMG ABNORMALITIES CONSISTENT WITH CIDP. MMN: SYMPTOMATIC DISEASE FOR A MIN. OF 2 MONTHS WITH FINDINGS OF CONDUCTION BLOCK ON A SINGLE NERVE OR PROBABLE CONDUCTION BLOCK IN 2 OR MORE NERVES OR NORMAL SENSORY NERVE CONDUCTION IN UPPER LIMB SEGMENTS AND NORMAL SENSORY NERVE ACTION POTENTIAL AMPLITUDE. KAWASAKI: MUST BEGIN TX W/IN 10 DAYS OF THE ONSET OF FEVER.

Age Restrictions:N/A

**Prescription Order Restrictions:**FOR CIDP AND MULTIFOCAL MOTOR NEUROPATHY: MUST BE PRESCRIBED BY A NEUROLOGIST OR RHEUMATOLOGIST

**Coverage Duration:**CDIP AND MULTIFOCAL MOTOR NEUROPATHY: 12 WEEKS. ALL OTHERS: 6 MONTHS.

Other Criteria: IVIG MAY BE COVERED UNDER MEDICARE PART B OR MEDICARE D DEPENDING UPON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE AND SETTING OF THE DRUG TO MAKE THE DETERMINATION. CONTINUATION OF COVERAGE WILL REQUIRE MEDICAL RECORD DOCUMENTATION OF A MEAURABLE RESPONSE OR IMPROVMENT IN SIGNS AND SYMPTOMS.

# **IXEMPRA**

### Affected Drugs:

Ixempra Kit

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF METASTATIC OR LOCALLY ADVANCED BREAST CANCER

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:DOCUMENTATION OF USE IN COMBO WITH CAPECITABINE FOR THE TREATMENT OF METASTATIC OR LOCALLY ADVANCED BREAST CANCER WITH RESISTANCE TO AN ANTHRACYCLINE AND A TAXANE OR CANCER THAT IS TAXANE RESISTANT AND FURTHER ANTHRACYCLINE THERAPY IS CONTRAINDICATED OR DOCUMENTATION OF USE AS A MONOTHERAPY WITH TUMORS RESISTANT OR REFRACTORY TO ANTHRACYCLINES, TAXANES AND CAPECITABINE. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# Affected Drugs:

Deferasirox Deferasirox Granules

Off-Label Uses:N/A

# Exclusion Criteria:N/A

**Required Medical Information:**Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis) OR diagnosis of chronic iron overload caused by non-transfusion dependent thalassemia

**Age Restrictions:** for transfusional hemosiderosis: must be 2 years of age or older. For non-transfusional dependent thalassemia: must be 10 years of age or older

# Prescription Order Restrictions:N/A

# Coverage Duration:6 MONTHS

**Other Criteria:**For transfusional hemosiderosis: documentation of a serum ferritin level greater than 1000 MCG/L. Continuation of coverage requires documentation of a serum ferritin greater than 500 MCG/L, but decreased from baseline. For non-transfusion dependent thalassemia: documentation of LIC (liver iron concentration) greater than 5 milligrams of iron per gram of dry liver tissue weight (FE/Gdw) AND serum ferritin greater than 300 MCG/L. Continuation of coverage requires documentation of a serum ferritin greater than 300 MCG/L.

Affected Drugs: Jemperli

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF RECURRENT OR ADVANCED ENDOMETRIAL CANCER WITH DOCUMENTATION OF DISEASE PROGRESSION ON OR FOLLOWING PRIOR TREATMENT WITH A PLATINUM CONTAINING REGIMEN AND DOCUMENTATION OF MISMATCH REPAIR DEFICIENT (DMMR) AS DETERMINED BY AN FDA APPROVED TEST. DIAGNOSIS OF RECURRENT OR ADVANCED SOLID TUMORS FOLLOWING AT LEAST ONE PRIOR TREATMENT WITH NO SATISFACTORY ALTERNATIVE TREATMENT OPTIONS and DOCUMENTATION OF MISMATCH REPAIR DEFICIENT (dMMR) AS DETERMINED BY AN FDA APPROVED TEST.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS REAUTH

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## JEVTANA

# Affected Drugs:

Jevtana

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF HORMONE-REFRACTORY METASTATIC PROSTATE CANCER USED IN COMBINATION WITH PREDNISONE

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

**Coverage Duration:**6 MONTHS

Other Criteria:DOCUMENTATION OF NEUTROPHIL COUNT GREATER THAN 1500 CELLS/MM(3) AND FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A DOCETAXEL-BASED REGIMEN. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

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Affected Drugs: Juxtapid

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

## Required Medical Information: DIAGNOSIS OF HOMOZYGOUS FAMILIAL

HYPERCHOLESTEROLEMIA AND DOCUMENTATION OF FAILURE TO ADEQUATELY CONTROL LDL LEVELS WITH MAXIMUM TOLERATED STATIN THERAPY DEFINED AS LESS THAN OR EQUAL TO 200 MG/DL IN PATIENTS WITHOUT CVD OR LESS THAN OR EQUAL TO 160 MG/DL IN PATIENTS WITH ESTABLISHED CVD AND DOCUMENTATION OF MEDICATION BEING USED IN ADJUNCT WITH MAXIMUM TOLERATED STATIN DOSE UNLESS STATIN INTOLERANCE IS PRESENT

Age Restrictions: MUST BE AT LEAST 18 YEARS OF AGE

**Prescription Order Restrictions:**HEPATOLOGIST, LIDIPOLOGIST, ENDOCRINOLOGIST OR CARDIOLOGIST REGISTERED WITH THE JUXTAPID REMS PROGRAM

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria:DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO REPATHA

# JYNARQUE

Affected Drugs: Jynarque

Off-Label Uses:N/A

Exclusion Criteria: Documentation of End Stage Renal Disease

**Required Medical Information:**Diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) as confirmed by cysts and family history or genetic testing AND documentation that the member is at high risk for rapidly progressing ADPKD

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: Nephrologist

Coverage Duration:12 MONTHS

**Other Criteria**:Risk for rapidly progressing ADPKD should be documented with one of the following: Mayo classification class 1C, 1D, or 1E OR Total kidney volume greater than 750 mL OR PROPKD score greater than 6 OR kidney length greater than 16.5 cm as measured by ultrasound (if CT and MRI contraindicated). Reauthorization will require documentation that continued therapy is medically appropriate and no documentation of progression to end-stage renal disease (ESRD)

# KADCYLA

Affected Drugs:

Kadcyla

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF HER2-POSITIVE, METASTATIC BREAST CANCER. DIAGNOSIS OF HER2- POSITIVE EARLY BREAST CANCER.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:METASTATIC BREAST CA: DOCUMENTATION OF PREVIOUS TREATMENT WITH TRASTUZUMAB (HERCEPTIN) AND A TAXANE (PACLITAXEL OR DOCETAXEL), SEPARATELY OR IN COMBINATION. MUST HAVE EITHER RECEIVED PRIOR THERAPY FOR METASTATIC DISEASE OR DEVELOPED DISEASE RECURRENCE DURING OR WITHIN SIX MONTHS OF COMPLETING ADJUVANT THERAPY. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. EARLY BREAST CA: DOCUMENTATION OF NEOADJUVANT TREATMENT WITH TRASTUZUMAB AND A TAXANE AND DOCUMENTATION OF RESIDUAL INVASIVE DISEASE DETECTED IN THE SURGICAL SPECIMEN OF THE BREAST OR AXILLARY NODES AFTER COMPLETION OF NEOADJUVANT THERAPY. REAUTHORIZATION FOR EARLY BREAST CANCER SHOULD NOT EXCEED THE FDA APPROVED TREATMENT DURATION OF 14 CYCLES OR WILL REQUIRE DOCUMENTATION OF PEER REVIEWED LITERATURE CITING WELL DESIGNED CLINICAL TRIALS INDICATING THAT THE MEMBERS HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA APPROVED TREATMENT DURATION. Affected Drugs: Kalydeco

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF CYSTIC FIBROSIS AND DOCUMENTATION OF ONE MUTATION IN CFTR GENE THAT IS RESPONSIVE TO IVACAFTOR POTENTIATION PER PRODUCT LABELING AS EVIDENCED BY AN FDA CLEARED CF MUTATION TEST, AND DOCUMENTATION THAT THE PATIENT IS NOT HOMOZYGOUS FOR THE F508DEL MUTATION IN THE CFTR GENE

Age Restrictions: MUST BE 4 MONTHS OF AGE OR OLDER

Prescription Order Restrictions: PULMONOLOGIST OR CYSTIC FIBROSIS SPECIALIST

Coverage Duration: 4 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT OR STABILIZATION IN THE SIGNS AND SYMPTOMS OF CYSTIC FIBROSIS.

Affected Drugs: Kevzara

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: RHEUMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF (1) HUMIRA AND (2) RINVOQ ER OR XELJANZ. DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION Affected Drugs: Keytruda

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: UNRESEC/METASTAT MELANOMA. METASTAT NSCLC OR METASTAT NONSQUAMOUS NSCLC. RECURRENT/METASTAT/UNRESEC HEAD/NECK SQUAMOUS CELL CA. CLASSICAL HODGKIN LYMPHOMA & ONE OF THE FOLLOWING: REFRACTORY DISEASE OR AGE GREATER THAN 18 YRS W/RELAPSE FOLLOWING 1 OR MORE PRIOR TX OR AGE LESS THAN 18 YRS W/RELAPSE FOLLOWING 2 OR MORE PRIOR TXS. UNRESEC/METASTAT MICROSATELLITE INSTABILITY-HIGH OR MISMATCH REPAIR DEFICIENT SOLID TUMORS W/PROGRESSION FOLLOWING PRIOR TX OR NO ALTERNATIVE TX OPTIONS, FIRST LINE COLORECTAL CANCER OR FOLLOWING TX WITH FLUOROPYRIMIDINE/OXALIPLATIN/IRINOTECAN. LOCALLY ADVANCED/METASTAT UROTHELIAL CA W/EITHER: 1)PROGRESSION AFTER PLATINUM CHEMO OR 2) PROGRESSION W/IN 12 MOS OF (NEO) ADJUVANT PLATINUM CHEMO OR 3) NOT ELIGIBLE FOR PLATINUM CHEMO OR 4) DX OF HIGH RISK, NON-MUSCLE INVASIVE BLADDER CA & IS UNRESPONSIVE TO A TRIAL OF BCG AND IS INELIGIBLE FOR CYSTECTOMY. RECURRENT LOCALLY ADVANCED/METASTATIC GASTRIC OR GEJ ADENOCARCINOMA. LOCALLY ADVANCED/METAST SQUAMOUS CELL CA OF THE ESOPHAGUS OR GEJ WHOSE TUMORS EXPRESS PDL1 (CPS GREATER THAN OR EQUAL TO 10), W/PROGRESSION ON 1 OR MORE PRIOR LINES OF SYSTEMIC TX OR IN COMBINATION WITH PLATINUM AND FLUOROPYRIMIDINE BASED CHEMOTHERAPY FOR DISEASE NOT AMENABLE TO SURGICAL **RESECTION OR CHEMORADIATION. RECURRENT/METASTAT CERVICAL CA & TUMORS** EXPRESS PDL1 (CPS GREATER THAN 1) & DISEASE PROGRESSION AFTER AT LEAST ONE PRIOR TX. REFRACTORY PRIMARY MEDIASTINAL LARGE B-CELL LYMPHOMA OR RELAPSE FOLLOWING 2 OR MORE TXS. HEPATOCELLULAR CA. METASTAT/RECURRENT MERKEL CELL CA. ADVANCED RENAL CELL CA. ADVANCED ENDOMETRIAL CA. RECURRENT/METASTAT OR LOCALLY ADVANCED CUTANEOUS SQUAMOUS CELL CA NOT CURABLE BY SURGERY/RADIATION. UNRESEC/METASTAT TUMOR MUTATIONAL BURDEN HIGH SOLID TUMORS WITH PROGRESSION FOLLOWING PRIOR TX & NO ALTERNATIVE TX OPTIONS. LOCALLY RECURRENT UNRESEC/METASTAT TRIPLE-NEGATIVE BREAST CA

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

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**Coverage Duration:**ADJUVANT TX OF MM/EARLY STAGE TNBC: 6 MONTHS, 6 MONTHS REAUTH. ALL OTHERS: 6 MONTHS, 12 MONTHS REAUTH

Other Criteria: FOR BREAST CA:(1)DX THAT TUMORS EXPRESS PD-L1 (CPS GREATER THAN OR EQUAL TO 10) AS DETERMINED BY AN FDA APPROVED TEST & DOCUMENTATION OF USE IN COMBINATION W/ CHEMOTX, or (2) HIGH-RISK, EARLY STAGE TNBC IN COMBINATION W/ CHEMOTX AS NEOADJUVANT TX & THEN CONTINUED AS A SINGLE AGENT AS ADJUVANT TX AFTER SURGERY. TMB-H DEFINED AS GREATER THAN OR EQUAL TO 10 MUTATIONS PER MEGABASE DETERMINED BY AN FDA APPROVED TEST. FOR GASTRIC OR GEJ CA: TUMORS EXPRESS PDL1 (CPS GREATER THAN OR EQUAL TO 1), W/PROGRESSION ON 2 OR MORE PRIOR LINES OF TX (INCLUDING FLUOROPYRIMIDINE, & PLATINUM CONTAINING CHEMO) & IF PATIENT HAS HER2-POSITIVE DISEASE, DOCUMENTATION OF PROGRESSION ON OR AFTER HER2/NEU-TARGETED THERAPY OR HER2 POSITIVE DISEASE USED AS 1ST-LINE TX IN COMBINATION WITH TRASTUZUMAB, FLUOROPYRIMIDINE & PLATINUM CONTAINING CHEMOTX. FOR HEAD/NECK SQUAMOUS CELL CARCINOMA, EITHER 1) USED AS A SINGLE AGENT FOR DISEASE PROGRESSION ON OR AFTER PLATINUM THERAPY, 2) USED AS A SINGLE AGENT FOR FIRST LINE TX & THAT TUMORS EXPRESS PD-L1 (TPS) AT LEAST 1%, 3) FOR USE AS FIRST LINE TX IN COMBINATION WITH PLATINUM CHEMOTHERAPY & FLUOROURACIL. FOR METASTATIC NSCLC: 1)USE AS FIRST-LINE, MONOTHERAPY FOR STAGE III, METASTATIC DISEASE, OR WHEN CANDIDATE IS NOT ELIGIBLE FOR SURGICAL RESECTION OR CHEMORADIATION & THAT TUMORS EXPRESS PD-L1 (TPS) AT LEAST 1% & THAT TUMORS DO NOT HAVE EGFR OR ALK GENOMIC ABERRATIONS OR 2)TPS GREATER THAN 1% WITH DISEASE PROGRESSION ON OR AFTER PLATINUM-BASED THERAPY & IF EGFR OR ALK ABERRATIONS ARE PRESENT. DOCUMENTATION OF DISEASE PROGRESSION ON ONE FDA APPROVED TX FOR THESE ABERRATIONS. FOR NONSQUAMOUS NSCLC: USED IN COMBINATION WITH PEMETREXED & EITHER CARBO/CISPLATIN & DOCUMENTATION THAT TUMORS DO NOT HAVE EGFR OR ALK GENOMIC TUMOR ABERRATIONS OR IN COMBINATION WITH CARBOPLATIN/(NAB)PACLITAXEL AS FIRST LINE TX. FOR METASTATIC MELANOMA: DOCUMENTATION THAT KEYTRUDA IS NOT BEING USED IN COMBINATION WITH ANY OTHER AGENTS & IF BEING USED FOR THE ADJUVANT TX OF COMPLETELY RESECTED METASTATIC MELANOMA: EVIDENCE OF PREVIOUS LYMPH NODE INVOLVEMENT WHICH HAS BEEN COMPLETELY RESECTED. FOR HCC: DOCUMENTATION OF A THERAPEUTIC FAILURE OR INTOLERANCE TO SORAFENIB. FOR RCC: DOCUMENTATION OF USE IN COMBINATION WITH AXITINIB OR LENVATINIB & OF BEING USED FOR FIRST LINE TX OF ADVANCED DISEASE. FOR ENDOMETRIAL CARCINOMA: 1)DISEASE PROGRESSION FOLLOWING AT LEAST ONE PRIOR SYSTEMIC TX & 2)PATIENT IS NOT A CANDIDATE FOR CURATIVE SURGERY OR RADIATION & 3)TUMORS ARE NOT MICROSATELLITE INSTABILITY-HIGH (MSI-H) OR MISMATCH REPAIR DEFICIENT (DMMR) & 4) WILL BE USED IN COMBINATION WITH LENVATINIB. SUBSEQUENT APPROVALS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. USE BEYOND 12 TOTAL MOS FOR THE ADJUVANT TREATMENT OF MM OR

BEYOND 24 WKS NEOADJ OR 27 WKS FOR ADJUV EARLY STAGE TNBC WILL REQUIRE DOCUMENTATION OF CLINICAL TRIALS TO INDICATE THAT THE HEALTHCARE OUTCOME WILL BE IMPROVED BEYOND THE FDA APPROVED TREATMENT DURATION.

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# Affected Drugs:

Kineret

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF NEONATAL-ONSET MULTISYSTEM INFLAMMATORY DISEASE (NOMID). DX OF CRYOPYRIN-ASSOCIATED PERIODIC SYNDROME (CAPS), INCLUDING FAMILIAL COLD AUTOINFLAMMATORY SYNDROME (FCAS), AND MUCKLE-WELLS SYNDROME (MWS) SUPPORTED BY DOCUMENTATION OF GENETIC TESTING TO IDENTIFY THE CIAS1/NLRP-3 GENE MUTATION. DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS. Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) supported by documentation of a homozygous or compound heterozygous mutation involving IL 1 RN (Interluekin 1 Receptor Antagonist gene).

Age Restrictions: FOR RA - MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**FOR NOMID OR CAPS: PRESCRIBED BY IMMUNOLOGIST, RHEUMATOLOGIST, PEDIATRICIAN OR ALLERGIST. FOR RHEUMATOID ARTHRITIS: PRESCRIBED BY RHEUMATOLOGIST. FOR DIRA: RHEUMATOLOGIST, GENETICIST, DERMATOLOGIST OR A PHYSICIAN SPECIALIZING IN THE TREATMENT OF AUTOINFLAMMATORY DISORDERS.

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RHEUMATOID ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF (1) HUMIRA AND (2) RINVOQ ER OR XELJANZ. FOR CONTINUED THERAPY. MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

# KISQALI

# Affected Drugs:

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

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of hormone receptor positive, HER2 negative metastatic breast cancer. For Kisqali: documentation of use for first line initial endocrine based therapy prescribed in combination with an aromatase inhibitor OR for first line initial endocrine based therapy in postmenopausal women prescribed in combination with fulvestrant OR in postmenopausal women in combination with fulvestrant after disease progression on endocrine therapy. For Kisqali Femara co-pack: documentation of use for initial endocrine based therapy.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

## Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs: Korlym

Off-Label Uses:N/A

Exclusion Criteria: PREGNANCY

**Required Medical Information:**DX OF ENDOGENOUS CUSHING'S SYNDROME AND DOCUMENTATION OF FAILED SURGICAL TREATMENT FOR CUSHING'S SYNDROME OR THAT PATIENT IS NOT A CANDIDATE FOR SURGERY. DOCUMENTATION OF A NEGATIVE PREGNANCY TEST WITHIN 14 DAYS OF INITIATING THERAPY IN WOMEN OF REPRODUCTIVE POTENTIAL

Age Restrictions:N/A

Prescription Order Restrictions: ENDOCRINOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**THERAPEUTIC FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO AT LEAST TWO FORMULARY ANTI-DIABETIC ALTERNATIVES

Affected Drugs: Koselugo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of Neurofibromatosis type 1 as defined by a positive NF1 mutation OR documentation of two of the following: 1) Six or more café-au-lait macules (more than 5 mm diameter in prepubertal individuals and more than 15 mm in post-pubertal individuals), 2) Freckling in axillary or inguinal regions, 3) two or more neurofibromas of any type or one plexiform neurofibroma, 4) optic glioma (tumor of nerve to eye), 5) two or more Lisch nodules (iris hamartomas), 6) a distinctive osseous lesion (sphenoid dysplasia or tibial pseudarthrosis), or 7) a first degree relative with NF1. Documentation of symptomatic, inoperable plexiform neurofibromas.

## Age Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**WRITTEN BY OR IN CONSULTATION WITH A PEDIATRIC ONCOLOGIST, NEUROLOGIST OR GENETICIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# KUVAN

#### Affected Drugs:

Kuvan Sapropterin Dihydrochloride

Off-Label Uses:N/A

Exclusion Criteria: BASELINE BLOOD PHE LEVEL LESS THAN 360 UMOL/L.

**Required Medical Information:**Diagnosis of hyperphenylalaninemia. Documentation of blood PHE levels

Age Restrictions:N/A

Prescription Order Restrictions: METABOLIC SPECIALIST

**Coverage Duration:**INITIALLY 2 MONTHS THEN EVERY 12 MONTHS IF PATIENT IS A RESPONDER

**Other Criteria:**INITIAL REAUTHORIZATION WILL REQUIRE A REDUCTION IN BLOOD PHE LEVELS FROM BASELINE or DOCUMENTATION OF AN INCREASE IN PHE TOLERANCE (such as addition of Phe in diet with stable Phe level). YEARLY REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF SUSTAINED REDUCTION IN BLOOD PHE LEVELS or DOCUMENTATION OF IMPROVEMENT IN NEUROPSYCHIATRIC SYMPTOMS or AN INCREASE IN PHE TOLERANCE.

# **KYPROLIS**

#### Affected Drugs:

Kyprolis

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DOCUMENTATION OF MULTIPLE MYELOMA

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST ONE PRIOR THERAPY. DOCUMENTATION THAT MEDICATION WILL BE USED AS MONOTHERAPY or IN COMBINATION WITH DEXAMETHASONE or IN COMBINATION WITH DEXAMETHASONE AND LENALIDOMIDE or IN COMBINATION WITH DARATUMUMAB AND DEXAMETHASONE. REAUTHORIZATION WILL REQUIRED DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# LARTRUVO

Affected Drugs:

Lartruvo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of soft tissue sarcoma with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery AND documentation that Lartruvo will be administered in combination with doxorubicin for the first eight treatment cycles

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATION WILL REQUIRED DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# LATUDA

# Affected Drugs:

Latuda

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF SCHIZOPHRENIA OR DX OF DEPRESSIVE EPISODES ASSOCIATED WITH BIPOLAR 1 DISORDER (BIPOLAR DEPRESSION)

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FOR SCHIZOPHRENIA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ATYPICAL ANTIPSYCHOTICS (OLANZAPINE, RISPERIDONE, QUETIAPINE, ZIPRASIDONE, ARIPIPRAZOLE) OR FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ZIPRASIDONE AND ABILIFY FOR MEMBERS WITH METABOLIC SYNDROME. FOR BIPOLAR DEPRESSION: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO QUETIAPINE.

# LAZANDA

# Affected Drugs:

Lazanda

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF CANCER AND OF USE TO MANAGE BREAKTHROUGH CANCER PAIN

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**MEDICAL RECORD DOCUMENTATION OF CONCOMITANT MORPHINE 60 MG/DAY OR MORE, TRANSDERMAL FENTANYL 25 MCG/H, OXYCODONE 30 MG/DAY, ORAL HYDROMORPHONE 8 MG/DAY, OR AN EQUIANALGESIC DOSE OF ANOTHER OPIOID FOR 1 WEEK OR LONGER AND FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO GENERIC FENTANYL LOZENGES.

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# LENVIMA

#### Affected Drugs:

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

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

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

**Required Medical Information:**Diagnosis of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer. Diagnosis of use in combination with Afinitor (everolimus) for surgically unresectable advanced or metastatic renal cell carcinoma following a therapeutic failure on or intolerance to one prior anti-angiogenic therapy OR documentation of use in combination with pembrolizumab for first line treatment of advanced renal cell carcinoma. Diagnosis of unresectable hepatocellular carcinoma (HCC) in those who have not received prior therapy AND documentation of Child-Pugh Class A liver disease. Diagnosis of advanced endometrial carcinoma with disease progression following at least one prior systemic therapy in patients not candidates for curative surgery or radiation AND documentation that tumors are NOT microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND documentation of use in combination with pembrolizumab.

#### Age Restrictions:N/A

#### Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

## Affected Drugs:

Ambrisentan

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DIAGNOSIS OF PULMONARY ARTERIAL HYPERTENSION. DOCUMENTATION OF ONE OF THE FOLLOWING: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL or DOCUMENTATION OF USE AS FIRST LINE THERAPY IN COMBINATION WITH ADCIRCA IN PATIENTS WITH WHO GROUP 1 PAH

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

# LEUKINE

# Affected Drugs:

Leukine

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:** For acceleration of myeloid recovery in patients undergoing allogeneic bone marrow transplantation from HLA-matched related donors. For treatment of delayed or failed neutrophil recovery in patients who have undergone allogeneic or autologous bone marrow transplantation. For mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis in patients undergoing autologous hematopoietic stem cell transplantation. In patients with AML receiving induction or consolidation therapy. Hematopoietic syndrome of acute radiation syndrome (H-ARS) with documentation of an acute exposure to myelosuppressive doses of radiation.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:6 MONTHS

**Other Criteria:**N/A

# Affected Drugs:

Libtayo

# Off-Label Uses:N/A

# **Exclusion Criteria:**N/A

**Required Medical Information**:Documentation of metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC AND documenation that the patient is not a candidate for curative surgery or curative radiation. Documentation of locally advanced basal cell carcinoma (laBCC) OR metastatic BCC (mBCC) AND documentation of previous treatment with a hedgehog pathway inhibitor or documentation that a hedgehog pathway inhibitor is inappropriate. Documentation of non-small cell lung cancer (NSCLC) AND 1) documentation of one of the following: metastatic disease OR locally advanced disease and the patient is not a candidate for surgical resection or definitive chemoradiation AND 2) documentation of high PD-L1 expression (Tumor Proportion Score (TPS) of 50% or greater as determined by an FDA approved test) AND 3) documentation of no EGFR, ALK or ROS1 genomic tumor aberrations AND 4) documentation that medication is being used as first line treatment.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

# Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

# Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorization will require documentation of continued disease improvement or lack of disease progression.

# LIDODERM

# Affected Drugs:

Lidocaine

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF POST-HERPETIC NEURALGIA

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

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## LOKELMA

#### Affected Drugs:

Lokelma

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of mild to moderate hyperkalemia

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**DOCUMENTATION THAT ATTEMPT HAS BEEN MADE TO IDENTIFY AND CORRECT THE UNDERLYING CAUSE OF THE HYPERKALEMIA OR RATIONALE AS TO WHY THE UNDERLYING CAUSE CANNOT BE CORRECTED.

# LONSURF

# Affected Drugs:

Lonsurf

## Off-Label Uses:N/A

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

**Required Medical Information:**Diagnosis of metastatic colorectal cancer AND documentation of previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy. Diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma AND documentation of previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum agent, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy.

## Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

## Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

## Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# LORBRENA

Affected Drugs: Lorbrena

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of a diagnosis of ALK-positive metastatic non-small cell lung cancer (NSCLC)

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorization will require documentation of continued disease improvement or lack of disease progression

# LUCEMYRA

Affected Drugs: Lucemyra

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of use to mitigate opioid withdrawal symptoms in patients abruptly discontinuing opioids

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:2 WEEKS

**Other Criteria:**Documentation of a therapeutic failure on, intolerance to, or contraindication to clonidine.

Affected Drugs: Lumakras

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of locally advanced or metastatic non-small cell lung cancer (NSCLC) AND documentation of a KRAS G12C mutation as detected by an FDA approved test AND documentation of treatement with a least one prior systemic therapy.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 months initial, 12 months reauth

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# LUMOXITI

Affected Drugs: Lumoxiti

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of a diagnosis of relapsed or refractory hairy-cell leukemia AND documentation of trial of at least 2 prior systemic therapies, one of which must be a purine nucleoside analog.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

**Other Criteria:**Reuthorization will require documentation of medical or scientific literature to support the use of this agent beyond the FDA approved treatment duration

## LUPKYNIS

Affected Drugs: Lupkynis

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF ACTIVE LUPUS NEPHRITIS, CLASS III, IV, V ALONE OR IN COMBINATION, CONFIRMED BY A KIDNEY BIOPSY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: RHEUMATOLOGIST OR NEPHROLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS REAUTH

Other Criteria:DOCUMENTATION THAT MEDICATION WILL BE PRESCRIBED IN COMBINATION WITH A BACKGROUND IMMUNOSUPPRESSIVE THERAPY REGIMEN (E.G. MYCOPHENOLATE MOFETIL (MMF) AND CORTICOSTEROIDS) AND DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO BENLYSTA. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF A POSITIVE CLINICAL RESPONSE (E.G. IMPROVEMENT/STABILIZATION IN UPCR, EGFR, RENAL RELATED EVENTS) AND DOCUMENTATION THAT MEDICATION WILL BE PRESCRIBED IN COMBINATION WITH A BACKGROUND IMMUNOSUPPRESSIVE THERAPY REGIMEN (E.G. MYCOPHENOLATE MOFETIL (MMF) AND CORTICOSTEROIDS).

# LYNPARZA TABLETS

Affected Drugs: Lynparza

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

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

Required Medical Information: Diagnosis of deleterious or suspected deleterious germline BRCAmutated advanced ovarian cancer as verified by an FDA approved test OR Maintenance therapy after a complete or partial response to platinum based chemotherapy for recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer OR diagnosis of deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer AND medical record documentation that member has been previously treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting AND if hormone receptor (HR)-positive, medical record documentation that prior treatment included endocrine therapy or documentation that endocrine therapy would be considered inappropriate. Dx of deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer AND documentation of a complete or partial response to first-line platinum based therapy. Maintenance treatment of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer in complete or partial response to firstline platinum based therapy with documentation of BOTH 1) homologous recombination deficiency (HRD)-positive status with a deleterious or suspected deleterious BRCA mutation OR genomic instability AND 2) documentation that medication will be used in combination with bevacizumab. Diagnosis of deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma AND documentation that member has not progressed on at least 16 weeks of a first-line platinumbased chemotherapy regimen. Dx of deleterious or suspected germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration resistant prostate cancer (mCRPC) AND documentation of progression following treatment with enzalutamide or abiraterone AND that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently or documentation of bilateral orchiectomy.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions: ONCOLOGIST OR HEMATOLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**For Ovarian cancer: documentation of therapeutic failure on, intolerance to, or contraindication to three or more prior lines of chemotherapy OR for maintenance treatment of recurrent and gBRCAm or sBRCAm advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy OR

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maintenance treatment of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer in complete or partial response to first-line platinum based therapy with documentation of BOTH 1) homologous recombination deficiency (HRD)-positive status with a deleterious or suspected deleterious BRCA mutation OR genomic instability AND 2) documentation that medication will be used in combination with bevacizumab. Subsequent approval after 12 months will require documentation of continued disease improvement or lack of disease progression.

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# LYRICA CR

# Affected Drugs:

Lyrica CR Pregabalin ER

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Medical record documentation of one of the following: postherpetic neuralgia OR neuropathic pain associated with diabetic peripheral neuropathy

Age Restrictions:N/A

## Prescription Order Restrictions:N/A

## Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**For postherpetic neuralgia: documentation of a therapeutic failure on, intolerance to, or contraindication to gabapentin and pregabalin. For neuropathic pain associated with diabetic peripheral neuropathy: documentation of a therapeutic failure on, intolerance to, or contraindication to duloxetine and pregabalin

Affected Drugs: Margenza

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of HER2-positive breast cancer AND documentation that medication will be used in combination with chemotherapy AND documentation of two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

Affected Drugs: Marqibo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**:DOCUMENTATION OF PHILADELPHIA CHROMOSOME-NEGATIVE (PH-) ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN SECOND OR GREATER RELAPSE OR WHOSE DISEASE HAS PROGRESSED FOLLOWING TWO OR MORE ANTI-LEUKEMIA THERAPIES.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO VINCRISTINE.

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## MAVENCLAD

#### Affected Drugs:

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

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of relapsing form of multiple sclerosis including relapsingremitting disease and active secondary progressive disease.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:NEUROLOGIST

#### Coverage Duration:48 WEEKS

**Other Criteria**:Documentation that medication will be used as monotherapy, that requested dose is appropriate for the patient's weight, that patient has not been treated with more than three previous treatment cycles AND documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary alternatives for the treatment of MS. Reauthorization will require documentation that patient has not received more than three previous cycles of Mavenclad for treatment of relapsing forms of multiple sclerosis (including relapsing-remitting disease and active secondary progressive disease) AND that member is not experiencing unacceptable toxicity or worsening of disease while on therapy.

Affected Drugs:

Mavyret

Off-Label Uses:N/A

# **Exclusion Criteria:**N/A

**Required Medical Information:**CRITERIA (INDICATION, DOSING, ETC.) WILL BE APPLIED CONSISTENT WITH CURRENT AASLD-IDSA GUIDANCE. MEDICAL RECORD DOCUMENTATION OF A DIAGNOSIS OF HEPATITIS C INFECTION WITH IDENTIFICATION OF GENOTYPE AND SUBTYPE. DOCUMENTATION OF METAVIR LIVER FIBROSIS. DOCUMENTATION OF PREVIOUS TREATMENT AND TREATMENT RESPONSE. DOCUMENTATION OF RECEIVING THE FOLLOWING WITHIN THE PAST 3 MONTHS:HEPATIC FUNCTION PANEL, COMPLETE BLOOD COUNT INCLUDING DIFFERENTIAL, BASIC METABOLIC PANEL, AND BASELINE HCV RNA VIRAL LOAD. DOCUMENTATION OF NO LIMITED LIFE EXPECTANCY OF LESS THAN 12 MONTHS DUE TO NON LIVER RELATED COMORBID CONDITIONS.

# Age Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**BOARD CERTIFIED GASTROENTEROLOGIST, HEPATOLOGIST, INFECTIOUS DISEASE SPECIALIST OR TRANSPLANT SPECIALIST

# Coverage Duration: PER AASLD/IDSA GUIDELINES

**Other Criteria:**Documentation of any potential drug interactions that may impact drug therapy addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the risks associated with the use of both medications when they interact). Documentation of either 1) completed hepatitis B series OR 2) Hepatitis B screening (sAb, sAg and cAb) and quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg AND either documentation of treatment for Hepatitis B if there is detectable hepatits B virus OR documentation of being vaccinated against Hepatitis B if negative for hepatitis B sAb.

## MEBENDAZOLE

Affected Drugs: Emverm

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of one of the following: Ancylostoma duodenale or Necator americanus (hookworms), Ascaris lumbricoides (roundworms), Enterobius vermicularis (pinworms), or Trichuris trichiura (whipworms)

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:1 MONTH

**Other Criteria:**N/A

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Affected Drugs: Mekinist

Off-Label Uses:N/A

# Exclusion Criteria:N/A

**Required Medical Information:**Diagnosis of unresectable or metastatic melanoma with one of the following: documentation of concurrent use with Tafinlar (dabrafenib) OR if being used as a single agent, documentation of no prior therapeutic failure with a BRAF inhibitor therapy (such as vemurafenib, dabrafenib, or encorafenib). Documentation of BRAF V600E or V600K mutation as detected by an FDA approved test. Diagnosis of metastatic non-small cell lung cancer with concomitant use of Tafinlar AND documentation of BRAF V600E mutation as detected by an FDA approved test. Diagnosis of use for adjuvant treatment of melanoma with involvement of lymph nodes following complete resection AND documentation. Diagnosis of locally advanced or metastatic anaplastic thyroid cancer AND documentation of concurrent use of Tafinlar (dabrafenib) AND documentation of BRAF V600E mutation advanced or metastatic anaplastic thyroid cancer AND documentation of concurrent use of Tafinlar (dabrafenib) AND documentation of BRAF V600E mutation of BRAF V600E mutatice anaplastic thyroid cancer AND documentation of concurrent use of Tafinlar (dabrafenib) AND documentation of BRAF V600E mutation.

## Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST OR HEMATOLOGIST OR DERMATOLOGIST

## Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATION BEYOND 12 MONTHS FOR ADJUVANT TREATMENT OF MELANOMA WILL REQUIRE LITERATURE CITING WELL DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND TEH FDA APPROVED TREATMENT DURATION. ALL OTHER REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION Affected Drugs: Mektovi

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of unresectable or metastatic melanoma AND documentation that medication is being prescribed in combination with Braftovi. Documentation of BRAF V600E OR V600K mutation as detected by an FDA approved test.

Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST OR HEMATOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

#### **MEPROBAMATE HRM**

#### Affected Drugs:

Meprobamate

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DIAGNOSIS OF ANXIETY

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**PRIOR AUTHORIZATION APPLIES ONLY TO MEMBERS 65 YEARS OF AGE AND OLDER WHO WILL BE EVALUATED FOR APPROPRIATE USE OF HIGH RISK MEDICATION AND WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OF THE FOLLOWING: BUSPIRONE, ESCITALOPRAM, OR VENLAFAXINE XR. Affected Drugs:

Mepsevii

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome) confirmed by the following: 1) Urinary glycosaminoglycans (GAGs) at least three times the upper limit of normal, 2) Enzyme activity assay (beta-glucuronidase deficiency) or genetic testing (mutation of chromosome 7q21.11) 3) at least one of the following clinical signs or symptoms: enlarged liver and spleen, joint limitations, airway obstruction or pulmonary dysfunction.

## Age Restrictions:N/A

**Prescription Order Restrictions:**METABOLIC SPECIALIST OR GENETICIST WITH EXPERIENCE TREATING MUCOPOLYSACCHARIDOSIS

Coverage Duration:6 months initial, 12 months reauth

**Other Criteria:**Documentation of a baseline evaluation, including a standardized assessment of motor function (i.e., 6-minute walk test, urinary GAGs level, and pulmonary function test). Reauthorization will require documentation of medical necessity and documentation of improvement or maintenance of motor function, urinary GAGs level, pulmonary function, or other clinical signs or symptoms (such as decreased liver/spleen size, improvement in joint function, etc.)

Affected Drugs: Monjuvi

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma AND documentation that member is not eligible for autologous stem cell transplant (ASCT) AND documentation that medication will be used in combination with lenalidomide.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs: Mulpleta

Off-Label Uses:N/A

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

**Required Medical Information:**Documentation of thrombocytopenia in adult patients with chronic liver disease AND documentation of a platelet count less than 50 x 1000000000 (10 TO THE 9TH POWER)/L measured within the past 30 days. Documentation of a planned invasive procedure to be performed 8 to 14 days after initiation of treatment.

## Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, transplant specialist, interventional radiologist or endocrinologist

## Coverage Duration:30 DAYS

**Other Criteria:**Documentation that the member is not receiving other TPO-Ras (i.e. romiplostin, eltrombopag). Documentation that the correct dose of medication is being used (3 mg orally once daily for 7 days). Documentation of a therapeutic failure on, intolerance to, or contraindication to Doptelet.

## **MYLOTARG**

Affected Drugs: Mylotarg

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Newly diagnosed CD33-positive Acute Myeloid Leukemia OR relapsed or refractory CD33-positive Acute Myeloid Leukemia

**Age Restrictions:**Relapsed or Refractory dx: 2 years of age or older. newly diagnosed: 1 month or older

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration: NEWLY DIAGNOSED PEDS: 6 MONTHS. ALL OTHERS: 12 MONTHS

**Other Criteria:**For newly diagnosed CD33-positive AML, and age less than 18 years of age: documentation that medication will be used in combination with standard chemotherapy. Requests for reauthorization will be based on medical necessity AND will require documentation that maximum treatment duration has not been exceeded OR peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

## NAGLAZYME

Affected Drugs:

Naglazyme

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF MUCOPOLYSACCHARIDOSIS VI (MAROTEAUX-LAMY DISEASE)

Age Restrictions:N/A

Prescription Order Restrictions: METABOLIC SPECIALIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**N/A

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## NATPARA

# Affected Drugs:

Natpara

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF HYPOCALCEMIA SECONDARY TO HYPOPARATHYROIDISM AND DOCUMENTATION OF NO INCREASED BASELINE RISK FOR OSTEOSARCOMA

Age Restrictions:N/A

Prescription Order Restrictions: ENDOCRINOLOGIST

**Coverage Duration:**6 MONTHS

**Other Criteria**:REAUTHORIZATION WILL REQUIRE DOCUMENTATION SUPPORTING THE CONTINUED USE OF THE LOWEST DOSE THAT ACHIEVES A TOTAL SERUM CALCIUM (ALBUMIN CORRECTED) WITHIN THE LOWER HALF OF THE NORMAL TOTAL SERUM CALCIUM RANGE

# Affected Drugs:

Nerlynx

Off-Label Uses:N/A

# Exclusion Criteria:N/A

**Required Medical Information:**Diagnosis of early stage (Stages 1-3A) breast cancer AND documentation of HER-2 overexpression or amplification AND documentation of prior treatment with trastuzumab based therapy. Diagnosis of advanced or metastatic HER2-positive breast cancer used in combination with capecitabine AND documentation of trial of two or more prior anti-HER2 based regimens given in the metastatic setting.

# Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

# Prescription Order Restrictions:ONCOLOGIST

## Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorization for advanced or metastatic breast cancer will require documentation of continued disease improvement or lack of disease progression

Affected Drugs: Neulasta Neulasta Onpro

## Off-Label Uses:N/A

**Exclusion Criteria**:PROPHYLAXIS DURING CHEMO REGIMENS WITH A FEBRILE NEUTROPENIA RISK LESS THAN 20% AND NO HIGH RISK FOR COMPLICATIONS, THOSE WHO ARE NEUTROPENIC BUT AFEBRILE, TO ALLOW AN INCREASE IN THE DOSE-INTENSITY OF CYTOTOXIC CHEMO BEYOND ESTABLISHED DOSE RANGES

**Required Medical Information:**PREVENTION OF FEBRILE NEUTROPENIA WHEN RISK DUE TO MYELOSUPPRESIVE CHEMO REGIMEN IS 20% OR GREATER OR TO PREVENT FEBRILE NEUTROPENIA WHEN THE RISK OF DEVELOPING FEBRILE NEUTROPENIA IS LESS THAN 20% WITH ONE ADDITIONAL RISK FACTOR. PREVENTION OF FEBRILE NEUTROPENIA WHEN A PREVIOUS CYCLE RESULTED IN A NEUTROPENIC COMPLICATION AND DOSE REDUCTION WILL COMPROMISE DISEASE FREE OR OVERALL SURVIVAL OR TREATMENT OUTCOME. HEMATOPOIETIC SYNDROME OF ACUTE RADIATION SYNDROME (H-ARS) WITH DOCUMENTATION OF AN ACUTE EXPOSURE TO MYELOSUPRESSIVE DOSES OF RADIATION.

#### Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

#### **Coverage Duration:6 MONTHS**

Other Criteria: ADDITIONAL RISK FACTORS FOR THE PREVENTION OF FEBRILE NEUTROPENIA INCLUDE, BUT ARE NOT LIMITED TO: 65 YRS OR OLDER, POOR PERFORMANCE STATUS, PREVIOUS HISTORY OF FEBRILE NEUTROPENIA, EXTENSIVE PRIOR RADIATION OR CHEMOTHERAPY TREATMENT, POOR NUTRITIONAL STATUS, RECENT SURGERY OR OPEN WOUNDS OR ACTIVE INFECTION, ADVANCED CANCER, PERSISTENT NEUTROPENIA, BONE MARROW INVOLVEMENT BY TUMOR, LIVER DYSFUNCTION (BILIRUBIN GREATER THAN 2), OR RENAL DYSFUNCTION (CrcL LESS THAN 50 ML/MIN).

# Affected Drugs:

Neupogen Nivestym

## Off-Label Uses:N/A

**Exclusion Criteria**:PROPHYLAXIS DURING CHEMO REGIMENS WITH A FEBRILE NEUTROPENIA RISK LESS THAN 20% AND NO HIGH RISK FOR COMPLICATIONS, THOSE WHO ARE NEUTROPENIC BUT AFEBRILE, TO ALLOW AN INCREASE IN THE DOSE-INTENSITY OF CYTOTOXIC CHEMO BEYOND ESTABLISHED DOSE RANGES

**Required Medical Information:**PREVENTION OF FEBRILE NEUTROPENIA WHEN RISK DUE TO MYELOSUPPRESIVE CHEMO REGIMEN IS 20% OR GREATER OR TO PREVENT FEBRILE NEUTROPENIA WHEN THE RISK OF DEVELOPING FEBRILE NEUTROPENIA IS LESS THAN 20% WITH ONE ADDITIONAL RISK FACTOR. PREVENTION OF FEBRILE NEUTROPENIA WHEN A PREVIOUS CYCLE RESULTED IN A NEUTROPENIC COMPLICATION AND DOSE REDUCTION WILL COMPROMISE DISEASE FREE OR OVERALL SURVIVAL OR TREATMENT OUTCOME. FOR STEM CELL TRANSPLANTATION WHEN ONE OF THE FOLLOWING IS MET: DOCUMENTATION OF NON-MYELOID MALIGNANCY UNDERGOING MYELOABLATIVE CHEMOTHERAPY FOLLOWED BY AUTOLOGOUS OR ALLOGENIC BONE MARROW TRANSPLANTATION or USED FOR MOBILIZATION OF AUTOLOGOUS HEMATOPOIETIC PROGENITOR CELLS INTO THE PERIPHERAL BLOOD FOR COLLECTION BY LEUKAPHARESIS. AML RECEIVING INDUCTION OR CONSOLIDATION THERAPY. FOR SEVERE CHRONIC NEUTROPENIA WHEN THE FOLLOWING ARE MET: DX OF CONGENITAL. CYCLIC OR IDIOPATHIC NEUTROPENIA and ABSOLUTE NEUTROPHIL COUNT IS LESS THAN 500 CELLS/MM3 ON THREE SEPARATE OCCASIONS DURING A 6 MONTH PERIOD OR FIVE CONSECUTIVE DAYS OF ANC LESS THAN 500 CELLS/MM3 PER CYCLE and DOCUMENTATION OF INFECTION, FEVER OR OROPHARYNGEAL ULCER DURING THE PAST 12 MONTHS. FOR NEUPOGEN ONLY: HEMATOPOIETIC SYNDROME OF ACUTE RADIATION SYNDROME (H-ARS) WITH DOCUMENTATION OF AN ACUTE EXPOSURE TO MYELOSUPRESSIVE DOSES OF RADIATION.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

**Coverage Duration:**6 MONTHS

**Other Criteria:**ADDITIONAL RISK FACTORS FOR THE PREVENTION OF FEBRILE NEUTROPENIA INCLUDE, BUT ARE NOT LIMITED TO: 65 YRS OR OLDER, POOR

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PERFORMANCE STATUS, PREVIOUS HISTORY OF FEBRILE NEUTROPENIA, EXTENSIVE PRIOR RADIATION OR CHEMOTHERAPY TREATMENT, POOR NUTRITIONAL STATUS, RECENT SURGERY OR OPEN WOUNDS OR ACTIVE INFECTION, ADVANCED CANCER, PERSISTENT NEUTROPENIA, BONE MARROW INVOLVEMENT BY TUMOR, LIVER DYSFUNCTION (BILIRUBIN GREATER THAN 2), OR RENAL DYSFUNCTION (CrcL LESS THAN 50 ML/MIN).

#### NEXAVAR

Affected Drugs:

NexAVAR

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**N/A

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria**: REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### **NEXIUM IV**

#### Affected Drugs:

Esomeprazole Sodium

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**N/A

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO PANTOPRAZOLE IV.

Ninlaro

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF MULTIPLE MYELOMA AND DOCUMENTATION OF MEDICATION BEING USED IN COMBINATION WITH REVLIMID AND DEXAMETHASONE. DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST ONE PRIOR THERAPY

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

#### NITYR

# Affected Drugs:

Nityr

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF HEREDITARY TYROSINEMIA TYPE 1 (HT-1). DOCUMENTATION OF ELEVATED PLASMA OR URINE SUCCINYLACETONE (SA) LEVELS

Age Restrictions:N/A

Prescription Order Restrictions: METABOLIC SPECIALIST OR GENETICIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### NOCDURNA

# Affected Drugs:

Nocdurna

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

**Exclusion Criteria:**History of hyponatremia or serum sodium less than 135 mEq/L. GFR less than 50 ml/min. Diagnosis of syndrome of inappropriate antidiuretic hormone (SIADH), New York Heart Association (NYHA) class II-IV congestive heart failure, or uncontrolled hypertension.

**Required Medical Information:**Documentation of a diagnosis of nocturia due to nocturnal polyuria, as defined by a night-time urine production exceeding one-third of the 24-hour urine production confirmed with a 24-hour urine frequency/volume chart AND documentation of waking at least two times per night to void.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:N/A

#### **Coverage Duration:6 MONTHS**

**Other Criteria**:Documentation that medication is not being used in combination with a loop diuretic or systemic or inhaled glucocorticoid. Reauthorization will require documentation of clinical benefit AND documentation of none of the following: hyponatremia, GFR less than 50 ml/min, SIADH, class II-IV NYHA CHF, uncontrolled hypertension or use of loop diuretics or systemic or inhaled glucocorticoids.

#### NORTHERA

#### Affected Drugs:

Droxidopa Northera

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF SYMPTOMATIC NEUROGENIC ORTHOSTATIC HYPOTENSION (NOH) CAUSE BY ONE OF THE FOLLOWING: PRIMARY AUTONOMIC FAILURE, DOPAMINE BETA-HYDROXYLASE DEFICIENCY OR NON-DIABETIC AUTONOMIC NEUROPATHY

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: CARDIOLOGIST OR NEUROLOGIST

Coverage Duration:4 WEEKS INITIAL AND 3 MONTHS CONTINUATION

Other Criteria: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO MIDODRINE

#### NOURIANZ

Affected Drugs: Nourianz

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of Parkinson's disease with 'OFF' episodes or motor fluctuations AND documentation that medication will be used as adjunctive treatment to carbidopa-levodopa

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: By or in consultation with a neurologist

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of therapeutic failure on, intolerance to, or contraindication to two formulary alternatives for the treatment of Parkinsons disease

Noxafil Posaconazole

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

Exclusion Criteria:N/A

**Required Medical Information:**DOCUMENTATION OF USE FOR PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTIONS IN SEVERELY IMMUNOCOMPROMISED PATIENTS (HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT) RECIPIENTS WITH GRAFT-VERSUS-HOST-DISEASE (GVHD) OR THOSE WITH HEMATOLOGIC MALIGNANCIES WITH PROLONGED NEUTROPENIA FROM CHEMOTHERAPY) OR DIAGNOSIS OF OROPHARYNGEAL CANDIDIASIS.

#### Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

**Coverage Duration:**Oropharyngeal candidiasis: 1 month. Prophylaxis of Aspergillus and Candida infections: 6 months

**Other Criteria:**For oropharyngeal candidiasis: failure on, intolerance to, or contraindication to itraconazole oral solution and fluconazole. Reauthorization for prophylaxis of invasive Aspergillus and Candida infections beyond 6 months will require documentation of medical necessity and continued disease risk from neutropenia or immunosuppression.

#### NPLATE

#### Affected Drugs:

Nplate

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF IMMUNE THROMBOCYTOPENIA PURPURA (ITP). DOCUMENTATION OF HEMATOPOIETIC SYNDROME OF ACTUE RADIATION SYNDROM (HS-ARS).

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 3 MONTHS INITIAL, 6 MONTHS CONTINUATION

**Other Criteria:**FOR HS-ARS: DOCUMENTATION OF SUSPECTED OR CONFIRMED ACUTE EXPOSURE TO MYELOSUPPRESSIVE DOSES OF RADIATION (ESTIMATED AS RADIATION LEVELS GREATER THAN 2 GRAY (GY)). FOR ITP: DOCUMENTATION OF SYMPTOMATIC ITP WITH BLEEDING SYMTPOMS WITH PLATELET COUNT LESS THAN 30,000/MICROL OR PLATELET COUNT OF LESS THAN 20,000/MICROL WITH AN INCREASED RISK OF BLEEDING AND FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO CORTICOSTEROIDS AND ELTROMBOPAG. SUBSEQUENT APPROVAL AFTER 3 MONTHS WILL REQUIRE DOCUMENTATION OF MEDICAL NECESSITY SUCH AS A PLATELET COUNT NECESSARY TO REDUCE THE RISK FOR BLEEDING OR A HEMATOLOGICAL RESPONSE.

#### NUBEQA

# Affected Drugs:

Nubeqa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of non-metastatic, castration-resistant prostate cancer AND documentation of concurrent use with a GnRH analog or that patient has had a bilateral orchiectomy

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: ONCOLOGIST OR UROLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Nucala

Off-Label Uses:N/A

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

**Required Medical Information**: Diagnosis of severe eosinophilic asthma and documentation that medication is being used as add-on maintenance treatment and documentation of a blood eosinophil count of 300 cells/mcL or greater during the 12 month period before screening or 150 cells/mcL or greater within 3 months of the the start of therapy OR Diagnosis of eosinophilic granulomatosis (EGPA) confirmed by biopsy evidence of vasculitis and 4 or more of the following criteria: Asthma, eosinophilia, mononeuropathy or polyneuropathy, migratory or transient pulmonary opacities detected radiographically, paranasal sinus abnormality or biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas. Diagnosis of hypereosinophilic syndrome (HES) for greater than or equal to 6 months AND documentation that member has been evaluated for and does not have an identifiable non-hematologic secondary cause or FIP1 like 1-platelet derived growth factor receptor (FIP1L1-PDGFRalpha) kinase-positive HES.

Age Restrictions: Asthma:6 years of age or older. EGPA:18 years or older. HES:12 years or older

**Prescription Order Restrictions:**for asthma or EGPA: ALLERGIST, IMMUNOLOGIST, PULMONOLOGIST, RHEUMATOLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**FOR EOSINOPHILIC ASTHMA: DOCUMENTATION OF CONTRAINDICATION, INTOLERANCE TO, OR POORLY CONTROLLED SYMPTOMS DESPITE AT LEAST A 30 DAY TRIAL OF MAXIMALLY TOLERATED INHALED CORTICOSTEROIDS AND/OR ORAL SYSTEMIC CORTICOSTEROIDS PLUS A LONG-ACTING BETA AGONIST or TWO OR MORE EXACERBATIONS IN THE PREVIOUS 12 MONTHS REQUIRING ADDITIONAL MEDICAL TREATMENT (ORAL CORTICOSTEROIDS, EMERGENCY DEPARTMENT OR URGENT CARE VISITS, OR HOSPITALIZATION) DESPITE CURRENT THERAPY OR INTOLERANCE TO INHALED CORTICOSTEROIDS PLUS A LONG-ACTING BETA AGONIST. FOR EGPA: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO SYSTEMIC GLUCOCORTICOID THERAPY AND AT LEAST ONE IMMUNOSUPPRESSANT THRAPY (I.E. CYCLOPHOSPHAMIDE, AZATHIOPRINE, METHOTREXATE). DOCUMENTATION THAT NUCALA IS NOT BEING USED IN COMBINATION WITH OMALIZUMAB, BENRALIZUMAB, OR RESLIZUMAB. FOR HES: (1)DOCUMENTATION OF A BLOOD EOSINOPHIL COUNT OF 1000 CELLS/MCL OR HIGHER and (2)DOCUMENTATION OF AT LEAST TWO HES FLARES WITHIN

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THE PREVIOUS 12 MONTHS WITH A WORSENING OF CLINICAL SYMPTOMS OF HES OR INCREASING BLOOD EOSINOPHIL LEVELS REQUIRING AN ESCLATION IN THERAPY AND (3)DOCUMENTATION THAT MEMBER IS ON STABLE HES THERAPY INCLUDING, BUT NOT LIMITED TO ORAL CORTICOSTEROIDS, IMMUNOSUPPRESSIVES OR CYCTOXIC THERAPY. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

#### NUEDEXTA

Affected Drugs:

Nuedexta

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF PSEUDOBULBAR AFFECT

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

Nulibry

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

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

**Required Medical Information**: DIAGNOSIS OF MOLYBDENUM COFACTOR DEFICIENCY (MOCD) TYPE A AS CONFIRMED BY GENETIC TESTING INDICATING A MUTATION IN THE MOLYBDENUM COFACTOR SYNTHESIS GENE 1 (MOSC1) GENE OR DOCUMENTATION OF BOTH OF THE FOLLOWING: 1) DOCUMENTATION OF BIOCHEMICAL AND CLINICAL FEATURES CONSISTENT WITH A DIAGNOSIS OF MOLYBDENUM COFACTOR DEFICIENCY (MOCD) TYPE A, INCLUDING BUT NOT LIMITED TO ENCEPHALOPATHY, INTRACTABLE SEIZURES, ELEVATED URINARY S-SULFOCYSTEINE LEVELS, AND DECREASED URIC ACID LEVELS AND 2) DOCUMENTATION THAT THE MEMBER WILL BE TREATED PRESUMPTIVELY WHILE AWAITING GENETIC CONFIRMATION.

#### Age Restrictions:N/A

**Prescription Order Restrictions:**NEONATOLOGIST, GENETICIST OR PEDIATRIC NEUROLOGIST

Coverage Duration: PRESUMPTIVE DX: 1 MONTH. CONFIRMED DX: 12 MONTHS.

**Other Criteria**: REAUTHORIZATION FOLLOWING INITIAL PRESUMPTIVE DIAGNOSIS WILL REQUIRE DOCUMENTATION OF GENETIC TESTING CONFIRMING A DIAGNOSIS OF MOLYBDENUM COFACTOR DEFICIENCY (MOCD) TYPE A. REAUTHORIZATION FOR GENETICIALLY CONFIRMED MOCD TYPE A WILL REQUIRE DOCUMENTATION OF A CLINICALLY SIGNIFICANT POSITIVE RESPONSE OR LACK OF DISEASE PROGRESSION WHILE ON THERAPY.

#### NULOJIX

#### Affected Drugs:

Nulojix

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DOCUMENTATION OF RENAL TRANSPLANT

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria: DOCUMENTATION OF EPSTEIN-BARR VIRUS (EBV) SEROPOSITIVITY

Affected Drugs: Nuplazid

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of a diagnosis of Parkinson's disease psychosis (defined by illusions, a false sense of presence, hallucinations, or delusions) established by or in consultation with a neurologist AND documentation that psychosis is not due to other conditions (which may include, but are not limited to, another mental disorder or physiological effects of a substance)

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:N/A

Coverage Duration: 3 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**SUBSEQUENT APPROVALS WILL REQUIRE DOCUMENTATION OF CLINICAL IMPROVEMENT OR LACK OF PROGRESSION IN SIGNS AND SYMPTOMS OF PARKINSON'S DISEASE PSYCHOSIS.

#### NURTEC

#### Affected Drugs:

Nurtec

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of use for the acute treatment of migraine with or without aura.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria**:Documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary triptans (e.g., almotriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan). Documentation that medication will not be used concomitantly with another CGRP antagonist indicated for the acute treatment of migraine.

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#### NUVIGIL

Affected Drugs:

Armodafinil

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME, NARCOLEPSY OR SHIFT-WORK

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

Nuzyra

Off-Label Uses:N/A

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

**Required Medical Information:**Diagnosis of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following: Staphylococcus aureus (including methicillin-resistant (MRSA) and methicillin-susceptible (MSSA) isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus Group (including S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae and Klebsiella pneumoniae OR Diagnosis of community acquired bacterial pneumonia caused by susceptible isolates of the following: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible (MSSA) isolates), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophilia, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**WRITTEN BY OR IN CONSULTATION WITH A INFECTIOUS DISEASE PROVIDER

#### Coverage Duration:2 WEEKS

**Other Criteria**:Documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to two other antibiotics shown to be susceptible on the culture and sensitivity OR documentation that therapy was initiated during an inpatient setting.

#### OCREVUS

## Affected Drugs:

Ocrevus

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

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

**Required Medical Information:**Diagnosis of primary progressive MS OR diagnosis of a relapsing form of MS (including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease).

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:NEUROLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**For relapsing form of MS: documentation of a therapeutic failure on, intolerance to , or contraindication to two formulary alternatives. Reauthorization will require documentation of improvement in signs and symptoms or maintenance of condition while on therapy.

Odomzo

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DIAGNOSIS OF LOCALLY ADVANCED BASAL CELL CARCINOMA (BCC) THAT HAS RECURRED FOLLOWING SURGERY OR RADIATION THERAPY OR THOSE WHO ARE NOT CANDIDATES FOR SURGERY OR RADIATION THERAPY. DOCUMENTATION THAT TREATMENT IS SUPPORTED BY MULTIDISCIPLINARY BOARD CONSULTATION PER NCCN GUIDELINES.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Ofev

Off-Label Uses:N/A

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

**Required Medical Information:**DOCUMENTATION OF IDIOPATHIC PULMONARY FIBROSIS (IPF) CONFIRMED BY EITHER A USUAL INTERSTITIAL PNEUMONIA PATTERN ON HIGH RESOLUTION CT SCAN OR BOTH HRCT AND SURGICAL LUNG BIOPSY PATTERN SUGGESTIVE OF IPF OR PROBABLE IPF MADE BY AN INTERDISCIPLINARY TEAM INCLUDING, BUT NOT LIMITED TO SPECIALISTS FROM PULMONARY MEDICINE, RADIOLOGY, THORACIC SURGERY, PATHOLOGY OR RHEUMATOLOGY AND DOCUMENTATION THAT THERE ARE NO OTHER KNOWN CAUSES OF INTERSTITIAL LUNG DISEASE SUCH AS DOMESTIC AND OCCUPATIONAL ENVIRONMENTAL EXPOSURES. CONNECTIVE TISSUE DISEASE OR DRUG TOXICITY AND DOCUMENTATION THAT THE PATIENT WAS TAUGHT PULMONARY REHABILITATION TECHNIQUES. Diagnosis of systemic sclerosis according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) AND documentation of related interstitial lung disease confirmed by: 1) greater than or equal to 10 % fibrosis on a chest high resolution CT scan, 2) FVC greater than or equal to 40% of predicted normal, and 3) DLCO (diffusion capacity of the lung for carbon monoxide) 30-89% of predicted normal. Diagnosis of chronic fibrosing interstitial lung disease (ILDs) with a progressive phenotype AND documentation of ILD confirmed by all of the following: 1)10% or more fibrosis on a chest high resolution computer tomography AND 2) FVC more than 45% of predicted normal AND 3) Diffusion capacity of the lung for carbon monoxide (DLCO) of 30-80% of predicted normal.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

### Prescription Order Restrictions: PULMONOLOGIST or RHEUMATOLOGIST

### Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria**:Documentation of ILD progression despite appropriate management with documentation of the following: 1) FVC decline of 10% or greater OR 2)FVC decline between 5-10% with documentation of worsening symptoms or increasing fibrotic changes on imaging OR 3) Documentation of BOTH worsening symptoms AND increasing fibrotic changes on imaging.

Affected Drugs: Olumiant

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of moderate to severe Rheumatoid Arthritis made in accordance with the American College of Rheumatology criteria for the classification and diagnosis of Rheumatoid Arthritis

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: RHEUMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**For RA: failure on, intolerance to, or contraindication to a minimum 3 month trial of (1) Humira and (2) Rinvoq ER or Xeljanz. Documentation that medication is not being used concurrently with a TNF blocker or other biologic agent. For continued therapy, documentation showing maintenance or improvement of condition while on therapy.

#### ONIVYDE

Affected Drugs:

Onivyde

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of a diagnosis of metastatic adenocarcinoma of the pancreas AND documentation that medication is being prescribed in combination with fluorouracil and leucovorin AND medical record documentation of disease progression following gemcitabine based therapy

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 months

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION Affected Drugs: Onpattro

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) as confirmed by genetic testing to confirm a pathogenic mutation in TTR AND one of the following: biopsy of tissue or organ to confirm amyloid presence OR a clinical manifestation typical of hATTR (such as neuropathy or CHF) without a better alternative explanation. Documentation of medication being used to treat polyneuropathy. Documentation of familial amyloid polyneuropathy (FAP) stage 1-2 OR polyneuropathy disability score (PND) indicating the patient is not wheelchair bound or bedridden.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**by or in consultation with a neurologist, geneticist, or specialist with experience treating hereditary transthyretin-mediated amyloidosis

#### Coverage Duration:12 MONTHS

**Other Criteria**:Documentation that medication will not be used in combination with other RNA interference treatments. Reauthorization will require medical necessity and no documentation of progression to FAP stage 3 AND no documentation of a polyneuropathy disability score indicating the patient is wheelchair bound or bedridden.

#### ONUREG

#### Affected Drugs: Onureg

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of acute myeloid leukemia AND documentation that patient achieved first complete remission (CR) or complete remission with incomplete blood count recovery (Cri) following intensive induction chemotherapy AND documentation that patient is not able to complete intensive curative therapy.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### OPDIVO

# Affected Drugs:

Opdivo

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

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

Required Medical Information: Unresectable/metastatic melanoma OR as single agent in adjuvant setting for completely resected metastatic melanoma. Metastatic NSCLC AND 1)progression on/after platinum-based therapy OR 2)PD-L1 of at least 1% and no EGFR or ALK genomic tumor aberrations used w/ Yervoy OR 3)no EGFR or ALK genomic tumor aberrations used for first line tx w/ Yervoy and 2 cycles of platinum-doublet chemotx. As a single agent for relapsed or surgically unresectable advanced/metastatic renal cell carcinoma (RCC) OR DX of previously untreated advanced RCC w/ one of the following: used in combo with Ipilimumab w/ intermediate to poor risk (1 or more prognostic risk factors as per the IMDC criteria) OR use in combination with Cabozantinib. Classical Hodgkin Lymphoma (CHL) that has relapsed or progressed after autologous HSCT and post-transplantation Brentuximab vedotin or after 3 or more lines of systemic chemotherapy that includes autologous HSCT. Recurrent metastat squamous cell carcinoma of the head and neck w/ progression on/after receiving a platinum-based tx. Locally advanced/metastatic urothelial carcinoma (UC) w/ either progression following platinum tx OR within 12 months of neoadjuvant/adjuvant tx w/ platinum therapy OR for use in the adjuvant setting with both of the following: 1)radial resection of UC AND 2)high risk of recurrence. Metastatic colorectal cancer with microsatellite instability high (MSI-H) or mismatch repair AND progression following tx w/ a fluoropyrimidine, oxaliplatin, or irinotecan-based therapy AND used as monotherapy OR in combo with ipilimumab. Hepatocellular carcinoma used alone or in combo with ipilimumab. Unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC). Adjuvant treatment of resected esophageal or gastroesophageal junction (GEJ) cancer. Gastric cancer, GEJ cancer or esophageal adenocarcinoma. Unresectable malignant pleural mesothelioma with documentation of use in combo with ipilimumab.

Age Restrictions: FOR MCRC MUST BE AT LEAST 12 YEARS OF AGE. ALL OTHERS: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

**Coverage Duration:**6 MO, 12 MO REAUTH. ADJ MELAN,GEJ,UC:6 MO. 1ST LINE NSCLC/mesoth/esoph adenoCA:6 MO.18 MO REAUTH

**Other Criteria:**FOR THE TREATMENT OF HCC: DOCUMENTATION OF A THERAPEUTIC FAILURE ON OR INTOLERANCE TO SORAFENIB. FOR THE TREATMENT OF NSCLC OR UROTHELIAL CARCINOMA, DOCUMENTATION THAT OPDIVO IS NOT BEING USED IN

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COMBINATION WITH ANY OTHER AGENTS. FOR THE TREATMENT OF UNRESECTABLE OR METASTATIC MELANOMA. DOCUMENTATION THAT OPDIVO IS NOT BEING USED IN COMBINATION WITH ANY OTHER AGENT, EXCEPT IPILIMUMAB. FOR THE TREATMENT OF RENAL CELL CARCINOMA, DOCUMENTATION OF A THERAPEUTIC FAILURE OR INTOLERANCE TO ONE PRIOR ANTI-ANGIOGENIC THERAPY, INCLUDING BUT NOT LIMITED TO SUNITINIB, PAZOPANIB, AXITINIB, SORAFENIB, BEVACIZUMAB, EVEROLIUMS, OR TEMSIROLIMUS. FOR THE TREATMENT OF ESCC: DOCUMENTATION OF PREVIOUS TRIAL OF FLUOROPYRIMIDINE AND PLATINUM BASED THERAPY. FOR TREATMENT OF RESECTED ESOPHAGEAL OR GEJ CANCER: DOCUMENTATION OF COMPLETE RESECTION WITH RESIDUAL PATHOLOGIC DISEASE AND DOCUMENTATION THAT MEMBER HAS RECEIVED NEOADJUVANT CHEMORADIOTHERAPY AND DOCUMENATION THAT MEDICATION IS BEING USED AS A SINGLE AGENT IN THE ADJUVANT SETTING. FOR GASTRIC, GEJ AND ESOPHAGEAL ADENOCARCINOMA: DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH FLUOROPYRIMIDINE AND PLATINUM BASED CHEMOTHERAPY. SUBSEQUENT APPROVALS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. REQUESTS BEYOND 12 MONTHS FOR ADJUVANT TREATMENT OF METASTATIC MELANOMA. ADJUVANT TREATMENT OF RESECTED ESOPHAGEAL OR GEJ CANCER, AND ADJUVANT UROTHELIAL CARCINOMA WILL REQUIRE PEER-REVIEWED LITERATURE CITING WELL-DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBER'S HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA-APPROVED TREATMENT DURATION.

#### OPSUMIT

Affected Drugs: Opsumit

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF WHO FUNCTIONAL CLASS II, III, OR IV PULMONARY ARTERIAL HYPERTENSION AND NEGATIVE PREGNANCY TEST IN FEMALES OF CHILDBEARING POTENTIAL

Age Restrictions:N/A

Prescription Order Restrictions: CARDIOLOGIST OR PULMONOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria**:DOCUMENTATION THAT OPSUMIT WILL BE USED IN COMBINATION WITH OR THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL

#### ORENCIA

### Affected Drugs:

Orencia Orencia ClickJect

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

#### Exclusion Criteria:N/A

**Required Medical Information:**DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS or DIAGNOSIS OF POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS or DIAGNOSIS OF PSORIATIC ARTHRITIS WHICH MUST INCLUDE DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS OR A DOCUMENTED HISTORY OF PSORIASIS.

Age Restrictions: FOR RA AND PSA: MUST BE 18 YEARS OF AGE OR OLDER. FOR PJIA: MUST BE 2 YEARS OF AGE OR OLDER.

Prescription Order Restrictions: RHEUMATOLOGIST OR DERMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: DOCUMENTATION OF AN INADEQUATE RESPONSE TO A 3 MONTH TRIAL OF (1) HUMIRA AND (2) RINVOQ ER OR XELJANZ. FOR PJIA: DOCUMENTATION OF AN INADEQUATE RESPONSE TO A 3 MONTH TRIAL OF HUMIRA. FOR PSA: DOCUMENTATION OF AN INADEQUATE RESPONSE TO A 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX OR XELJANZ. FOR CONTINUED THERAPY. MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

#### ORGOVYX

Affected Drugs:

Orgovyx

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Documentation of a diagnosis of advanced prostate cancer.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST, ONCOLOGIST OR UROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

#### ORILISSA

Affected Drugs: Orilissa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of a diagnosis of moderate to severe pain associated with endometriosis, which may include endometriosis-related dyspareunia

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:GYNECOLOGIST

**Coverage Duration:**150 MG: 6 MONTHS INITIAL, 18 MONTHS REAUTH. 200 MG: 6 MONTHS, ONE TIME AUTHORIZATION

**Other Criteria:**Documentation of a therapeutic failure on, intolerance to, or contraindication to one extended cycle contraceptive AND one formulary NSAID. Reauthorization for the 150 mg strength will require documentation that the correct strength/dose is being prescribed for the condition AND documentation that the patient has not been treated for more than a total of 24 months with Orilissa 150 mg daily OR more than a total of 6 months with Orilissa 200 mg twice daily OR documentation of medical or scientific literature to support the use of this agent beyond the FDA approved treatment duration.

#### ORKAMBI

Affected Drugs: Orkambi

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF CYSTIC FIBROSIS. DOCUMENTATION THAT THE MEMBER IS HOMOZYGOUS FOR THE F508DEL CFTR MUTATION AS DOCUMENTED BY AN FDA-CLEARED TEST.

Age Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: PULMONOLOGIST OR CYSTIC FIBROSIS SPECIALIST

Coverage Duration: 4 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria**: REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT OR STABILIZATION IN THE SIGNS AND SYMPTOMS OF CYSTIC FIBROSIS

Affected Drugs: Orladeyo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF HEREDITARY ANGIOEDEMA and FOR HAE TYPE I AND TYPE II: THE PRESENCE OF SPECIFIC ABNORMALITIES IN COMPLEMENT PROTEINS IN THE SETTING OF A SUGGESTIVE CLINICAL HISTORY OF EPISODIC ANGIOEDMEA WITHOUT URTICARIA SUPPORTED BY DOCUMENTATION OF LOW C4 LEVELS AND LESS THAN 50 PERCENT OF THE LOWER LIMIT OF NORMAL C1-INH ANTIGENIC PROTEIN LEVELS OR FUNCTION LEVELS

Age Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR DERMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS BEING USED AS PROPHYLACTIC THERAPY. Documentation that medication is not being used in combination with another prophylactic human C1 esterase inhibitor (Cinryze or Haegarda) or lanadelumab (Takhzyro) therapy for hereditary angioedema. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

Otezla

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DOCUMENTATION OF ACTIVE PSORIATIC ARTHRITIS WHICH MUST INCLUDE DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS OR A DOCUMENTED HISTORY OF PSORIASIS. DOCUMENTATION OF MODERATE TO SEVERE PLAQUE PSORIASIS CHARACTERIZED BY 5% OR GREATER INVOLVMENT OF BODY SURFACE AREA OR DISEASE INVOVLING CRUCIAL BODY AREAS SUCH AS THE HANDS, FEET, FACE, OR GENITALS. DIAGNOSIS OF ORAL ULCERS ASSOCIATED WITH BEHCET'S DISEASE.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: RHEUMATOLOGIST OR DERMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**FOR PSORIATIC ARTHRITIS: DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST A 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTX, OR XELJANZ. FOR PSORIASIS: DOCUMENTATION OF FAIULRE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST A 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX, OR SKYRIZI. FOR ALL INDICATION, FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION OF CLINICAL OR SUSTAINED IMPROVEMENT OF SIGNS AND SYMPTOMS OF DISEASE.

#### OXBRYTA

Affected Drugs:

Oxbryta

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Documentation of diagnosis of sickle cell disease.

Age Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

Prescription Order Restrictions: by or in consultation with a hematologist

Coverage Duration:12 MONTHS

**Other Criteria:**Documentation of baseline hemoglobin. Documentation of intolerance to, contraindication or therapeutic failure on 3 month trial of hydroxyurea AND Endari. If the requested dose is 2500 mg daily: documentation of using in combination with a strong or moderate CYP3A4 inducer, including but not limited to apalutamide, bosentan, carbamazepine, efavirenz, etravirine, enzalutamide, nitotane, phenobarbital, phenyotin, primidone, rifampin or St. John's Wort. Reauthorization will require an increase in hemoglobin from baseline or an improvement in complications of sickle cell disease (i.e., decrease in vasoocclusive crisis related emergencies), and if requesting a dose of 2500 mg daily, that medication is being used in combination with a strong or moderate CYP3A4 inducer.

Affected Drugs: Oxervate

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of diagnosis of neurotrophic keratitis (NK) as confirmed by a decrease or loss in corneal sensitivity AND one of the following: 1) superficial keratopathy, 2) persistent epithelial defects or 3) corneal ulcers.

Age Restrictions: MUST BE 2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: OPHTHALMOLOGIST

#### Coverage Duration:8 WEEKS

**Other Criteria**:Documentation of therapeutic failure on, intolerance to, or contraindication to at least one conventional non-surgical treatment for neurotrophic keratitis (NK) (e.g. preservative free artificial tears, gels or ointments, discontinuation of preserved topical drops and medications that can decrease corneal sensitivity, or therapeutic contact lenses). Reauthorization for treatment beyond 8 weeks will require documentation of medical or scientific literature to support the use of this agent beyond the FDA approved treatment duration.

Oxlumo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of primary hyperoxaluria type 1 (PH1) as confirmd by one of the following: molecular genetic testing that confirms a mutation of alanin:glyoxylate aminotransferase gene (AGXT) OR a liver biopsy to confirm absent or significantly reduced alanin-glyoxylate aminotransferase (AGT).

Age Restrictions:N/A

**Prescription Order Restrictions:**specialist with experience managing hyperoxaluria (i.e. nephrologist, urologist, geneticist, hepatologist)

Coverage Duration: 6 MONTHS INITIAL AND 12 MONTHS CONTINUATION

**Other Criteria:**Documentation of metabolic screening that demonstrates one of the following: markedly increased urinary oxalate excretion (i.e. generally greater than 0.7 mmol/1.73m2/day or greater than the upper limit of normal) OR increased urinary oxalate to creatinine ratio (i.e. greater than the age-specific upper limit of normal). Documentation of sufficent kindey function as defined by one of the following: documentation of an eGFR greater than or equal to 30ml/min/1.73m2) OR if eGFR is not calculated due to age limitations, a serum creatinine within the normal age-specific reference range. Documentation that member does not have a history of liver transplant. Reauthorization will require documentation of continued disease improvement or lack of disease progression, continued adequate renal function (greater than or equal to 30 ml per min) and documentation of not receiving a liver transplant.

Padcev

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

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

**Required Medical Information:**Diagnosis of locally advanced or metastatic urothelial cancer AND documentation of one of the following: (1) that member has received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting OR (2) that member has received at least one prior line of therapy and is ineligible for cisplatin-containing chemotherapy.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

#### PALYNZIQ

## Affected Drugs:

Palynziq

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

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

**Required Medical Information:**Documentation of a diagnosis of phenylketonuria (PKU) AND documentation of phenylalanine (Phe) concentrations greater than 600 micromol/L on existing management.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions: METABOLIC SPECIALIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**Documentation that the member has (or will receive) a prescription for epinephrine auto-injector. Documentation of failure on, intolerance to, or contraindication to Kuvan. Documentation that medication will not be used in combination with Kuvan. Reauthorization will require documentation of a 20% reduction in Phe concentration from baseline OR a blood Phe concentration less than 600 micromol/L OR documentation of improvement in neuropsychiatric symptoms or an increase in Phe tolerance.

#### PEMAZYRE

Affected Drugs: Pemazyre

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of unresectable locally advanced or metastatic cholangiocarcinoma AND documentation of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as verified by an FDA approved test AND documentation of trial of one prior line of therapy.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Pepaxto

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of relapsed or refractory multiple myeloma AND documentation of treatmeant with at least 4 prior therapies and are refractory to at least one anti-CD38 monoclonal antibody, one proteasome inhibitor, and one immunomodulatory agent

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

**Other Criteria:**Reauthorization will require documentation of continued disease improvement or lack of disease progression

#### PERFOROMIST

#### Affected Drugs:

Formoterol Fumarate Perforomist

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information:DX OF COPD

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SEREVENT OR DOCUMENTATION OF INABILITY TO USE AN INHALER.

GHP Medicare Formulary - Prior Authorization Criteria

#### PERSERIS

Affected Drugs:

Perseris

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Documentation of a diagnosis of schizophrenia

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria**:Documentation of a therapeutic failure on or intolerance to the oral equivalent form of the medication.

Piqray (200 MG Daily Dose) Piqray (250 MG Daily Dose) Piqray (300 MG Daily Dose)

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Diagnosis of advanced or metastatic breast cancer that is hormone receptor-positive, HER2-negative (HR+/HER2-) AND documentation of a PIK3CA mutation determined using a FDA approved test, AND documentation that member is either a male or a postmenopausal female.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:ONCOLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**Documentation of a therapeutic failure on, intolerance to, or contraindication to prior endocrine therapy AND documentation of use in combination with fulvestrant. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

Polivy

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Diagnosis of relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified AND documentation of use in combination with bendamustine and rituximab AND documentation of use as subsequent therapy after a trial of 2 or more prior therapies.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

#### Coverage Duration:6 MONTHS

**Other Criteria:**Reauthorization will require documentation of continued disease improvement or lack of disease progression AND documentation that the FDA approved treatment duration (6, 21 day cycles) has not been exceeded. Treatment beyond FDA approved labeling will require documentation of peer reviewed literature citing well designed clinical trials to indicate that the members healthcare outcome will be improved by dosing beyond the FDA approved treatment duration.

Pomalyst

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF MULTIPLE MYELOMA and DOCUMENTATION THAT POMALYST IS BEING PRESCRIBED IN COMBINATION WITH DEXAMETHASONE OR DOCUMENTATION THAT THE PATIENT IS STEROID INTOLERANT. Documentation of Kaposi sarcoma with one of the following: 1) AIDS-related Kaposi sarcoma with documentation of progression despite the use of antiretroviral therapy AND documentation that antiretroviral therapy will be continued OR 2) documentation of HIV-negative status.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**For Multiple Myeloma: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO PRIOR THERAPIES: BORTEZOMIB (VELCADE) AND LENALIDOMIDE (REVLIMID). REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### PORTRAZZA

Affected Drugs: Portrazza

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**:DOCUMENTATION OF A DIAGNOSIS OF METASTATIC SQUAMOUS NON-SMALL CELL LUNG CANCER and DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH GEMCITABINE AND CISPLATIN

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

**Coverage Duration:**6 MONTHS

**Other Criteria**:DOCUMENTATION OF DISEASE PROGRESSION OR AN INTOLERANCE TO ONE ALTERNATIVE CATEGORY 1 OR CATEGORY 2 RECOMMENDED REGIMEN PER NCCN GUIDELINES. SUBSEQUENT APPROVAL AFTER 6 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

#### PRALUENT

Affected Drugs: Praluent

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

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

Required Medical Information: Documentation of either clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin OR primary hyperlipidemia OR Heterozygous familial hypercholesterolemia (HeFH) OR Homozygous familial hypercholesterolemia (HoFH). For HeFH one of the following: Genetic testing to confirm mutation in the LDL receptor, PCSK9, or ApoB gene OR documentation of definite HeFH (score greater than 8) on the diagnostic criteria scoring system as defined by the ESC/EAS guidelines and the WHO. Documentation of a baseline LDL drawn within 3 months of the start of PCSK9 therapy showing an LDL greater than 100 if using Praluent for primary prevention OR an LDL greater than 70 if using Praluent for secondary prevention. Documentation that Praluent is not being used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro. For statin tolerant patients, documentation of an inability to achieve and maintain LDL goal with one of the following (1) maximum tolerated dose of a high intensity statin (atorvastatin 40 mg or higher or rosuvastatin 20 mg or higher) or (2) a maximally tolerated dose of any statin given that the patient has had a previous trial of either atorvastatin or rosuvastatin, with prescribers documentation regarding length of previous trials of statins. Patient must intend to continue on maximal statin therapy once Praluent is started. For statin intolerant patients, documentation of reason for statin intolerance.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions: Cardiologist, endocrinologist or lipidologist

#### Coverage Duration:12 MONTHS

**Other Criteria:**For HoFH one of the following: genetic testing to confirm diagnosis showing at least one low-density lipoprotein (LDL) receptor-defective mutation OR Dx made based on history of an untreated LDL-C greater than 500 mg/dL and either xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia (HeFH) in both paretns. Therapeutic failure is defined as an inability to reach target LDL goals (less than 100 mg/dL for patients with HeFH in primary prevention or less than 70 mg/dL for ASCVD or for patients with HeFH using Praluent as secondary prevention) despite at least a 3 month trial. Intolerance to statins is defined as increased LFTs, intolerable myalgia (muscle symptoms without creatinine kinase (CK) elevations) or myopathy

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(muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms), which persist after two retrials with a different dose or different dosing strategy (every other day) of alternative moderate- or high-intensity statin. Contraindications to statins are defined as active liver disease, previous history of rhabdomyolysis, or hypersensitivity. Renewal criteria: Documentation of an up to date LDL cholesterol level since the previous review showing a clinically significant response to treatment AND documentation of no significant adverse events related to therapy AND documentation of still taking statin (if statin tolerant) AND documentation that Praluent continues to not be used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro.

#### PRETOMANID

Affected Drugs: Pretomanid

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of pulmonary infection due to Mycobacterium tuberculosis AND either documentation of extensively drug resistant tuberculosis OR treatment-intolerant or nonresponsive multidrug-resistant tuberculosis.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**By or in consultation with a physician specializing in infection disease

Coverage Duration:26 WEEKS

**Other Criteria:**Documentation that medication will be used in combination with bedaquiline and linezolid.

Affected Drugs: Prevymis

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation that the member is a recipient of an allogeneic hematopoietic stem cell transplant AND documentation that member is a confirmed CMV seropositive recipient (R+) AND documentation that medication is being used for CMV prophylaxis AND therapy is being initiated between Day 0 and Day 28 post-transplantation.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**BY OR IN CONSULTATION WITH A HEMATOLOGIST, ONCOLOGIST, INFECTIOUS DISEASE OR TRANSPLANT SPECIALIST

Coverage Duration:100 DAYS

**Other Criteria:**Documentation that medication is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), or pitavastatin or simvastatin (if co-administered with cyclosporine). Requests for injectable form will require documentation of intolerance to or reason why Preymis tablets cannot be used

#### PROCYSBI

Affected Drugs: Procysbi

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF NEPHROPATHIC CYSTINOSIS

Age Restrictions: MUST BE 1 YEARS OF AGE OR OLDER

Prescription Order Restrictions: NEPHROLOGIST, GENETICIST OR METABOLIC SPECIALIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO CYSTAGON

#### PROLIA

#### Affected Drugs:

Prolia

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

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

Required Medical Information: Dx of postmenopausal osteoporosis with documentation of previous osteoporotic fracture or high risk of fracture defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors and/or FRAX calculation showing a 3% or more probability of hip fracture OR 20% or more probability of major osteoporosis related fracture OR failure on, intolerance to, or contraindication to one oral bisphosphonate. Dx of osteopenia in those at high risk of fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. Dx of osteoporosis with documentation of previous osteoporotic fracture or high risk of fracture defined as a spine or hip DXA T-score of less than or equal to -2.0, supporting clinical factors and/or FRAX calculation showing a 3% or more probability of hip fracture OR 20% or more probability of major osteoporosis related fracture OR failure on, intolerance to, or contraindication to one oral bisphosphonate. Dx of osteopenia in those at high risk of fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. Dx of glucocorticoid induced osteoporosis AND documentation of high risk of fracture defined as a DXA T-score of less than or equal to -2.0 at the lumbar spine, total hip, or femoral neck, supporting clinical factors and/or FRAX calculation showing a 3% or more probability of hip fracture OR 20% or more probability of major osteoporosis related fracture OR failure on, intolerance to, or contraindication to one oral bisphosphonate AND documentation of either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone AND documentation of expectation of remaining on glucocorticoid therapy for at least 6 months.

#### Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

#### Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**For high risk of fracture receiving aromatase inhibitor or androgen deprivation therapy: failure on, intolerance to, or contraindication to one oral bisphosphonate

Affected Drugs: Promacta

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of Chronic immune (idiopathic) thrombocytopenic purpura (ITP) with failure on, intolerance to, or contraindication to corticosteroids and Rituxan AND a platelet count less than 30,000/microL with symptomatic ITP with bleeding symptoms or an increased risk of bleeding. Diagnosis of chronic Hepatitis C with thrombocytopenia and plan to initiate or continue interferon-based therapy AND documentation of failure on, intolerance to, or contraindication to corticosteroids. Diagnosis of aplastic anemia with a platelet count less than 30,000/microL and failure on one prior immunosuppressive therapy such as cyclosporine or Atgam OR for use as first line treatment in combination with standard immunosuppressive therapy (such as antithymocyte globulin and cyclosporine).

Age Restrictions:N/A

**Prescription Order Restrictions:**FOR ITP AND APLASTIC ANEMIA: PRESCRIBED BY HEMATOLOGIST OR ONCOLOGIST. FOR CHRONIC HEPATITIS C: PRESCRIBED BY GASTROENTEROLOGIST, HEMATOLOGIST, HEPATOLOGIST OR INFECTIOUS DISEASE PHYSICIAN.

Coverage Duration: 3 MONTHS INITIAL, 12 MONTHS CONTINUATION

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 3 MONTHS WILL REQUIRE DOCUMENTATION OF MEDICAL NECESSITY SUCH AS A PLATELET COUNT NECESSARY TO REDUCE THE RISK FOR BLEEDING or A HEMATOLOGICAL RESPONSE.

**Promethazine HCI** 

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:PRIOR AUTHORIZATION APPLIES ONLY TO MEMBERS 65 YEARS OF AGE AND OLDER WHO WILL BE EVALUATED FOR APPROPRIATE USE OF HIGH RISK MEDICATION. DIAGNOSIS OF ALLERGIC CONDITIONS (PRURITUS, URTICARIA, SEASONAL OR PERENNIAL ALLERGIES) WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO DESLORATADINE AND LEVOCETIRIZINE. DIAGNOSIS OF NAUSEA AND VOMITING WILL REQUIRE DIAGNOSIS OF CANCER OR FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONDANSETRON AND PROCHLORPERAZINE. DIAGNOSIS OF MOTION SICKNESS WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO MECLIZINE. FOR USE IN SEDATION INCLUDING PRODUCTION OF LIGHT SLEEP, REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ROZEREM AND SILENOR.

#### PROVIGIL

Affected Drugs: Modafinil

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME, NARCOLEPSY OR SHIFT-WORK

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

#### PULMOZYME

Affected Drugs:

Pulmozyme

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF CYSTIC FIBROSIS

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

#### QINLOCK

Affected Drugs: Qinlock

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of advanced gastrointestinal stromal tumor (GIST) AND documentation of prior treatment with three or more kinase inhibitors, including imatinib.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### QUDEXY

#### Affected Drugs:

Topiramate ER

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF PARTIAL ONSET SEIZURES, PRIMARY GENERALIZED TONIC CLONIC SEIZURES, OR LENNOX GASTAUT SYNDROME or DIAGNOSIS OF MIGRAINE PROPHYLAXIS

**Age Restrictions:**12 YEARS OR OLDER FOR MIGRAINE PROPHYLAXIS, 2 YEARS OF AGE OR OLDER FOR OTHER INDICATIONS

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ALTERNATIVES, ONE OF WHICH MUST BE IMMEDIATE-RELEASE TOPIRAMATE.

#### QUININE

Affected Drugs: quiNINE Sulfate

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**FOR TREATMENT OF UNCOMPLICATED PLASMODIUM FALCIPARUM MALARIA

Age Restrictions:N/A

Prescription Order Restrictions:N/A

**Coverage Duration:7 DAYS** 

**Other Criteria:**N/A

Radicava

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of ALS (amyotrophic lateral sclerosis) AND documentation of baseline functional status (as evidenced by a scoring system such as ALSFRS-R, or by physician documentation of subjective reports on speech, motor function, pulmonary function, etc.)

Age Restrictions:N/A

**Prescription Order Restrictions:**MUST BE PRESCRIBED BY OR IN CONSULTATION WITH A NEUROLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Documentation that Radicava is being given in combination with riluzole, or have an intolerance or contraindication to riluzole. Reauthorization will require documentation that member is tolerating regimen with documentation of regular physican follow-up

#### RAVICTI

#### Affected Drugs:

Ravicti

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**:DOCUMENTATION OF A DIAGNOSIS OF UREA CYCLE DISORDER (UCD) AND DOCUMENTATION OF INCREASED BLOOD AMMONIA LEVELS

Age Restrictions:N/A

Prescription Order Restrictions: METABOLIC DISORDER SPECIALIST OR GENETICIST

**Coverage Duration:**6 MONTHS

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SODIUM PHENYLBUTYRATE POWDER AND TABLETS. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT IN EITHER FASTING AMMONIA LEVELS, 24 HOUR AUC, OR NUMBER OF HYPERAMMONEMIC CRISES. Affected Drugs: Reblozyl

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of beta thalassemia and documentation that patient requires regular red blood cell (RBC) transfusions. Diagnosis of very low to intermediate risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) WITH one of the following: 1) documentation of 15% or more ring sideroblasts or 2) 5% or more ring sideroblasts AND an SF3B1 mutation. Documentation of requiring two or more red blood cell (RBC) units over 8 weeks.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: By or in consultation with a hematologist

Coverage Duration:6 MONTHS

**Other Criteria**:Documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous 6 months. Documentation that medication is being doses consistent with FDA approved labeling. For anemia associated with MDS: documentation of a therapeutic failure on, intolerance to, or contraindication to an erythropoiesis stimulating agent. Reauthorization will require an initial decrease in red blood cell (RBC) transfusion burden, followed by a sustained reduction of red blood cell (RBC) transfusion burden AND that medication continues to be dosed consistent with FDA approved labeling.

Affected Drugs: Recarbrio

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

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

**Required Medical Information**:Documentation of complicated urinary tract infection caused by the following suceptible gram negative microorganisms: Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella penumoniae or Pseudomonas aeruginosa OR complicated intra-abdominal infection caused by the following susceptible gram negative microorganisms: Bacteroides caccae, Bacteroides fragilis, Bacteroides ovatus, Bacteroides stercoris, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Fusobacterium nucleatum, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Parabacteroides distasonis or Pseudomonas aeruginosa OR diagnosis of hospital acquired bacterial pneumonia or ventilator associated bacterial pneumonia caused by the following susceptible gram-negative microorganisms: Acinetobacter calcoaceticus-baumannii complex, Enterobacter cloacae, Escherichia coli, Haemophilus influenza, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, pneumoniae, Pseudomonas aeruginosa, and Serratia marcescens.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**WRITTEN BY OR IN CONSULTATION WITH A INFECTIOUS DISEASE PROVIDER

#### **Coverage Duration:2 WEEKS**

**Other Criteria**:DOCUMENTATION OF A CULTURE AND SENSITIVITY SHOWING THE PATIENT'S INFECTION IS NOT SUSCEPTIBLE TO PREFERRED ALTERNATIVE ANTIBIOTICS TREATMENTS OR A DOCUMENTED HISTORY OF PREVIOUS INTOLERANCE TO OR CONTRAINDICATION TO TWO OTHER ANTIBIOTICS SHOWN TO BE SUSCEPTIBLE ON THE CULTURE AND SENSITIVITY. Documentation of a therapeutic failure on imipenem-cilastin OR medical rationale of why imipenem-cilastin cannot be used.

Relistor

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**: MEDICAL RECORD DOCUMENTATION OF OPIOID INDUCED CONSTIPATION IN THOSE WITH ADVANCED ILLNESS RECEIVING PALLIATIVE CARE AND CONCURRENT USE OF OPIOID THERAPY OR FOR OPIOID INDUCED CONSTIPATION WITH CHRONIC NONCANCER PAIN, INCLUDING PATIENTS WITH CHRONIC PAIN RELATED TO PRIOR CANCER AND ITS TREATMENT AND CONCURRENT USE OF OPIOID THERAPY.

Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:FOR OPIOID INDUCED CONSTIPATION WITH ADAVANCED ILLNESS RECEIVING PALLIATIVE CARE: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO LACTULOSE AND POLYETHYLENE GLYCOL 3350. FOR OPIOID INDUCED CONSTIPATION WITH CHRONIC NONCANCER PAIN: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO LACTULOSE or POLYETHYLENE GLYCOL 3350 AND AMITIZA

#### REPATHA

#### Affected Drugs:

Repatha Repatha Pushtronex System Repatha SureClick

Off-Label Uses:N/A

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

**Required Medical Information:**Dx of either clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a hx of MI or unstable angina), coronary or other arterial revascularization, stroke, TIA, or PAD presumed to be of atherosclerotic origin OR primary hyperlipidemia, including Heterozygous familial hypercholesterolemia (HeFH). For HeFH one of the following: Genetic testing to confirm mutation in the LDL receptor, PCSK9, or ApoB gene or dx of definite HeFH (score greater than 8) on the diagnostic scoring system as defined by the ESC/EAS guidelines and the WHO OR Homozygous familial hypercholesterolemia (HoFH) with either: Genetic testing to confirm at least one LDL receptor-defective mutation or dx made based on history of an untreated LDL greater than 500 mg/dL with either xanthoma before 10 years of age or evidence of HeFH in both parents. Documentation of a LDL drawn within 3 months of the start of PCSK9 therapy showing an LDL greater than 100 if using Repatha for primary prevention OR an LDL greater than 70 if using Repatha for secondary prevention. Dx that Repatha is not being used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro. For statin tolerant patients, dx of an inability to achieve and maintain LDL goal with one of the following (1) max tolerated dose of a high intensity statin (atorvastatin 40 mg or higher or rosuvastatin 20 mg or higher) or (2) a max tolerated dose of any statin given that the patient has had a previous trial of either atorvastatin or rosuvastatin, with prescriber's documentation regarding length of previous trials of statins. Patient must intend to continue on maximal statin therapy once Repatha started. For statin intolerant patients documentation of reason for statin intolerance and in those with HoFH, dx of an inability to achieve and maintain LDL goal on at least 12 weeks on maximal lipid lowering therapy

# **Age Restrictions:**FOR ASCVD OR HEFH: MUST BE 18 YEARS OF AGE OR OLDER. FOR HOFH: MUST BE 13 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions: Cardiologist, endocrinologist or lipidologist

#### Coverage Duration:12 MONTHS

**Other Criteria:** If requesting syringe or sureclick dosing of 420 mg every 28 day: documentation of therapeutic failure on, intolerance to, or contraindication to use of Repatha Pushtronex. Therapeutic failure is defined as an inability to reach target LDL goals (less than 100 mg/dL for patients with HeFH

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or HoFH in primary prevention or less than 70 mg/dL for ASCVD or for patients with HeFH or HoFH using Repatha as secondary prevention) despite at least a 3 month trial. Intolerance to statins is defined as increased LFTs, intolerable myalgia (muscle symptoms without creatinine kinase (CK) elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms), which persist after two retrials with a different dose or different dosing strategy (every other day) of alternative moderate- or high-intensity statin. Contraindications to statins are defined as active liver disease, previous history of rhabdomyolysis, or hypersensitivity. Renewal criteria: Documentation of an up to date LDL cholesterol level since the previous review showing a clinically significant response to treatment AND documentation of no significant adverse events related to therapy AND documentation of still taking statin (if statin tolerant) AND documentation that Repatha continues to not be used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro.

Affected Drugs: Retevmo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of diagnosis of RET-fusion positive non-small cell lung cancer (NSCLC). Documentation of advanced metastatic RET-mutant medullary thyroid cancer (MTC) AND documentation that systemic therapy is required. Documentation of advanced or metastatic RET-fusion positive thyroid cancer AND documentation that systemic therapy is required AND documentation that patient radioactive-iodine refractory when radioactive iodine is appropriate.

Age Restrictions:NSCLC: 18 YEARS OR OLDER. THYROID CA: 12 YEARS OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### **REVATIO**

#### Affected Drugs:

Sildenafil Citrate

Off-Label Uses:N/A

Exclusion Criteria:CONCOMITANT USE OF ORGANIC NITRATES

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF FUNCTIONAL CLASS 2, 3, OR 4 PULMONARY ARTERIAL HYPERTENSION.

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

Revcovi

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

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

**Required Medical Information:**Documentation of a diagnosis of adenosine deaminase deficiencyassociated severe combined immune deficiency (ADA-SCID) confirmed by either a very low presence or absence of ADA (adenosine deaminase) activity in red blood cells or other samples AND an increase in adenosine, deoxyadenosine, and deoxyadenosine triphosphate (dATP) levels in red blood cells, plasma, or urine OR biallelic mutations in the ADA1 gene.

#### Age Restrictions:N/A

**Prescription Order Restrictions:**By or in consultation with an immunologist, geneticist, or a physician who specializes in inherited metabolic disorders

#### Coverage Duration:6 MONTHS

**Other Criteria:**If Adagen naive, documentation that dosing is based on ideal body weight. Reauthorization will require documentation of continued or sustained improvement in trough plasma ADA and dAXP levels while on therapy AND documentation of planned hematopoietic cell transplantation or gene therapy or documentation of not being a suitable candidate for hematopoietic cell transplantation and gene therapy at the time of the request Affected Drugs: Revlimid

Off-Label Uses:N/A

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

**Required Medical Information:**DX OF MULTIPLE MYELOMA. DX OF MYELODYSPLASTIC SYNDROMES (MDS) EITHER WITH A DELETION 5Q CYTOGENETIC ABNORMALITY WITH OR WITHOUT ADDITIONAL CYTOGENETIC ABNORMALITIES OR WITH NO DELETION 5Q CYTOGENETIC ABNORMALITY. DX OF RELAPSED, REFRACTORY, OR PROGRESSIVE MANTLE CELL LYMPHOMA WITH THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE PRIOR THERAPY INCLUDING BUT NOT LIMITED TO HYPERCVAD, NORDIC REGIMEN, CALGB REGIMEN, RCHOP/RICE, RCHOP/RDHAP, BENDAMUSTINE PLUS RITUXIMAB, CHOP PLUS RITUXIMAB, CLADRIBINE PLUS RITUXIMAB, CVP PLUS RITUXIMAB, EPOCH PLUS RITUXIMAB. DX OF FOLLICULAR LYMPHOMA OR MARGINAL ZONE LYMPHOMA, USED IN COMBINATION WITH RITUXIMAB, FOLLOWING THERAPEUTIC FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO AT LEAST 1 PRIOR THERAPY.

### Age Restrictions:N/A

### Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

### Coverage Duration:12 MONTHS

Other Criteria:FOR MDS WITH NO DELETION 5Q CYTOGENETIC ABNORMALITY: DOCUMENTATION OF INITIAL USE IN LOWER RISK PATIENT WITH SYMPTOMATIC ANEMIA AND SERUM ERYTHROPOIETIN LEVELS GREATER THAN 500 MU/ML AND A LOW PROBABILITY (DEFINED AS MEMBERS WHO LACK ANY OF THE FOLLOWING FEATURES: AGE LESS THAN OR EQUAL TO 60, OR THOSE WITH HYPOCELLULAR MARROW, HLA-DR 15 OR PHN CLONE POSITIVITY) OF RESPONSE TO IMMUNOSUPPRESSIVE THERAPY OR DOCUMENTATION OF LOWER RISK PATIENT WITH SYMPTOMATIC ANEMIA AND NO RESPONSE TO INITIAL TREATMENT WITH EPOETIN ALFA OR DARBOPOETIN ALFA, HYPOMETHYLATING AGENTS, OR IMMUNOSUPPRESSIVE THERAPY. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# REXULTI

# Affected Drugs:

Rexulti

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF SCHIZOPHRENIA OR ADJUNCTIVE TREATMENT FOR MAJOR DEPRESSIVE DISORDER (MDD).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria**:FOR MDD, DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST A 4 WEEK TRIAL OF COMBINATION THERAPY WITH ARIPIPRAZOLE AND AN ANTIDEPRESSANT AND EITHER DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST A 4 WEEK TRIAL OF COMBINATION ANTIDEPRESSANT THERAPY (SUCH AS AN SSRI AND BUPROPION OR AN SNRI AND BUPROPION) OR DOCUMENTATION OF THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST A 4 WEEK TRIAL OF AN ANTIDEPRESSANT WITH AUGMENTATION THERAPY (INCLUDING, BUT NOT LIMITED TO LITHIUM, VALPROATE, CARBAMAZEPINE AND LAMOTRIGINE). FOR SCHIZOPHRENIA, DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY MEDICATIONS ONE OF WHICH MUST BE ARIPIPRAZOLE (ARIPIPRAZOLE, OLANZAPINE, RISPERIDONE, QUETIAPINE IR, OR ZIPRASIDONE).

## REYVOW

# Affected Drugs:

Reyvow

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of use for the acute treatment of migraine with or without aura.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary triptans (e.g., almotriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan).

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# RINVOQ

# Affected Drugs:

Rinvoq

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of moderate to severe Rheumatoid Arthritis made in accordance with the American Colege of Rheumatology Criteria for the classification and diagnosis of RA.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: Rheumatologist

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**Documentation that medication is not being used concurrently with a TNF blocker or other biologic agent. For RA: Failure on, intolerance to, or contraindication to a minimum three month trial of methotrexate or other DMARD if methotrexate not tolerated or contraindicated. Reauthorization will require documentation showing maintenance or improvement of condition.

Rituxan Truxima

# Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RA AND DOCUMENTATION THAT METHOTREXATE WILL BE CONTINUED DURING RITUXIMAB THERAPY. DX OF CHRONIC LYMPHOID LEUKEMIA. DX OF MICROSCOPIC POLYARTERITIS NODOSA USED IN COMBO WITH GLUCOCORTICOIDS. DX OF DIFFUSE NON-HODGKINS LYMPHOMA. DX of Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis or Microscopic Polyangiitis (MPA) used in combination with glucocorticoids. DX OF CHRONIC ITP AND PLATELET COUNT OF LESS THAN 30,000/MICROL WITH ACTIVE BLEEDING OR PLATELET COUNT OF LESS THAN 20,000/MICROL WITH INCREASED RISK OF BLEEDING AND DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO CORTICOSTEROIDS AND IVIG. DX OF MULTIPLE SCLEROSIS. DX OF MODERATE TO SEVERE PEMPHIGUS VULGARIS (PV).

Age Restrictions: FOR RA AND PV: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: FOR RA: RHEUMATOLOGIST, FOR PV: DERMATOLOGIST

**Coverage Duration:**FOR RA AND ITP: 3 MONTHS. FOR CLL, NHL AND MS: INDEFINITE, ALL OTHER DIAGNOSES: 12 MONTHS

Other Criteria:DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: DOCUMENTATION OF AN INADEQUATE RESPONSE TO A MINIMUM 3 MONTH TRIAL OF (1) HUMIRA AND (2) RINVOQ ER OR XELJANZ. ONE COURSE OF THERAPY IS DEFINED AS TWO INFUSIONS GIVEN ON DAY 1 AND ANOTHER ON DAY 15. ADDITIONAL COURSES MAY BE CONSIDERED MEDICALLY NECESSARY IF AT LEAST 6 MONTHS HAS ELAPSED SINCE THE PREVIOUS TREATMENT COURSE AND DOCUMENTATION OF IMPROVEMENT. FOR PV: DOCUMENTATION OF A CONTRAINDICATION TO, INTOLERANCE OR THERAPEUTIC FAILURE ON CORTICOSTEROIDS and A 12-WEEK TRIAL OF AT LEAST ONE NONSTEROIDAL IMMUNOMODULATORY MEDICATION (i.e. AZATHIOPRINE, CYCLOPHOSPHAMIDE OR MYCOPHENOLATE)

Rituxan Hycela

### Off-Label Uses:N/A

# **Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of Chronic Lymphocytic Leukemia (CLL) given in combination with fludarabine and cyclophosphamide AND documentation of tolerating a minimum of one cycle of intravenous rituximab. Diagnosis of Diffuse Large B-Cell Lymphoma (DLBCL) AND documentation of no prior treatment for DLBCL AND documentation of being given in combination with cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP) or other anthracycline-based chemotherapy regimen AND documentation of tolerating a minimum of one cycle of intravenous rituximab. Diagnosis of Follicular Lymphoma (FL) AND documentation of tolerating a minimum of one cycle of intravenous rituximab.

### Age Restrictions:N/A

### Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

### Coverage Duration: 6 MONTHS INITIAL AND 12 MONTHS CONTINUATION

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

Affected Drugs: Rozlytrek

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of unresectable or metastatic solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation AND one of the following 1)documentation of progression following treatment or 2) documentation of no satisfactory alternative treatments. Diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive.

Age Restrictions: For NTRK positive tumors: 12 yrs or older. For NSCLC: 18 yrs or older

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs: Rubraca

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of deleterious BRCA mutation (germline or somatic) associated epithelial ovarian, fallopian tube, or primary peritoneal cancer as verified by an FDA approved test who have been treated with two or more chemotherapies OR for the maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer after a complete or partial response to platinum based chemotherapy. Diagnosis of deleterious BRCA mutation (germline or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) with documentation of prior treatment with androgen receptor-directed therapy and a taxane based chemotherapy.

### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**For mCRPC: documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently OR documentation of bilateral orchiectomy. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

Jakafi

Off-Label Uses:N/A

# **Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF INTERMEDIATE OR HIGH-RISK MYELOFIBROSIS, INCLUDING PRIMARY MYELOFIBROSIS, POST-POLYCYTHEMIA VERA MYELOFIBROSIS OR POST-ESSENTIAL THROMBOCYTHEMIA MYELOFIBROSIS AND PLATELET COUNT GREATER THAN OR EQUAL TO 50 X 10(9)/L AND SPLENOMEGALY AND BASELINE TOTAL SYMPTOM SCORE AS MEASURED BY THE MODIFIED MYELOFIBROSIS SYMPTOM ASSESSMENT FORM (MFSAF). DIAGNOSIS OF POLYCYTHEMIA VERA REQUIRING THE PRESENCE OF SPLENOMEGALY, AND MEMBER REQUIRES PHLEBOTOMY. DIAGNOSIS OF STEROID REFRACTORY ACUTE GRAFT-VERSUS-HOST DISEASE (GVHD).

### Age Restrictions:N/A

# Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

# Coverage Duration:6 MONTHS

Other Criteria:DOCUMENTATION THAT MEDICATION WILL NOT BE USED IN COMBINATION WITH ANOTHER JANUS KINASE INHIBITOR (i.e. fedratinib). FOR MYELOFIBROSIS: CONTINUED COVERAGE EVERY 6 MONTHS WILL REQUIRE MEDICAL RECORD DOCUMENTATION OF PLATELET COUNT GREATER THAN OR EQUAL TO 50 x 10(9)/L IF BASELINE COUNT WAS GREATER THAN 100 X 10(9)/L or GREATER THAN 25 X 10(9)/L IF BASELINE COUNT WAS BETWEEN 50 AND 100 X 10(9)/L, AND DOCUMENTATION OF RESPONSE TO THERAPY SUCH AS A REDUCTION FROM PRETREATMENT BASELINE SPLEEN VOLUME OR A REDUCTION IN THE TOTAL SYMPTOM SCORE FROM BASELINE AS MEASURED BY THE MODIFIED MYELOFIBROSIS SYMPTOM ASSESSMENT FORM (MFSAF). FOR POLYCYTHEMIA VERA DOCUMENTATION OF OF AN INADEQUATE RESPONSE OR INTOLERANCE TO EITHER HYDROXYUREA OR INTERFERON THERAPY OR DOCUMENTATION OF POST POLYCYTHEMIA VERA MYELOFIBROSIS WITH HYDROXYUREA REFRACTORY SYMPTOMATIC SPLENOMEGALY. REAUTHORIZATION FOR ACUTE GRAFT VERSUS HOST DISEASE AND POLYCYTHEMIA VERA WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

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Rybrevant

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) AND DOCUMENTATION OF EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 20 INSERTION MUTATATIONS AS DETERMINED BY AN FDA APPROVED TEST AND DOCUMENTATION OF DISEASE PROGRESSION ON OR FOLLOWING PRIOR TREATEMENT WITH A PLATINUM BASED THERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:6 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs: Rydapt

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of acute myeloid leukemia (AML) that is FLT3 mutation positive as detected by a Food and Drug Administration (FDA)-approved test used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation OR documentation of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS RENEWAL

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs: Rylaze

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of use as a component of a multi-agent chemotherapeutic regimen in patients with a diagnosis of actue lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL)

Age Restrictions:1 MONTH OF AGE OR OLDER

### Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Documentation of a hypersesitivity to E.Coli-derived asparaginase. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

# SABRIL

### Affected Drugs:

Sabril Vigabatrin Vigadrone

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DX OF REFRACTORY COMPLEX PARTIAL SEIZURES. DX OF INFANTILE SPASMS.

Age Restrictions: INFANTILE SPASMS - 1 MONTH TO 2 YEARS OF AGE

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FOR REFRACTORY COMPLEX PARTIAL SEIZURES MUST BE ON CONCOMMITANT THERAPY WITH ANOTHER SEIZURE CONTROL MEDICATION

# SAPHRIS

#### **Affected Drugs:**

Asenapine Maleate Saphris

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DX OF BIPOLAR DISORDER OR SCHIZOPHRENIA

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**MEDICAL RECORD DOCUMENTATION OF TRIAL ON TWO FORMULARY ALTERNATIVES (aripiprazole, ziprasidone, risperidone, quetiapine, olanzapine).

Affected Drugs: Sarclisa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of one of the following (1) diagnosis of multiple myeloma AND documentation of use in combination with pomalidomide and dexamethasone AND documentation of prior treatment with at least two therapies which included lenalidomide and a proteasome inhibitor (including but not limited to Velcade, Kyprolis or Ninlaro) OR (2) diagnosis of relapsed or refractory multiple myeloma AND documentation of use in combination with carfilzomib and dexamethasone AND documentation of prior treatment with one to three lines of therapy.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# SECUADO

Affected Drugs:

Secuado

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of schizophrenia

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria**:Medical record documentation of a therapeutic failure on, intolerance to or contraindication to asenapine (Saphris) sublingual tablets and one other formulary alternative (aripiprazole, ziprasidone, risperidone, quetiapine, olanzapine)

# SEROSTIM

Affected Drugs: Serostim

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**FOR THE TREATMENT OF HIV PATIENTS WITH WASTING OR CACHEXIA

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

# SIGNIFOR

# Affected Drugs:

Signifor

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF CUSHING'S DISEASE AND DOCUMENTATION THAT PITUITARY SURGERY IS NOT AN OPTION OR HAS NOT BEEN CURATIVE

Age Restrictions:N/A

#### Prescription Order Restrictions: ENDOCRINOLOGIST

**Coverage Duration:**6 MONTHS

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO KETOCONAZOLE AND METYRAPONE. REAUTHORIZATION REQUIRES DOCUMENTATION OF IMPROVEMENT IN URINARY FREE CORTISOL LEVELS COMPARED TO BASELINE

Signifor LAR

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF ACROMEGALY AND DOCUMENTATION OF AN INADEQUATE RESPONSE TO OR THE INABILITY TO BE TREATED WITH SURGERY OR RADIOTHERAPY. DOCUMENTATION OF A DIAGNOSIS OF CUSHING'S DISEASE and DOCUMENTATION THAT PITUITARY SURGERY IS NOT AN OPTION OR HAS NOT BEEN CURATIVE.

Age Restrictions:N/A

Prescription Order Restrictions: ENDOCRINOLOGIST

Coverage Duration:6 MONTHS

**Other Criteria:**FOR ACROMEGALY: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO OCTREOTIDE AND SOMATULINE DEPOT. REAUTHORIZATION REQUIRES IMPROVEMENT OF IGF-1 OR GH LEVELS. FOR CUSHING'S DISEASE: FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO KETOCONAZOLE AND METYRAPONE. REAUTHORIZATION WILL REQUIRE DOCUMENTATION THAT URINARY FREE CORTISOL LEVELS ARE WITHIN NORMAL LIMITS.

# SIKLOS

# Affected Drugs:

Siklos

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Documentation of a diagnosis of sickle cell anemia.

Age Restrictions:2 YEARS OF AGE OR OLDER

Prescription Order Restrictions: by or in consultation with a hematologist

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of a therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of generic hydroxyurea

Affected Drugs: Simponi

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information:DX OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSICIATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS AND BEING USED IN CONJUNCTION WITH METHOTREXATE. DX OF ACTIVE PSORIATIC ARTHRITIS AND DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS OR A DOCUMENTED HISTORY OF PSORIASIS AND PRESCRIPTION IS NOT WRITTEN FOR SIMPONI ARIA (IV FORMULATION). DX OF ANKYLOSING SPONDYLITIS AND PRESCRIPTION IS NOT WRITTEN FOR SIMPONI ARIA (IV FORMULATION). DX OF MODERATE TO SEVERE ULCERATIVE COLITIS AND PRESCRIPTION IS NOT WRITTEN FOR SIMPONI ARIA (IV FORMULATION).

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**RHEUMATOLOGIST, GASTROENTEROLOGIST, DERMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF (1) HUMIRA AND (2) RINVOQ ER OR XELJANZ. FOR ANKYLOSING SPONDYLITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA AND COSENTYX. FOR PSORIATIC ARTHRITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX, OR XELJANZ. FOR ULCERATIVE COLITIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA AND XELJANZ. FOR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA AND XELJANZ. FOR CONTINUED THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

Sirturo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF RESISTANCE TO ISONIAZID AND RIFAMPIN AND DOCUMENTATION THAT AN EFFECTIVE TREATMENT REGIMEN CANNOT BE ATTAINED WITH OTHER AVAILABLE TREATMENT OPTIONS AND DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH AT LEAST THREE OTHER DRUGS TO WHICH THE PATIENT'S MULTI DRUG RESISTANT TB ISOLATE HAS BEEN SHOWN TO BE SUSCEPTIBLE IN VITRO

Age Restrictions:N/A

Prescription Order Restrictions: INFECTIOUS DISEASE SPECIALIST

Coverage Duration:24 WEEKS

**Other Criteria:**IF IN VITRO TESTING RESULTS ARE UNAVAILABLE, DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH AT LEAST 4 OTHER DRUGS TO WHICH THE PATIENTS MDR-TB ISOLATE IS LIKELY TO BE SUSCEPTIBLE

Sivextro

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**: DIAGNOSIS OF AN ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION (INCLUDING CELLULITIS/ERYSIPELAS, WOUND INFECTION, AND MAJOR CUTANEOUS ABSCESS) CAUSED BY STAPHYLOCOCCUS AUREUS, STREPTOCOCCUS PYOGENES, STREPTOCOCCUS AGALACTIAE, STREPTOCOCCUS ANGINOSUS, STREPTOCOCCUS INTERMEDIUS, STREPTOCOCCUS CONSTELLATUS, OR ENTEROCOCCUS FAECALIS

Age Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**DIAGNOSED AND DOCUMENTED WITH INFECTIOUS DISEASE CONSULTATION

Coverage Duration: ONE-TIME COURSE OF THERAPY OF 6 DAYS

**Other Criteria**:DOCUMENTATION OF A CULTURE AND SENSITIVITY SHOWING THE PATIENT'S INFECTION IS NOT SUSCEPTIBLE TO ALTERNATIVE ANTIBIOTICS TREATMENTS OR A DOCUMENTED HISTORY OF PREVIOUS INTOLERANCE TO OR CONTRAINDICATION TO TWO OTHER ANTIBIOTICS SHOWN TO BE SUSCEPTIBLE ON THE CULTURE AND SENSITIVITY.

Skyrizi Skyrizi (150 MG Dose) Skyrizi Pen

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Diagnosis of moderate to severe plaque psoriasis with at least 5% BSA or disease affecting crucial body areas such as hands, feet, face or genitals.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: Dermatologist

# Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**For Psoriasis: failure on, intolerance to, or contraindication to one formulary topical corticosteroid and at least 3 months of one systemic therapy including but not limited to methotrexate or cyclosporine or phototherapy. Documentation that medication is not being used concurrently with a TNF blocker or other biologic agent. Reauthorizations will require documentation of continued disease improvement or lack of disease progression

# **SLEEPERS HRM**

#### Affected Drugs:

Eszopiclone Zaleplon Zolpidem Tartrate Zolpidem Tartrate ER

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**PRIOR AUTHORIZATION APPLIES ONLY TO MEMBERS 65 YEARS OF AGE AND OLDER WHO WILL BE EVALUATED FOR APPROPRIATE USE OF HIGH RISK MEDICATION. DOCUMENTATION OF FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO RAMELTEON (GENERIC ROZEREM) AND DOXEPIN (GENERIC SILENOR).

## SORIATANE

Affected Drugs:

Acitretin

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF SEVERE PSORIASIS WITH AT LEAST 5% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE OR GENITALS

Age Restrictions:N/A

Prescription Order Restrictions: DERMATOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE TOPICAL CORTICOSTEROID AND AT LEAST 2 TO 3 MONTHS OF METHOTREXATE OR PHOTOTHERAPY.

Spravato (56 MG Dose) Spravato (84 MG Dose)

# Off-Label Uses:N/A

# Exclusion Criteria:N/A

**Required Medical Information:**Diagnosis of treatment-resistant major depression disorder (MDD). Documentation of baseline depression status using an appropriate rating scale (such as PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D). Documentation of major depression disorder AND documentation of a recent hospital admission (within 4 weeks) due to depressive symptoms with acute suicidal ideation and behavior.

# Age Restrictions: MUST BE 18 YEARS OR OLDER

### Prescription Order Restrictions:N/A

# Coverage Duration: 1 MONTH INITIAL, 12 MONTHS CONTINUATION. MDD with SI: 1 MONTH

**Other Criteria**:Documentation that significant drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary about the risks associated with the use of both medications when they interact). For treatment resistant MDD: Documentation of therapeutic failure on, intolerance to or contraindication to olanzapine/fluoxetine capsules. Documentation that medication will be used in combination with a newly initiated antidepressant. Treatment-resistant depression as defined by failure of at least two antidepressants from two different classes at an optimized dose for at least 6 weeks. Reauthorization will require documentation of clinical improvement in depression symptoms as measured by an appropriate rating scale (compared to previous measurement). For MDD with SI: documentation that dosing does not exceed FDA approved treatment duration of 4 weeks OR that therapy was initiated as an inpatient. MDD with SI Reauthorization beyond FDA treatment duration will require documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the members healthcare outcome will be improved by dosing beyond the FDA approved treatment duration.

# SPRYCEL

# Affected Drugs:

Sprycel

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF NEWLY DIAGNOSED CHRONIC PHASE CML or DX OF CHRONIC, ACCELERATED, OR MYELOID/LYMPHOID BLAST PHASE Ph+ CML or DX OF Ph+ ALL

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**FOR CHRONIC, ACCELERATED OR BLASTIC PHASE Ph+ CML -DOCUMENTATION OF RESISTANCE OR INTOLERANCE TO ONE PRIOR THERAPY, INCLUDING IMATINIB. FOR PH+ ALL - DOCUMENTATION OF RESISTANCE OR INTOLERANCE TO ONE PRIOR THERAPY or DOCUMENTATION OF USE TO TREAT NEWLY DIAGNOSED Ph+ ALL IN PEDIATRIC PATIENTS IN COMBINATION WITH CHEMOTHERAPY. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Stelara

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF MODERATE TO SEVERE PLAQUE PSORIASIS WITH AT LEAST 5% BSA OR AFFECTING CRUCIAL BODY AREAS SUCH AS HANDS, FEET, FACE OR GENITALS. DX OF ACTIVE PSORIATIC ARTHRITIS WITH DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS OR A DOCUMENTED HISTORY OF PSORIASIS. DX OF MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE. Diagnosis of moderately to severely active ulcerative colitis.

**Age Restrictions:**FOR PLAQUE PSORIASIS: MUST BE 6 YEARS OF AGE OR OLDER, ALL OTHERS: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**DERMATOLOGIST, RHEUMATOLOGIST OR GASTROENTEROLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR PSORIASIS: DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX, OR SKYRIZI. FOR PSORIATRIC ARTHRITIS: DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING: HUMIRA, COSENTYX, OR XELJANZ. FOR PEDIATRIC PLAQUE PSORIASIS (6 TO 18 YEARS OF AGE): DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO TOPICAL CORTICOSTEROIDS. FOR CROHNS DISEASE, DOCUMENTATION OF AN INTOLERANCE TO, CONTRAINDICATION TO, OR THERAPEUTIC FAILURE ON A MINIMUM 3 MONTH TRIAL OF TWO OF THE FOLLOWING (HUMIRA, CIMZIA, ENTYVIO, INFLIXIMAB OR TYSABRI). FOR ULCERATIVE COLITIS, DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA AND XELJANZ. FOR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA AND XELJANZ. FOR MINIMURD THERAPY, MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

Stivarga

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF METASTATIC COLORECTAL CANCER OR DOCUMENTATION OF LOCALLY ADVANCED, UNRESTECTABLE OR METASTATIC GASTROINTESTINAL STROMAL TUMOR (GIST). DOCUMENTATION OF HEPATOCELLULAR CARCINOMA WITH FAILURE ON, INTOLERANCE TO OR CONTRAINDICATION TO SORAFENIB.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**FOR METASTATIC COLORECTAL CANCER: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO THREE OF THE FOLLOWING PRIOR THERAPIES (BASED ON CLINICAL TRIAL DESIGN) - FLUOROPYRIMIDINE BASED CHEMO, OXALIPLATIN BASED CHEMO, IRINOTECAN BASED CHEMO, ANTI-VEGF THERAPY (BEVACIZUMAB) OR IF KRAS WILD TYPE AN ANTI-EGFR THERAPY (CETUXIMAB OR PANITUMUMAB). FOR GIST: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO IMATINIB MESYLATE (GLEEVEC) AND SUNITINIB MALATE (SUTENT). REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# STRATTERA

#### **Affected Drugs:**

Atomoxetine HCI

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF ADD/ADHD

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

# STRENSIQ

Affected Drugs:

Strensiq

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**:DOCUMENTATION OF A DIAGNOSIS OF PERINATAL- OR INFANTILE- OR JUVENILE-ONSET HYPOPHOSPHATASIA (HPP) and DOCUMENTATION OF LOW TOTAL SERUM ALKALINE PHOSPHATASE ACTIVITY and DOCUMENTATION THAT MEMBER WILL RECEIVE A WEIGHT AND DIAGNOSIS APPROPRIATE DOSING REGIMEN

Age Restrictions:N/A

**Prescription Order Restrictions:**ENDOCRINOLOGIST, GENETICIST OR METABOLIC SPECIALIST

Coverage Duration: 3 MONTH INITIAL AND 12 MONTH CONTINUATION

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 3 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

glyBURIDE glyBURIDE Micronized glyBURIDE-metFORMIN

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**PRIOR AUTHORIZATION APPLIES ONLY TO MEMBERS 65 YEARS OF AGE AND OLDER WHO WILL BE EVALUATED FOR APPROPRIATE USE OF HIGH RISK MEDICATION AND WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO GLIPIZIDE

# SUNOSI

# Affected Drugs:

Sunosi

Off-Label Uses:N/A

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

**Required Medical Information:**Diagnosis of excessive daytime sleepiness associated with either narcolepsy or obstructive sleep apnea.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

### Prescription Order Restrictions:N/A

### Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**For sleepiness associated with narcolepsy: documentation of therapeutic failure on, intolerance to, or contraindication to either modafinil or armodafinil AND methylphenidate IR or amphetamine-dextroamphetamine IR. For sleepiness associated with obstructive sleep apnea: documentation that underlying airway obstruction has been treated for at least one month prior to initiation of therapy, and will continue to be treated AND documentation of a therapeutic failure on, intolerance to, or contraindication to modafinil or armodafinil.

# **SUPPRELIN LA**

#### Affected Drugs:

Supprelin LA

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information:DX OF CENTRAL PRECOCIOUS PUBERTY

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO LUPRON DEPOT-PED

# SUTENT

#### **Affected Drugs:**

SUNItinib Malate Sutent

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

Exclusion Criteria:N/A

**Required Medical Information:**DX OF GASTROINTESTINAL STROMAL TUMOR (GIST). DX OF PROGRESSIVE, WELL-DIFFERENTIATED PANCREATIC NEUROENDOCRINE TUMORS (pNET) WITH UNRESECTABLE LOCALLY ADVANCED OR METASTATIC DISEASE. DX OF ADVANCED RENAL CELL CARCINOMA. DX OF ADJUVANT TREATMENT OF RENAL CELL CARCINOMA WITH HIGH RISK OF RECURRENT DISEASE FOLLOWING NEPHRECTOMY.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**FOR GASTROINTESTINAL STROMAL TUMOR THERE MUST BE A FAILURE ON, CONTRAINDICATION TO, OR INTOLERANCE TO IMATINIB. SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## SYLATRON

Affected Drugs: Sylatron

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF MELANOMA WITH MICROSCOPIC OR GROSS NODAL INVOLVEMENT WITHIN 84 DAYS OF DEFINITIVE SURGICAL RESECTION INCLUDING COMPLETE LYMPHADENECTOMY

Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST OR DERMATOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

## SYLVANT

#### Affected Drugs:

Sylvant

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DIAGNOSIS OF MULTICENTRIC CASTLEMAN DISEASE

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

**Coverage Duration:**6 MONTHS

Other Criteria:DOCUMENTATION THAT PATIENT IS HIV AND HHV-8 NEGATIVE AND DOCUMENTATION OF ANC GREATER THAN 1 X 100000000 (10 TO THE 9TH POWER) / L AND PLATELETS GREATER THAN 75 X 1000000000 (10 TO THE 9TH POWER) / L AND HGB LESS THAN 17 G/DL. SUBSEQUENT APPROVAL AFTER 6 MONTHS WILL REQUIRE DOCUMENTATION OF NO DISEASE PROGRESSION AND THE FOLLOWING CRITERIA, ANC GREATER THAN 1 X 100000000 (10 TO THE 9TH POWER) / L AND PLATELETS GREATER THAN 50 X 100000000 (10 TO THE 9TH POWER) / L AND HGB LESS THAN 17 G/DL. Affected Drugs: Symdeko

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of cystic fibrosis AND documentation as evidenced by an FDA cleared CF mutation test of at least one mutation in CFTR gene that is responsive to tezacaftor/ivacaftor per product labeling OR documentation that the member is homozygous for the F508del CFTR mutation.

Age Restrictions: MUST BE 6 YEARS OF AGE OR OLDER

Prescription Order Restrictions: PULMONOLOGIST OR CYSTIC FIBROSIS SPECIALIST

Coverage Duration: 4 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**Reauthorization will require documentation of improvement or stabilization in the signs of symptoms of cystic fibrosis.

## SYMLIN

#### Affected Drugs:

SymlinPen 120 SymlinPen 60

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**MEDICAL RECORD DOCUMENTATION OF USE AS AN ADJUNCT TREATMENT IN PATIENT'S WHO USE MEALTIME INSULIN THERAPY.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE TO ACHIEVE DESIRED CONTROL DESPITE OPTIMAL MEALTIME INSULIN THERAPY, WHICH MAY BE WITH OR WITHOUT A CONCURRENT SULFONYLUREA AND/OR METFORMIN FOR THOSE WITH TYPE 2 DM

GHP Medicare Formulary - Prior Authorization Criteria

## SYMPAZAN

#### Affected Drugs:

Sympazan

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

## Required Medical Information: DX OF LENNOX-GASTAUT SYNDROME

Age Restrictions:N/A

Prescription Order Restrictions:NEUROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of a therapeutic failure on, intolerance to, or contraindication to at least two prior anti-epileptic therapies for the treatment of Lennox-Gastaust, one of which must be clobazam tablets or solution

Synagis

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**PROPHYAXIS OF SERIOUS LOWER RESPIRATORY TRACT DISEASE CAUSED BY RESPIRATORY SYNCYTIAL VIRUS (RSV) IN PEDIATRIC PATIENTS AT HIGH RISK, INCLUDING THOSE WITH BRONCHOPULMONARY DYSPLASIA OR COGENITAL HEART DISEASE, AND THOSE BORN PREMATURELY.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

**Coverage Duration:5 MONTHS** 

**Other Criteria:**N/A

## SYNERCID

Affected Drugs: Synercid

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS CAUSED BY STREPTOCOCCUS PYOGENES OR METHICILLIN-SENSITIVE STAPHYLOCOCCUS AUREUS.

Age Restrictions:N/A

**Prescription Order Restrictions:**INFECTIOUS DISEASE SPECIALIST OR UPON CONSULT FROM INFECTIOUS DISEASE SPECIALIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**N/A

## **SYNRIBO**

## Affected Drugs:

Synribo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF CHRONIC OR ACCELERATED PHASE CHRONIC MYELOID LEUKEMIA (CML)

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO OR MORE TYROSINE KINASE INHIBITORS (GLEEVEC, SPRYCEL, TASIGNA, BOSULIF). REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

GHP Medicare Formulary - Prior Authorization Criteria

## SYPRINE

Affected Drugs:

Trientine HCI

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DIAGNOSIS OF WILSON DISEASE

Age Restrictions: MUST BE 6 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria**:Documentation of a therapeutic failure on, intolerance to or contraindication to penicillamine

## TABRECTA

# Affected Drugs:

Tabrecta

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## **TAFAMIDIS MEGLUMINE**

## Affected Drugs:

Vyndamax Vyndaqel

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Diagnosis of cardiomyopathy resulting from wild type transthyretinmediated amyloidosis OR hereditary transthyretin-mediated amyloidosis as confirmed by ONE of the following: 1) bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD or 2) biopsy of tissue of the affected organ to confirm amyloid presence and chemical typing to confirm presence of transthyretin (TTR) protein.

## Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: by or in consultation with a cardiologist

#### Coverage Duration:12 MONTHS

**Other Criteria:**Documentation of NYHA Class I, II, or III heart failure. Reauthorizations will require prescriber attestation that the patient continues to benefit from tafamidis therapy AND no documenTation of NYHA class IV heart failure.

Tafinlar

## Off-Label Uses:N/A

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

**Required Medical Information:**Diagnosis of unresectable or metastatic melanoma with one of the following: documentation for use as single therapy OR documentation of use in combination with Mekinist (trametinib). Documentation of BRAF V600E or V600K mutation as detected by an FDA approved test. Diagnosis of metastatic non-small cell lung cancer with concomitant use of Mekinist AND documentation of BRAF V600E mutation as detected by an FDA-approved test. Diagnosis of use for adjuvant treatment of melanoma with involvement of lymph nodes following complete resection AND documentation of concurrent use Mekinist (trametinib) AND documentation of BRAF V600E or V600K mutation of BRAF V600E or Mekinist (trametinib) AND documentation of BRAF V600E or V600K mutation. Diagnosis of locally advanced or metastatic anaplastic thyroid cancer AND documentation of concurrent use of Mekinist (trametinib) AND documentation of BRAF V600E mutation.

Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST OR HEMATOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Effective 12/2021

Tagrisso

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

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF METASTATIC EGFR T790M MUTATION POSITIVE NON SMALL CELL LUNG CANCER AS DETECTED BY AN FDA APPROVED TEST with DOCUMENTATION OF FAILURE ON OR INTOLERANCE TO PRIOR TYROSINE KINASE INHBITOR THERAPY (IRESSA, GILOTRIF, OR TARCEVA). DOCUMENTATION OF USE AS FIRST LINE THERAPY FOR METASTATIC NON-SMALL CELL LUNG CANCER WITH EGFR EXON 19 DELETION OR EXON 21 L858R MUTATION AS DETECTED BY AN FDA APPROVED TEST. DOCUMENTATION OF ADJUVANT TREAMENT FOLLOWING COMPLETE TUMOR RESECTION OF NON-SMALL CELL LUNG CANCER WITH EGFR EXON 19 DELETION OR EXON 21 L858R MUTATION AS DETECTED BY AN FDA APPROVED TEST.

#### Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

#### Coverage Duration:12 MONTHS

Other Criteria:SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. ADJUVANT TREATMENT OF NON-SMALL CELL LUNG CANCER BEYOND 3 YEARS WILL REQUIRE DOCUMENTATION THAT THE MEMBERS HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA APPROVED TREATMENT DURATION.

Takhzyro

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DX OF HEREDITARY ANGIOEDEMA and FOR HAE TYPE I AND TYPE II: THE PRESENCE OF SPECIFIC ABNORMALITIES IN COMPLEMENT PROTEINS IN THE SETTING OF A SUGGESTIVE CLINICAL HISTORY OF EPISODIC ANGIOEDMEA WITHOUT URTICARIA SUPPORTED BY DOCUMENTATION OF LOW C4 LEVELS AND LESS THAN 60 PERCENT OF THE LOWER LIMIT OF NORMAL C1-INH ANTIGENIC PROTEIN LEVELS OR FUNCTION LEVELS

Age Restrictions: MUST BE 12 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**ALLERGIST, IMMUNOLOGIST, HEMATOLOGIST OR DERMATOLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**DOCUMENTATION THAT MEDICATION IS BEING USED AS PROPHYLACTIC THERAPY. REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

## TALZENNA

Affected Drugs:

Talzenna

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of deleterious or suspected deleterious germline BRCAmutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer as verified by an FDA approved test

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorization will require documentation of continued disease improvement or lack of disease progression.

Erlotinib HCl

## Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DOCUMENTATION OF METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH ONE OF THE FOLLOWING: USED AS FIRST LINE TREATMENT or MAINTENANCE TREATMENT or SECOND LINE OR GREATER TREATMENT AFTER PROGRESSION ON AT LEAST ONE PRIOR CHEMOTHERAPY REGIMEN. DOCUMENTATION OF ONE OF THE FOLLOWING EGFR MUTATIONS AS DETECTED BY AN FDA APPROVED TEST: EXON 19 DELETION OR EXON 21 (L858R) SUBSTITUTION. DOCUMENTATION OF LOCALLY ADVANCED, UNRESECTABLE OR METASTASIZED PANCREATIC CANCER IN COMBO THERAPY WITH GEMCITABINE.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Tasigna

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF NEWLY DIAGNOSED (NOT PREVIOUSLY TREATED) CHRONIC PHASE PH+ CML. DIAGNOSIS OF ADULT CHRONIC OR ACCELERATED PHASE PH+ CML IN PATIENT'S RESISTENT TO, OR INTOLERANT TO PRIOR THERAPY INCLUDING GLEEVEC. DIAGNOSIS OF CHRONIC PHASE PH+ CML IN PEDIATRIC PATIENT'S RESISTENT TO, OR INTOLERANT TO PRIOR TYROSINE KINASE INHIBITOR THERAPY

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## TAVALISSE

Affected Drugs: Tavalisse

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of chronic immune thrombocytopenia AND documentation of a platelet count less than 30,000/microL.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: By or in consultation with a hematologist

Coverage Duration: 3 MONTHS INITIAL, 12 MONTHS CONTINUATION

**Other Criteria**:Documentation of a therapeutic failure on, intolerance to, or contraindication to two of the following: corticosteroids, IVIG, Rhogam (if RhD-positive and spleen intact), Rituximab, splenectomy, eltrombopag olamine or romiplostim. Subsequent approval after 3 months will require documentation of medical necessity such as a platelet count necessary to reduce the risk for bleeding.

## TAZORAC

#### Affected Drugs:

Tazorac

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF ACNE, ACNE VULGARIS, ADULT ONSET ACNE, OR PLAQUE PSORIASIS

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FOR ACNE: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY TOPICAL RETINOIDS, INCLUDING BUT NOT LIMITED TO ADAPALENE AND TRETINOIN. FOR PSORIASIS: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE TOPICAL CORTICOSTEROID AND AT LEAST 2 TO 3 MONTHS OF METHOTREXATE OR PHOTOTHERAPY.

GHP Medicare Formulary - Prior Authorization Criteria

Tazverik

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of metastatic or locally advanced epithelioid sarcoma AND documentation that member is not eligible for complete resection. Diagnosis of relapsed or refractory follicular lymphoma with documentation of one of the following: 1)documentation of an EZH2 mutation as detected by an FDA approved test with documentation of trial of at least two prior systemic therapies OR 2)documentation of no satisfactory alternative treatment options.

Age Restrictions: SARCOMA: 16 YRS OR OLDER. LYMPHOMA: 18 YRS OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

## **TCA HRM**

Affected Drugs: Amitriptyline HCl Amoxapine chlordiazePOXIDE-Amitriptyline Doxepin HCl Imipramine HCl Imipramine Pamoate Nortriptyline HCl Perphenazine-Amitriptyline Protriptyline HCl Trimipramine Maleate

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**PRIOR AUTHORIZATION APPLIES ONLY TO MEMBERS 65 YEARS OF AGE AND OLDER WHO WILL BE EVALUATED FOR APPROPRIATE USE OF HIGH RISK MEDICATION AND WILL REQUIRE DOCUMENTATION OF AN FDA LABELED INDICATION AND DOCUMENTATION THAT THE PRESCRIBER HAS INDICATED THAT THE BENEFITS OF THE REQUESTED HIGH RISK MEDICATION OUTWEIGHS THE RISKS FOR THE PATIENT AND DOCUMENTATION THAT THE PROVIDER DISCUSSED THESE RISKS AND POTENTIAL SIDE EFFECTS OF THE REQUESTED HIGH RISK MEDICATION WITH THE PATIENT.

## **TECENTRIQ**

Affected Drugs: Tecentriq

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

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

Required Medical Information: Dx of locally advanced or metastatic urothelial carcinoma AND one of the following: patient is not eligible for cisplatin-containing chemotherapy and tumors express PDL1 (greater than or equal to 5%) as determined by an FDA-approved test OR patient is not eligible for any platinum containing chemotherapy (regardless of PDL1 status). Dx of metastatic non small cell lung cancer meeting one of the following: disease progression during or following platinum containing chemotherapy OR progression on at least one FDA approved therapy targeting EGFR or ALK if the patient has EGFR or ALK genomic tumor aberrations OR documentation of non-squamous histologic subtype used as first line in combination with either 1)bevacizumab, paclitaxel and carboplatin or 2) paclitaxel protein-bound and carboplatin with no EGFR or ALK genomic tumor aberrations OR as first line treatment for metastatic disease with high PD-L1 expression (PD-L1 stained tumor cells of at least 50% or PD-L1 stained tumor infiltrating immune cells covering 10% or more of the tumor area as determined by an FDA approved test) AND documentation of no EGFR or ALK genomic tumor aberrations. Dx of use as first line treatment for extensive stage small cell lung cancer (ES-SCLC) AND documentation of use in combination with carboplatin and etoposide. Dx of unresectable or metastatic hepatocellular carcinoma (HCC) used in combination with bevacizumab AND documentation of no prior systemic treatment for HCC. Dx of unresectable or metastatic melanoma with documentation of BRAF V600 mutation as determined by an FDA approved test AND documentation of use in combination with cobimetinib and vemurafenib.

#### Age Restrictions:N/A

#### Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

Tegsedi

## Off-Label Uses:N/A

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

**Required Medical Information:**Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) as confirmed by genetic testing to confirm a pathogenic mutation in TTR AND documentation of either biopsy of tissue or organ to confirm amyloid presence OR a clinical manifestation typical of hATTR (such as neuropathy or CHF) without a better alternative explanation. Documentation of medication being used to treat polyneuropathy. Documentation of familial amyloid polyneuropathy (FAP) stage 1-2 OR polyneuropathy disability score indicating the patient is not wheelchair bound or bedridden.

## Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**Neurologist, geneticist, or specialist with experience treating hATTR

#### Coverage Duration:12 MONTHS

**Other Criteria:**Documentation that medication will not be used in combination with other RNA interference treatments. Reauthorization will require medical necessity and no documentation of FAP stage 3 OR polyneuropathy disability score indicating the patient is wheelchair-bound or bedridden.

Tepezza

Off-Label Uses:N/A

## Exclusion Criteria:N/A

**Required Medical Information:**Documentation of a diagnosis of Grave's disease AND documentation of moderate to severe thyroid eye disease with documentation of one or more of the following: 1)lid retraction of greater than or equal to 2 mm 2) moderate or severe soft-tissue involvement 3) proptosis greater than or equal to 3 mm above normal values for race and sex, 4) periodic or constant diplopia

## Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

## Prescription Order Restrictions: OPHTHALMOLOGIST

## Coverage Duration:6 MONTHS

**Other Criteria:**Documentation that member is euthyroid or has mild hypo- or hyperthyroidism (free T4 and free T3 levels less than 50% above or below normal limits prior to starting Tepezza therapy. Documentation of being prescribed an appropriate dose and duration of Tepezza per product labeling. Documentation of therapeutic failure on, intolerance to, or contraindication to systemic steroids. Requests for authorizations exceeding 8 total doses will require documentation of peer-reviewed literature citing well-designed clinical trials indicating that the member's healthcare outcome will be improved by dosing beyond the FDA approved treatment duration.

## **TEPMETKO**

Affected Drugs: Tepmetko

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Thioridazine HCI

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**N/A

Age Restrictions: ONLY APPLIES TO MEMBERS 65 YEARS OF AGE AND OLDER

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**PRIOR AUTHORIZATION APPLIES ONLY TO MEMBERS 65 YEARS OF AGE AND OLDER WHO WILL BE EVALUATED FOR APPROPRIATE USE OF HIGH RISK MEDICATION AND WILL REQUIRE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TWO FORMULARY ATYPICAL ANTIPSYCHOTICS (OLANZAPINE, RISPERIDONE, QUETIAPINE, ZIPRASIDONE, ARIPIPRAZOLE)

Tibsovo

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**1)Diagnosis of relapsed or refractory acute myeloid leukemia with documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by and FDA approved test OR 2)Diagnosis of newly diagnosed acute myeloid leukemia in members greater than or equal to 75 years of age or in those with comorbidities that preclude the use of intensive induction chemotherapy AND documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by and FDA approved test

## Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

## Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

## Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression

## TIGLUTIK

## Affected Drugs:

Tiglutik

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of ALS (amyotrophic lateral sclerosis)

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: BY OR IN CONSULTATION WITH A NEUROLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of a therapeutic failure on, intolerance to, or contraindication to riluzole tablets OR documentation that the patient has dysphagia or is unable to swallow tablets.

## TOBI

## Affected Drugs:

Tobi Podhaler

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF CYSTIC FIBROSIS

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

## **TOBRAMYCIN NEB**

## Affected Drugs:

Tobramycin

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information:DX OF CYSTIC FIBROSIS

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR INFECTIOUS DISEASE SPECIALIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

## TORISEL

## Affected Drugs:

Temsirolimus

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information:DX OF ADVANCED RENAL CELL CARCINOMA

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

## TRACLEER

#### Affected Drugs:

Bosentan Tracleer

Off-Label Uses:N/A

Exclusion Criteria:N/A

# **Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF FUNCTIONAL CLASS 2, 3, OR 4 PULMONARY ARTERIAL HYPERTENSION

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

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## TRETINOIN

#### Affected Drugs:

Avita Tretinoin Tretinoin Microsphere Tretinoin Microsphere Pump

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF ACNE, ACNE VULGARIS, OR ADULT ONSET ACNE

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

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Affected Drugs: Trikafta

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of cystic fibrosis AND documentation of at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as determined by an FDA-cleared cystic fibrosis mutation test.

Age Restrictions: MUST BE 6 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**By or in consultation with a pulmonologist or physician who specializes in the treatment of CF

Coverage Duration: 4 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria:**REAUTHORIZATION WILL REQUIRE DOCUMENTATION OF IMPROVEMENT OR STABILIZATION IN THE SIGNS AND SYMPTOMS OF CYSTIC FIBROSIS.

## TRIPTODUR

Affected Drugs:

Triptodur

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: Diagnosis of central precocious puberty

Age Restrictions:N/A

Prescription Order Restrictions: BY OR IN CONSULTATION WITH ENDOCRINOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of a therapeutic failure on, intolerance to, or contraindication to Lupron Depot-Ped

Trodelvy

## Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF DIAGNOSIS OF UNRESECTABLE LOCALLY ADVANCED OR METASTATIC TRIPLE NEGATIVE BREAST CANCER WITH DOCUMENTATION OF TRIAL OF AT LEAST TWO PREVIOUS LINES OF SYSTEMIC THERAPY, OR WHICH AT LEAST ONE WAS FOR METASTATIC DISEASE. DOCUMENTATION OF DIAGNOSIS OF LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER AND DOCUMENTATION OF PROGRESSION ON PLATINUM-CONTAINING CHEMOTHERAPY AND DOCUMENTATION OF PROGRESSION ON A PROGRAMMED DEATH RECEPTOR-1 (PD-1) OR PROGRAMMED DEATH-LIGAND 1 (PDL1) INHIBITOR.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

**Coverage Duration:**6 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### **TROKENDI XR**

#### Affected Drugs:

Trokendi XR

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF PARTIAL ONSET SEIZURES, PRIMARY GENERALIZED TONIC CLONIC SEIZURES, OR LENNOX GASTAUT SYNDROME or DIAGNOSIS OF MIGRAINE PROPHYLAXIS

**Age Restrictions:**12 YEARS OR OLDER FOR MIGRAINE PROPHYLAXIS, 6 YEARS OF AGE OR OLDER FOR OTHER INDICATIONS

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TOPIRAMATE ER.

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### TRUSELTIQ

#### **Affected Drugs:**

Truseltiq (100MG Daily Dose) Truseltiq (125MG Daily Dose) Truseltiq (50MG Daily Dose) Truseltiq (75MG Daily Dose)

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of unresectable locally advanced or metastatic cholangiocarcinoma AND documentation of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as verified by an FDA approved test AND documentation of trial of one prior line of therapy

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 months

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## TUKYSA

# Affected Drugs:

Tukysa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of advanced unresectable or metastatic HER2positive breast cancer, including those with brain metastases AND documentation of prior treatment with at least one anti-HER2 based regimen in the metastatic setting.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Documentation that medication will be given in combination with trastuzumab and capecitabine. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

## TURALIO

# Affected Drugs:

Turalio

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of tenosynovial giant cell tumor that meets both of the following criteria 1) associated with functional limitations or severe morbidity and 2) that condition is not amenable to improvement with surgery.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## TYKERB

#### **Affected Drugs:**

Lapatinib Ditosylate Tykerb

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DOCUMENTATION OF USE IN COMBINATION WITH LETROZOLE FOR THE TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR-POSITIVE, HER2+ METASTATIC BREAST CANCER OR DOCUMENTATION OF USE IN COMBINATION WITH CAPECITABINE FOR ADVANCED OR METASTATIC BREAST CANCER WHOSE TUMORS OVEREXPRESS HER2 AND HAVE RECEIVED PRIOR THERAPY INCLUDING AN ANTHRACYCLINE, A TAXANE, AND TRASTUZUMAB (HERCEPTIN)

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## TYMLOS

## Affected Drugs:

Tymlos

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of postmenopausal osteoporosis AND documentation that member has not previously been on a parathyroid hormone analog for greater than 2 years

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:24 MONTHS

**Other Criteria**:DOCUMENTATION OF AN ATTEMPT OF THERAPY WITH OR CONTRAINDICATION TO BISPHOSPHONATES or EITHER A PREVIOUS OSTEOPOROTIC FRACTURE OR HIGH RISK OF FRACTURE (T-SCORE LESS THAN -2.5 WITH DOCUMENTED RISK FACTORS)

Tysabri

Off-Label Uses:N/A

**Exclusion Criteria:**COMBINATION THERAPY WITH IMMUNOSUPPRESSANTS (E.G. 6-MERCAPTOPURINE, AZATHIOPRINE, CYCLOSPORINE, METHOTREXATE) OR INHIBITORS OF TNF-A

**Required Medical Information:**DX OF RELAPSING/REMITING MS (INCLUDING CLINICALLY ISOLATED SYNDROME, RELAPSING-REMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE), DOCUMENTATION OF TYSABRI BEING USED AS MONOTHERAPY AND THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO THERAPY WITH TWO FORMULARY ALTERNATIVES FOR THE TREATMENT OF MS AND DOCUMENTATION OF TESTING FOR ANTI-JCV ANTIBODY WITHIN THE LAST 6 MONTHS PRIOR TO START OF THERAPY AND IF ANTI-JCV ANTIBODY POSITIVE, DOCUMENTATION THAT BENEFITS OF DRUG OUTWEIGH THE RISKS OF PML AND PATIENT IS AWARE OF PML RISK. DIAGNOSIS OF MODERATE TO SEVERE CROHN'S BASED ON CLINICAL SIGNS AND SYMPTOMS.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**FOR MS: WRITTEN BY A NEUROLOGIST. FOR CROHN'S: WRITTEN BY A GASTROENTEROLOGIST

**Coverage Duration:**CROHNS: 6 MONTHS INITIAL, 12 MONTHS CONTINUATION. MS: 12 MONTHS

Other Criteria:FOR CROHNS: DOCUMENTATION OF A THERAPEUTIC FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF HUMIRA AND INFLIXIMAB (INFLECTRA). FOR REAUTHORIZATION, MUST SHOW IMPROVEMENT IN SIGNS AND SYMPTOMS OF DISEASE AND FOR PATIENTS WHO WERE PREVIOUSLY ANTI-JCV ANTIBODY NEGATIVE, DOCUMENTATION OF RETEST YEARLY. FOR THOSE PATIENTS WHO WERE ANTI-JCV ANTIBODY POSITIVE AT BASELINE OR RETEST, DOCUMENTATION THAT BENEFITS OF CONTINUING DRUG OUTWEIGH RISKS.

## TYVASO

#### Affected Drugs:

Tyvaso Tyvaso Refill Tyvaso Starter

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DIAGNOSIS OF FUNCTIONAL CLASS III OR IV PULMONARY ARTERY HYPERTENSION. DIAGNOSIS OF PULMONARY HYPERTENSION ASSOCIATED WITH INTERSTITIAL LUNG DISEASE (WORLD HEALTH ORGANIZATION GROUP 3 PULMONARY HYPERTENSION).

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FOR PAH: DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO OR USE IN COMBINATION WITH SILDENAFIL OR BOSENTAN

## UBRELVY

# Affected Drugs:

Ubrelvy

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of use for the acute treatment of migraine with or without aura.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary triptans (e.g., almotriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan). Documentation that medication will not be used concurrently with another CGRP antagonist indicated for the actue treatment of migraine.

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Affected Drugs: Udenyca

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

**Exclusion Criteria:**PROPHYLAXIS DURING CHEMO REGIMENS WITH A FEBRILE NEUTROPENIA RISK LESS THAN 20% AND NO HIGH RISK FOR COMPLICATIONS, THOSE WHO ARE NEUTROPENIC BUT AFEBRILE, TO ALLOW AN INCREASE IN THE DOSE-INTENSITY OF CYTOTOXIC CHEMO BEYOND ESTABLISHED DOSE RANGES

**Required Medical Information:**PREVENTION OF FEBRILE NEUTROPENIA WHEN RISK DUE TO MYELOSUPPRESIVE CHEMO REGIMEN IS 20% OR GREATER OR TO PREVENT FEBRILE NEUTROPENIA WHEN THE RISK OF DEVELOPING FEBRILE NEUTROPENIA IS LESS THAN 20% WITH ONE ADDITIONAL RISK FACTOR. PREVENTION OF FEBRILE NEUTROPENIA WHEN A PREVIOUS CYCLE RESULTED IN A NEUTROPENIC COMPLICATION AND DOSE REDUCTION WILL COMPROMISE DISEASE FREE OR OVERALL SURVIVAL OR TREATMENT OUTCOME.

#### Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

#### Coverage Duration:6 MONTHS

Other Criteria: ADDITIONAL RISK FACTORS FOR THE PREVENTION OF FEBRILE NEUTROPENIA INCLUDE, BUT ARE NOT LIMITED TO: 65 YRS OR OLDER, POOR PERFORMANCE STATUS, PREVIOUS HISTORY OF FEBRILE NEUTROPENIA, EXTENSIVE PRIOR RADIATION OR CHEMOTHERAPY TREATMENT, POOR NUTRITIONAL STATUS, RECENT SURGERY OR OPEN WOUNDS OR ACTIVE INFECTION, ADVANCED CANCER, PERSISTENT NEUTROPENIA, BONE MARROW INVOLVEMENT BY TUMOR, LIVER DYSFUNCTION (BILIRUBIN GREATER THAN 2), OR RENAL DYSFUNCTION (CrcL LESS THAN 50 ML/MIN).

Ukoniq

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of marginal zone lymphoma AND documentation of relapsed or refractory disease after at least one prior anti-CD20-based regimen. Diagnosis of follicular lymphoma AND documentation of relapsed or refractory disease after at least three prior lines of systemic therapy.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Unituxin

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**:DOCUMENTATION OF TREATMENT OF PEDIATRIC PATIENTS WITH HIGH-RISK NEUROBLASTOMA WHO ACHIEVE AT LEAST A PARTIAL RESPONSE TO PRIOR FIRST-LINE MULTIAGENT, MULTIMODALITY THERAPY AND DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH GRANULOCYTE-MACROPHAGE COLONY-STIMULATING FACTOR (GM-CSF), INTERLEUKIN-2 (IL-2), AND 13-CIS-RETINOIC ACID (ISOTRETINOIN)

Age Restrictions:N/A

Prescription Order Restrictions:N/A

**Coverage Duration:5 MONTHS** 

Other Criteria:N/A

## UPTRAVI

#### Affected Drugs:

Uptravi

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DIAGNOSIS OF WHO GROUP I PULMONARY HYPERTENSION.

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**DOCUMENTATION OF USE IN COMBINATION WITH, OR FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO SILDENAFIL AND/OR AND ENDOTHELIN RECEPTOR ANTAGONIST (BOSENTAN, AMBRISENTAN OR MACITENTAN).

## VALCHLOR

Affected Drugs:

Valchlor

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF STAGE IA OR IB MYCOSIS FUNGOIDES-TYPE CUTANEOUS T-CELL LYMPHOMA

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE OF THE FOLLOWING SKIN-DIRECTED THERAPIES: TOPICAL CORTICOSTEROID, TOPICAL RETINOID, TOPICAL NITROGEN MUSTARD, OR PHOTOTHERAPY. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### VANDETANIB

Affected Drugs: Caprelsa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF MEDULLARY THYROID CANCER IN PATIENTS WITH UNRESECTABLE, LOCALLY ADVANCED, OR METASTATIC DISEASE.

Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

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Varubi (180 MG Dose)

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DOCUMENTATION OF USE FOR PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH MODERATELY TO HIGHLY EMETOGENIC CHEMOTHERAPY REGIMENS and DOCUMENTATION THAT MEDICATION IS BEING USED IN COMBINATION WITH OTHER ANTIEMETIC AGENTS.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST, ONCOLOGIST OR GASTROENTEROLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**N/A

Vectibix

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DX OF METASTATIC COLORECTAL CANCER IN COMBINATION WITH FOLFOX AS FIRST LINE THERAPY OR AS MONOTHERAPY WITH DISEASE PROGRESSION ON (OR INTOLERANCE OR CONTRAINDICATION TO) FLUOROPYRIMIDINE, OXALIPLATIN, AND IRINOTECAN CONTAINING CHEMOTHERAPY REGIMENS.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**DOCUMENTATION OF WILD-TYPE RAS (DEFINED AS WILD-TYPE (NEGATIVE) IN BOTH KRAS AND NRAS) AS DETERMINED BY AN FDA-APPROVED TEST.

### VELCADE

## Affected Drugs:

Bortezomib

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF MULTIPLE MYELOMA OR DIAGNOSIS OF MANTLE CELL LYMPHOMA.

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### VELTASSA

Affected Drugs:

Veltassa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF MILD TO MODERATE HYPERKALEMIA (SERUM POTASSIUM GREATER THAN OR EQUAL TO 5.1 MEQ/L AND LESS THAN 6.5 MEQ/L)

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**DOCUMENTATION THAT ATTEMPT HAS BEEN MADE TO IDENTIFY AND CORRECT THE UNDERLYING CAUSE OF THE HYPERKALEMIA OR RATIONALE AS TO WHY THE UNDERLYING CAUSE CANNOT BE CORRECTED.

#### VEMURAFENIB

Affected Drugs: Zelboraf

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E MUTATION AS DETECTED BY AN FDA APPROVED TEST. DIAGNOSIS OF ERDHEIM-CHESTER DISEASE (ECD) WITH BRAF V600 MUTATION AS DESTECTED BY AN FDA APPROVED TEST.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR DERMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria**: REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

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### VENCLEXTA

## Affected Drugs:

Venclexta Venclexta Starting Pack

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DIAGNOSIS OF CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) or SMALL LYMPHOCYTIC LEUKEMIA (SLL). DOCUMENTATION OF NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML) USED IN COMBINATION WITH AZACITIDINE, DECITABINE, OR LOW-DOSE CYTARABINE and DOCUMENTATION OF AGE GREATER THAN 75 YEARS or DOCUMENTATION OF A COMORBIDITY THAT PRECLUDES PATIENT FROM RECEIVING INTENSIVE INDUCTION CHEMOTHERAPY

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

Ventavis

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**FOR THE TREATMENT OF PRIMARY PULMONARY HYPERTENSION (WORLD HEALTH ORGANIZATION [WHO] GROUP I) IN PATIENTS WITH NEW YORK HEART ASSOCIATION (NYHA) CLASS III SYMPTOMS WITH AN ADEQUATE TRIAL OF BOSENTAN AND SILDENAFIL OR FOR THE TREATMENT OF PRIMARY PULMONARY HYPERTENSION (WORLD HEALTH ORGANIZATION [WHO] GROUP I) IN PATIENTS WITH NEW YORK HEART ASSOCIATION (NYHA) CLASS IV SYMPTOMS WITH AN ADEQUATE TRIAL OF BOSENTAN.

Age Restrictions:N/A

Prescription Order Restrictions: PULMONOLOGIST OR CARDIOLOGIST

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

Verquvo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of symptomatic chronic New York Heart Association Class II-IV heart failure, documentation of a left ventricular ejection fraction (LVEF) less than or equal to 45%, AND documentation of one of the following: hospital admission due to heart failure within the previous 6 months OR documentation of outpatient intravenous diuretic treatment for heart failure within the previous 3 months.

#### Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions: BY OR IN CONSULTATION WITH CARDIOLOGIST

#### Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**Documentation of therapeutic failure on, intolerance to, or contraindication to: 1) one formulary angiotensin converting enzyme inhibitor (ACEi), angiotensin receptor blocer (ARB) or angiotensin receptor and neprilysin inhibitor (ARNI) AND 2) one formulary beta-blocker.

Affected Drugs: Verzenio

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+/HER2-) advanced or metastatic breast cancer WITH one of the following (1) administered with fulvestrant in patients who experienced disease progression following prior endocrine therapy AND documentation of postmenopausal status OR if pre/perimenopausal, that the member has received a gonadotropin-releasing hormone agonist for at least 4 weeks prior to and will continue for the duration of Verzenio therapy or (2) used as monotherapy if the patient experienced disease progression following prior endocrine therapy and prior chemotherapy in the metastatic setting or (3) for initial endocrine-based therapy in combination with an aromatase inhibitor with documentation of postmenopausal status.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: Oncologist

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorizations will require documentation of continued disease improvement or lack of disease progression

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## VIIBRYD

#### Affected Drugs:

Viibryd Viibryd Starter Pack

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO BUPROPION AND ONE OTHER CLASS OF ANTIDEPRESSANTS (INCLUDING, BUT NOT LIMITED TO SSRI, MAOI, SNRI OR TCA).

Affected Drugs: Viltepso

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of Duchenne's Muscular Dystrophy (DMD) confirmed by genetic testing AND documentation of a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. Documentation that medication is being given concurrently with oral corticosteroids.

Age Restrictions:N/A

Prescription Order Restrictions: Neurologist or genetic specialist

#### Coverage Duration:6 MONTHS

**Other Criteria**:Documentation that patient does not have a symptomatic cardiac abnormality. Documentation of dosing consistent with the FDA approved labeling (maximum dose of 80 mg per kg infused once weekly). Documentation that the patient is ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) as proven by documentation of a 6-Minute Walk Test Distance (6MWT) within the past 3 months of initiation of medication. Reauthorization will require the following: documentation of continued benefit from treatment with viltolarsen AND documentation of concurrent use with oral corticosteroids AND documentation of no symptomatic cardiac abnormality AND documentation of a dose consistent with FDA approved labeling, AND documentation that patient remains ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) as proven by documentation of a follow-up 6-Minute Walk Test Distance (6MWT) within the past 6 months.

#### VIMPAT

## Affected Drugs:

Vimpat

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF A DIAGNOSIS OF PARTIAL ONSET SEIZURES or DOCUMENTTATION OF ADJUNCTIVE TREATMENT FOR PRIMARY GENERALZED TONIC-CLONIC SEIZURES

Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

#### Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria**:Documentation of a therapeutic failure on, intolerance to or contraindication to two formulary anticonvulsant alternatives used for the treatment of indicated seizure type, including but not limited to carbamazepine, lacosamide, lamotrigine, levetiracetam, perampanel, phenytoin, topiramate, valproic acid, and divalproex sodium.

#### VIRAZOLE

Affected Drugs:

Ribavirin

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**TREATMENT OF HOSPITALIZED INFANTS AND YOUNG CHILDREN WITH SEVERE LOWER RESPIRATORY TRACT INFECTIONS DUE TO RESPIRATORY SYNCYTIAL VIRUS (RSV).

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

Other Criteria:N/A

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Vitrakvi

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Documentation of unresectable or metastatic solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation AND documentation that the member must have progressed following treatment or have no satisfactory alternative treatments

Age Restrictions:N/A

## Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

## Coverage Duration:12 MONTHS

**Other Criteria:**Subsequent approval after 12 months will require documentation of continued disease improvement or lack of disease progression.

Affected Drugs: Vizimpro

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Reauthorization will require documentation of continued disease improvement or lack of disease progression.

#### VOTRIENT

#### Affected Drugs:

Votrient

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DX OF ADVANCED RENAL CELL CARCINOMA WITH CLEAR CELL OR PREDOMINANTLY CLEAR CELL HISTOLOGY OR DX OF ADVANCED RENAL CELL CARCINOMA WITH NON-CLEAR CELL HISTOLOGY OR DX OF ADVANCED SOFT TISSUE SARCOMA (STS)

Age Restrictions:N/A

#### Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

Other Criteria:FOR DX OF ADVANCED RENAL CELL CARCINOMA WITH NON-CLEAR CELL HISTOLOGY SUBTYPE: MUST HAVE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO TEMSIROLIMUS AND SUTENT. FOR DX OF ADVANCED SOFT TISSUE SARCOMA MUST HAVE FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ONE PRIOR CHEMOTHERAPY TREATMENT INCLUDING BUT NOT LIMITED TO DOXORUBICIN, IFOSFAMIDE, EPIRUBICIN, GEMCITABINE, DACARBAZINE, LIPOSOMAL DOXORUBICIN, TEMOZOLOMIDE, VINORELBINE, AD REGIMEN, AIM REGIMEN, MAID REGIMEN. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### VPRIV

# Affected Drugs:

Vpriv

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF TYPE 1 GAUCHER DISEASE WITH AT LEAST ONE OF THE FOLLOWING - ANEMIA, THROMBOCYTOPENIA, BONE DISEASE, HEPATOMEGALY OR SPLENOMEGALY

Age Restrictions: MUST BE 4 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**METABOLIC SPECIALIST, GENETICIST OR HEMATOLOGIST WITH EXPERIENCE TREATING GAUCHER DISEASE

Coverage Duration:6 MONTHS

**Other Criteria:**DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO ELELYSO IF PATIENT IS 18 YEARS OF AGE OR OLDER.

**Affected Drugs:** Vraylar

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF SCHIZOPHRENIA OR ACUTE TREATMENT OF MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER or documentation of use for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression)

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**For schizophrenia or manic/mixed episodes associated with bipolar I: MEDICAL RECORD DOCUMENTATION OF TRIAL ON TWO FORMULARY ALTERNATIVES (ARIPIPRAZOLE, OLANZAPINE, QUETIAPINE, ZIPRASIDONE OR RISPERIDONE). For depressive episodes associated with bipolar I disorder (bipolar depression): medical record documentation of therapeutic failure on, intolerance to, or contraindication to quetiapine.

Vyepti

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria AND documentation of the number of baseline migraine or headache days per month.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: by or in consultation with a neurologist or headache specialist

Coverage Duration:3 MONTHS INITIAL AND 1 YEAR CONTINUATION

**Other Criteria**: Documentation of the patient experiencing four or more migraines per month. Documentation of a therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality. Documentation that medication is not being used concurrently with botulinum toxin OR if being used in combination documentation of the following: therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND documentation of a therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist. Documentation that medication will not be used concomitantly with another CGRP antagonist indicated for the preventive treatment of migraine. If request is for 300 mg every 3 month dosing: documentation of therapeutic failure on 100 mg every 3 month dosing. Reauthorization will require documentation of continued or sustained reduction in migraine or headache frequency or a decrease in severity or duration of migraine AND either documentation the medication is not being used concurrently with botulinum toxin OR if the request is for combination use with Botox documentation of the following: previous therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox AND documentation of a previous therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist. Documentation that medication will not be used concomitantly with another CGRP antagonist indicated for the preventive treatment of migraine. If request is for 300 mg every 3 month dosing: documentation of therapeutic failure on 100 mg every 3 month dosing.

Vyondys 53

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

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of Duchenne's Muscular Dystrophy (DMD) confirmed by genetic testing AND documentation of a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. Documentation that medication is being given concurrently with oral corticosteroids.

Age Restrictions:N/A

Prescription Order Restrictions: Neurologist or genetic specialist

#### Coverage Duration:6 MONTHS

**Other Criteria:**Documentation that patient has stable pulmonary and cardiac function. Documentation of dosing consistent with the FDA approved labeling (maximum dose of 30 mg per kg infused once weekly). Documentation that the patient is ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) as proven by documentation of a 6-Minute Walk Test Distance (6MWT) within the past 3 months of initiation of medication. Reauthorization will require the following: documentation of continued benefit from treatment with golodirsen AND documentation of concurrent use with oral corticosteroids AND documentation of stable pulmonary and cardiac function AND documentation of a dose consistent with FDA approved labeling, AND documentation that patient remains ambulatory (e.g. able to walk with assistance, not wheelchair bound, does not have full-time dependence on motorized wheelchairs or scooters for mobility) as proven by documentation of a follow-up 6-Minute Walk Test Distance (6MWT) within the past 6 months.

### VYXEOS

## Affected Drugs:

Vyxeos

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) OR AML with myelodysplasia-related changes (AML-MRC).

Age Restrictions: MUST BE 1 YEAR OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria**:Documentation of rationale why cytarabine plus daunorubicin (7 plus 3) is not a medically appropriate treatment. Reauthorizations will require documentation of continued disease improvement or lack of disease progression.

### WELIREG

Affected Drugs: Welireg

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of von Hippel-Lindau (VHL) disease and documentation that member does not require immediate surgery.

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Disease confirmed with a germline VHL alterantion and at least one of the following: associated renal cell carcinoma (RCC) OR associated central nervous system (CNS) hemangioblastomas OR associated pancreatic neuroendocrine tumors (pNET). Reauthorization will require documentation of continued disease improvement or lack of disease progression.

Xatmep

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DIAGNOSIS OF ACUTE LYMPHOBLASTIC LEUKEMIA USED AS PART OF A COMBINATION CHEMOTHERAPY MAINTENANCE REGIMEN or DIAGNOSIS OF POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS FOLLOWING AN INSUFFICIENT RESPONSE OR INTOLERANCE TO A 3 MONTH TRIAL OF A FORMULARY NSAID OR OTHER FIRST LINE THERAPY

Age Restrictions:18 YEARS OF AGE OR YOUNGER

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

Other Criteria:N/A

## XCOPRI

#### Affected Drugs:

Xcopri Xcopri (250 MG Daily Dose) Xcopri (350 MG Daily Dose)

Off-Label Uses:N/A

Exclusion Criteria:N/A

Required Medical Information: Documentation of a diagnosis of partial onset seizures

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: by or in consultation with a neurologist

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria**:Documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary anticonvulsant medications used to treat the same indication (such as, but not limited to carbamazepine, lamotrigine, levetiracetam, phenytoin, topiramate, valproic acid or zonisamide).

Xeljanz Xeljanz XR

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

Exclusion Criteria:N/A

**Required Medical Information:**DIAGNOSIS OF RHEUMATOID ARTHRITIS MADE IN ACCORDANCE WITH THE AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA FOR THE CLASSIFICATION AND DIAGNOSIS OF RHEUMATOID ARTHRITIS or DX OF MODERATE TO SEVERE PSORIATIC ARTHRITIS WHICH MUST INCLUDE DOCUMENTATION OF EITHER ACTIVE PSORIATIC LESIONS or A DOCUMENTED HISTORY OF PSORIASIS. DIAGNOSIS OF MODERATE TO SEVERE ULCERATIVE COLITIS. Documentation of active polyarticular course juvenile idiopathic arthritis.

Age Restrictions: for PcJIA: 2 yrs or older. All others: 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**RHEUMATOLOGIST, DERMATOLOGIST OR GASTROENTEROLOGIST

Coverage Duration: 6 MONTHS INITIAL AND 1 YEAR CONTINUATION

Other Criteria:DOCUMENTATION THAT MEDICATION IS NOT BEING USED CONCURRENTLY WITH A TNF BLOCKER OR OTHER BIOLOGIC AGENT. FOR RA: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO A MINIMUM 3 MONTH TRIAL OF METHOTREXATE OR OTHER DMARD IF METHOTREXATE NOT TOLERATED OR CONTRAINDICATED. FOR PSA: MEDICAL RECORD DOCUMENTATION THAT MEDICATION IS BEING PRESCRIBED IN COMBINATION WITH NON-BIOLOGIC DMARD THERAPY (INCLUDING BUT NOT LIMITED TO METHOTREXATE, SULFASALAZINE, AND/OR LEFLUNOMIDE). FOR PERIPHERAL PSA: INTOLERANCE OR FAILURE TO MTX AND ONE FORMULARY NSAID. FOR AXIAL PSA: INTOLERANCE, CONTRAINDICATION OR FAILURE TO TWO FORMULARY NSAIDS. FOR UC: FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AZATHIOPRINE OR 6-MP. FOR PcJIA: INTOLERANCE, CONTRAINDICATION OR FAILURE OF A MINIMUM 3 MONTH TRAIL OF ONE NSAID AND METHOTREXATE OR OTHER DMARD IF METHOTREXATE IS NOT TOLERATED OR CONTRAINDICATED OF DOCUMENTATION OF FAILURE ON OR INTOLERANCE TO PRIOR BIOLOGIC THERAPY. FOR CONTINUED THERAPY. MEDICAL RECORD DOCUMENTATION SHOWING MAINTENANCE OR IMPROVEMENT OF CONDITION.

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Xenleta

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**Documentation of a diagnosis of community acquired bacterial pneumonia (CABP) caused by susceptible isolates of the following: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenza, Legionella pneumophila, Mycoplasma pneumoniae, or Chlamydophila pneumoniae.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**WRITTEN BY OR IN CONSULTATION WITH A INFECTIOUS DISEASE PROVIDER

Coverage Duration:1 week

**Other Criteria:**Documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to two other antibiotics shown to be susceptible on the culture and sensitivity OR documentation that therapy was initiated during an inpatient setting.

## XERMELO

Affected Drugs: Xermelo

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of carcinoid syndrome diarrhea AND documentation that medication is being used in combination with a somatostatin analog

Age Restrictions:18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

**Other Criteria:**Documentation of an inadequate response on a somatostatin analog monotherapy. Reauthorization will require documentation that medication is still being used in combination with a somatostatin analog AND documentation of sustained reduction in bowel movement frequency from baseline.

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Xgeva

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**: DOCUMENTATION OF BONE METASTASES RELATED TO DISEASE PROGRESSION FROM A SOLID TUMOR (E.G. BREAST, PROSTATE, THYROID) or DOCUMENTATION OF TREATMENT OF ADULTS OR SKELETALLY MATURE ADOLESCENTS WITH GIANT CELL TUMOR OF BONE THAT IS UNRESECTABLE OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY or DOCUMENTATION OF HYPERCALCEMIA OF MALIGNANCY THAT IS REFRACTORY TO INTRAVENOUS BISPHOSPHONATE THERAPY OR DOCUMENTATION OF USE FOR THE PREVENTION OF SKELETAL RELATED EVENTS IN ADULT PATIENTS WITH MULTIPLE MYELOMA

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:12 MONTHS

**Other Criteria:**N/A

#### XIFAXAN

Affected Drugs: Xifaxan

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of a diagnosis of traveler's diarrhea (TD) OR diagnosis of hepatic encephalopathy (HE) OR Irritable bowel syndrome with diarrhea (IBS-D).

Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

Coverage Duration: For TD: 3 days. for IBS-D: 14 days. For HE: remainder of contract year

**Other Criteria**:Documentation of a dose and duration of therapy consistent with product labeling for requested indication. For TD: documentation of a therapeutic failure on, intolerance to or contraindication to azithromycin and one oral fluoroquinolone. For HE: documentation of use concurrently with lactulose or documentation of a therapeutic failure on, intolerance to, or contraindication to lactulose. For IBS-D: documentation of a therapeutic failure on, intolerance to, or contraindication to dicyclomine and loperamide. Reauthorization for IBS-D will require documentation of having a recurrence of symptoms related to IBS-D AND documentation that member has not received more than two previous courses of this medication for the treatment of IBS-D.

Xolair

Off-Label Uses:N/A

## Exclusion Criteria:N/A

**Required Medical Information:**IGE LEVEL OF GREATER THAN 30 IU/ML AND LESS THAN 700 IU/ML FOR INDIVIDUALS AGE 12 AND OLDER or IGE LEVEL OF GREATER THAN 30 IU/ML AND LESS THAN 1300 IU/ML FOR INDIVIDUALS AGE 6 THROUGH 11, DIAGNOSIS OF MODERATE TO SEVERE PERSISTENT ASTHMA WITH EVIDENCE OF REVERSIBLE AIRWAY DISEASE AND DOCUMENTATION OF A SPECIFIC ALLERGY REACTIVITY BY POSTIVE SKIN OR BLOOD TEST FOR A SPECIFIC IGE. DIAGNOSIS OF MODERATE TO SEVERE CHRONIC IDIOPATHIC URTICARIA AND AT LEAST 6 WEEK HISTORY OF SYMPTOMS SUCH AS HIVES ASSOCIATED WITH ITCHING OR ANGIOEDEMA. DIAGNOSIS OF ADD-ON MAINTENANCE TREATMENT OF NASAL POLYPS.

Age Restrictions: ASTHMA: 6 YRS OR OLDER, URTICARIA: 12 YRS OR OLDER, POLYPS: 18 YRS OR OLDER

**Prescription Order Restrictions:**ASTHMA: ALLERGIST, IMMUNOLOGIST OR PULMONOLOGIST. URTICARIA: ALLERGIST, IMMUNOLOGIST, OR DERMATOLOGIST. POLYPS: BY OR IN CONSULTATION WITH OTOLARYNGOLOGIST

## Coverage Duration:12 MONTHS

Other Criteria:KNOWN ENVIRONMENTAL TRIGGERS HAVE BEEN ELIMINATED. DOCUMENTATION THAT MEDICATION IS NOT BEING USED IN COMBINATION WITH BENRALIZUMAB, MEPOLIZUMAB OR RESLIZUMAB. FOR ASTHMA: DOCUMENTATION OF INADEQUATE CONTROL OR INTOLERANCE TO A 3 MONTH TRIAL OF COMBINATION PRODUCT GLUCOCORTICOID WITH LONG ACTING BETA AGONIST (SUCH AS ADVAIR, DULERA, OR BREO) AND LEUKOTRIENE RECEPTOR MODIFIER OR ANTAGONIST. FOR URTICARIA: FAILURE ON FOUR WEEK TRIAL OF MAXIMAL DOSE OF ONE ANTIHISTAMINE USED IN COMBINATION WITH EITHER A H2 RECEPTOR ANTAGONIST OR LEUKOTRIENE RECEPTOR MODIFIER OR ANTAGONIST. FOR CHRONIC IDIOPATHIC URTICARIA MUST HAVE TRIED AND FAILED 150 MG DOSE BEFORE 300 MG DOSE IS USED. FOR NASAL POLYPS: THERAPEUTIC FAILURE ON, INTOLERANCE TO , OR CONTRAINDICATION TO INTRANASAL FLUTICASONE AND MOMETASONE. REAUTHORIZATION FOR ALL INDICATIONS WILL REQUIRE DOCUMENTATION OF IMPROVEMENT IN THE SIGNS AND SYMPTOMS OF DISEASE

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## XOSPATA

Affected Drugs: Xospata

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of a diagnosis of relapsed or refractory acute myeloid leukemia (AML) AND documentation of a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA approved test

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Subsequent approval after 12 months will require documentation of continued disease improvement or lack of disease progression.

## **XPOVIO**

## Affected Drugs:

Xpovio (100 MG Once Weekly) Xpovio (40 MG Once Weekly) Xpovio (40 MG Twice Weekly) Xpovio (60 MG Once Weekly) Xpovio (60 MG Twice Weekly) Xpovio (80 MG Once Weekly) Xpovio (80 MG Twice Weekly)

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

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

**Required Medical Information:**Diagnosis of use in combination with dexamethasone for relapsed or refractory multiple myeloma AND documentation of previously receiving four prior regimens which include at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. Documentation of use for multiple myeloma, used in combination with bortezomib and dexamethasone following at least one prior therapy. Documentation of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma AND documentation of treatment with at least two prior lines of therapy.

## Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

#### Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

#### Coverage Duration:6 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

#### **XTANDI**

#### Affected Drugs:

Xtandi

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF PROSTATE CANCER AND DOCUMENTATION OF EITHER 1) NO LONGER RESPONDING TO CASTRATION OR HORMONE RESISTANT, OR 2) THAT MEMBER AS METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER.

#### Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST OR UROLOGIST

#### Coverage Duration:12 MONTHS

**Other Criteria:**DOCUMENTATION THAT A GONADOTROPIN-RELEASING HORMONE (GnRH) ANALOG WILL BE USED CONCURRENTLY OR DOCUMENTATION OF BILATERAL ORCHIECTOMY. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

### **XYREM**

## Affected Drugs:

Xyrem

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of cataplexy in a patient with narcolepsy OR diagnosis of excessive daytime sleepiness in a patient with narcolepsy.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**For excessive daytime sleepiness with narcolepsy: therapeutic failure on, intolerance to, or contraindication to modafinil AND either methylphenidate IR or amphetamine/dextroamphetamine IR

### XYWAV

## Affected Drugs:

Xywav

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of cataplexy in a patient with narcolepsy OR diagnosis of excessive daytime sleepiness in a patient with narcolepsy.

Age Restrictions:N/A

Prescription Order Restrictions:N/A

#### Coverage Duration:12 MONTHS

**Other Criteria:**For excessive daytime sleepiness with narcolepsy: therapeutic failure on, intolerance to, or contraindication to modafinil, methylphenidate IR or amphetamine/dextroamphetamine IR AND for excessive daytime sleepiness with narcolepsy OR Cataplexy with narcolepsy: therapeutic failure on, intolerance to, or contraindication to Xyrem OR documentation of requiring a low sodium alternative alternative such as due to a concomitant diagnosis of heart failure, hypertension, or renal impairment. Reauthorization will require documentation of reduction in frequency of catplexy attacks OR reduction in symptoms of excessive daytime sleepiness.

Yervoy

Off-Label Uses:N/A

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

**Required Medical Information: DIAGNOSIS OF UNRESECTABLE OR METASTATIC MELANOMA** WITH ONE OF THE FOLLOWING: DOCUMENTATION OF USE IN COMBINATION WITH NIVOLUMAB FOR FIRST LINE THERAPY OR DOCUMENTATION OF USE AS A SINGLE AGENT OR IN COMBINATION WITH NIVOLUMAB AS SECOND LINE OR SUBSEQUENT THERAPY FOR DISEASE PROGRESSION IF NOT PREVIOUSLY USED OR DOCUMENTATION OF USE AS SINGLE AGENT REINDUCTION THERAPY IN SELECT PATIENTS WHO EXPERIENCED NO SIGNIFICANT TOXICITY DURING PRIOR IPILIMUMAB THERAPY AND WHO RELAPSE AFTER INITIAL CLINICAL RESPONSE OR PROGRESS AFTER STABLE DISEASE FOR GREATER THAN 3 MONTHS OR DOCUMENTATION OF USE AS A SINGLE AGENT FOR ADJUVANT THERAPY FOR STAGE IIIA WITH METASTASES GREATER THAN 1 MM, OR STAGE IIIB OR STAGE IIIC CUTANEOUS MELANOMA WITH NODAL METASTASES FOLLOWING A COMPLETE LYMPH NODE DISSECTION OR RESECTION OR FOLLOWING COMPLETE LYMPH NODE DISSECTION OR COMPLETE RESECTION OF NODAL RECURRENCE. DIAGNOSIS OF PREVIOUSLY UNTREATED ADVANCED RENAL CELL CARCINOMA USED IN COMBINATION WITH NIVOLUMAB WITH DOCUMENTATION OF INTERMEDIATE TO POOR RISK (DEFINED AS HAVING 1 OR MORE PROGNOSTIC RISK FACTORS AS PER THE IMDC CRITERIA). DIAGNOSIS OF MICROSATELLITE INSTABILITY-HIGH (MSI-H) OR MISMATCH REPAIR DEFICIENT (DMMR) METASTATIC COLORECTAL CANCER WITH PROGRESSION FOLLOWING TREATMENT WITH A FLUOROPYRIMIDINE, OXALIPLATIN OR IRINOTECAN BASED THERAPY AND DOCUMENTATION THAT MEDICATION WILL BE USED IN COMBINATION WITH NIVOLUMAB. DOUMENTATION OF HEPATOCELLULAR CARCINOMA USED IN COMBINATION WITH NIVOLUMAB. DIAGNOSIS OF FIRST LINE METASTATIC OR RECURRENT NON SMALL CELL LUNG CANCER (NSCLC) WITH DOCUMENTION OF NO EFGR OR ALK GENOMIC TUMOR ABBERATIONS AND EITHER DOCUMENTATION OF PD-L1 GREATER THAN 1% USED IN COMBINATION WITH OPDIVO OR DOCUMENTATION OF USE IN COMBINATION WITH OPDIVO AND 2 CYCLES OF PLATINUM DOUBLET CHEMOTHERAPY. DIAGNOSIS OF UNRESECTABLE MALIGNANT PLEURAL MESOTHELIOMA AND DOCUMENTATION OF USE IN COMBINATION WITH NIVOLOUMAB.

#### Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

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**Coverage Duration:**ADJ. MELANOMA:6 MO W/12 MO REAUTH. NSCLC &MESOTHELIOMA:6 MO W/18 MO REAUTH. ALL OTHERS: 6 MO.

Other Criteria:FOR HCC: DOCUMENTATION OF A THERAPEUTIC FAILURE ON OR INTOLERANCE TO SORAFENIB. REAUTHORIZATION FOR ADJUVANT TREATMENT OF MELANOMA WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION. REAUTHORIZATION FOR OTHER INDICATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION AND DOCUMENTATION OF PEER REVIEWED LITERATURE CITING WELL DESIGNED CLINICAL TRIALS TO INDICATE THAT THE MEMBERS HEALTHCARE OUTCOME WILL BE IMPROVED BY DOSING BEYOND THE FDA APPROVED TREATMENT DURATION.

#### YONDELIS

Affected Drugs: Yondelis

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**:DIAGNOSIS OF UNRESECTABLE OR METASTATIC LIPOSARCOMA OR LEIOMYOSARCOMA AND DOCUMENTATION OF PRIOR THERAPY WITH AN ANTHRACYCLINE CONTAINING REGIMEN

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**SUBSEQUENT APPROVAL AFTER 12 MONTHS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION.

#### YONSA

## Affected Drugs:

Yonsa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of prostate cancer with evidence of metastatic disease AND member is no longer responding to castration or is hormone resistant.

Age Restrictions:N/A

Prescription Order Restrictions: ONCOLOGIST OR UROLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**Documentation that methylprednisolone will be administered concomitantly with Yonsa. Reauthorization will require documentation of continued disease improvement or lack of disease progression.

Zaltrap

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF METASTATIC COLORECTAL CANCER THAT IS RESISTANT TO OR HAS PROGRESSED FOLLOWING AN OXALIPLATIN CONTAINING REGIMEN AND USE IN COMBINATION WITH IRINOTECAN OR FOLFIRI (5-FLUOROURACIL, LEUCOVORIN, IRINOTECAN)

Age Restrictions:N/A

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## ZAVESCA

#### **Affected Drugs:**

migLUstat

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

Required Medical Information: DX OF MILD TO MODERATE TYPE 1 GAUCHER DISEASE

Age Restrictions:N/A

Prescription Order Restrictions:N/A

Coverage Duration:6 MONTHS

**Other Criteria:**FOR WHOM ENZYME REPLACEMENT THERAPY IS NOT A THERAPEUTIC OPTION (I.E. BECAUSE OF CONSTRAINTS SUCH AS ALLERGY, HYPERSENSITIVITY, OR POOR VENOUS ACCESS).

Zejula

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information**:Diagnosis of recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer AND documentation the medication is being used as maintenance therapy after a complete or partial response to platinum-based chemotherapy OR diagnosis of advanced ovarian, fallopian tube, or primary peritoneal cancer with either 1) both of the following: documentation of treatment with three or more prior chemotherapy regimens AND documentation of homologous recombination deficiency (HRD) positive status defined by either a deleterious or suspected deleterious BRCA mutation OR genomic instability with progression more than six months after response to last platinum-based chemotherapy or 2) documentation of use as maintenance treatment AND documentation of complete or partial response to platinum based chemotherapy AND documentation that medication is being given at a dosage consistent with product labeling.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## ZEPZELCA

Affected Drugs: Zepzelca

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Documentation of metastatic small cell lung cancer (SCLC) AND documentation of disease progression on or after platinum-based chemotherapy

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

**Coverage Duration:**6 MONTHS

**Other Criteria**: REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

Affected Drugs: Zerbaxa

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of complicated intra-abdominal infection (cIAI) caused by one of the following susceptible microorganisms: Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus, or Streptococcus salivarius OR Diagnosis of complicated Urinary tract infection (including pyelonephritis) caused by Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, or Pseudomonas aeruginosa OR Diagnosis of Hospital acquired bacterial pneumonia or Ventilator associated bacterial pneumonia (HABP/VABP) caused by Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, or Serratia marcescens.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**WRITTEN BY OR IN CONSULTATION WITH A INFECTIOUS DISEASE PROVIDER

Coverage Duration: For UTI 1 week. For cIAI or HABP/VABP 2 weeks.

**Other Criteria:**Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatements OR a documented history of previous intolerance to or contraindication to two preferred alternative formulary antibiotics shown to be susceptible on the culture and sensitivity.

Affected Drugs: Ziextenzo

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

**Exclusion Criteria:**PROPHYLAXIS DURING CHEMO REGIMENS WITH A FEBRILE NEUTROPENIA RISK LESS THAN 20% AND NO HIGH RISK FOR COMPLICATIONS, THOSE WHO ARE NEUTROPENIC BUT AFEBRILE, TO ALLOW AN INCREASE IN THE DOSE-INTENSITY OF CYTOTOXIC CHEMO BEYOND ESTABLISHED DOSE RANGES

**Required Medical Information:**PREVENTION OF FEBRILE NEUTROPENIA WHEN RISK DUE TO MYELOSUPPRESIVE CHEMO REGIMEN IS 20% OR GREATER OR TO PREVENT FEBRILE NEUTROPENIA WHEN THE RISK OF DEVELOPING FEBRILE NEUTROPENIA IS LESS THAN 20% WITH ONE ADDITIONAL RISK FACTOR. PREVENTION OF FEBRILE NEUTROPENIA WHEN A PREVIOUS CYCLE RESULTED IN A NEUTROPENIC COMPLICATION AND DOSE REDUCTION WILL COMPROMISE DISEASE FREE OR OVERALL SURVIVAL OR TREATMENT OUTCOME.

#### Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

#### Coverage Duration:6 MONTHS

Other Criteria: ADDITIONAL RISK FACTORS FOR THE PREVENTION OF FEBRILE NEUTROPENIA INCLUDE, BUT ARE NOT LIMITED TO: 65 YRS OR OLDER, POOR PERFORMANCE STATUS, PREVIOUS HISTORY OF FEBRILE NEUTROPENIA, EXTENSIVE PRIOR RADIATION OR CHEMOTHERAPY TREATMENT, POOR NUTRITIONAL STATUS, RECENT SURGERY OR OPEN WOUNDS OR ACTIVE INFECTION, ADVANCED CANCER, PERSISTENT NEUTROPENIA, BONE MARROW INVOLVEMENT BY TUMOR, LIVER DYSFUNCTION (BILIRUBIN GREATER THAN 2), OR RENAL DYSFUNCTION (CrcL LESS THAN 50 ML/MIN). Affected Drugs: Zinplava

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information**: DOCUMENTATION THAT PATIENT IS AT HIGH RISK FOR CLOSTRIDUM DIFFICILE INFECTION RECURRENCE AS EVIDENCED BY ONE OF THE FOLLOWING: ONE RISK FACTOR FOR RECURRENT DISEASE (SUCH AS BUT NOT LIMITED TO: AGE 65 OR OLDER, GREATER THAN OR EQUAL TO 10 UNFORMED STOOLS PER 24 HOURS, SERUM CREATININE GREATER THAN OR EQUAL TO 1.2 MG/DL) or AT LEAST ONE PREVIOUS C.DIFF INFECTION WITHIN THE PAST 6 MONTHS or HISTORY OF AT LEAST 2 PREVIOUS C.DIFF INFECTIONS EVER. DOCUMENTATION THAT MEDICATION IS BEING ADMINISTERED CONCURRENTLY WITH A STANDARD OF CARE ANTIBACTERIAL TREATMENT FOR C.DIFF (ORAL VANCOMYCIN, METRONIDAZOLE, FIDAXOMICIN). DOCUMENTATION OF ONE OF THE FOLLOWING: PATIENT DOES NOT HAVE HEART FAILURE or RATIONALE FOR USE IN A HEART FAILURE PATIENT (THAT RISKS OUTWEIGH BENEFITS). DOCUMENTATION THAT PATIENT HAS NOT RECEIVED A PREVIOUS DOSE OF ZINPLAVA.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**PRESCRIBED BY GASTROENTEROLOGIST OR WITH CONSULTATION FROM INFECTIOUS DISEASE PROVIDER

Coverage Duration: ONE FILL FOR ONE DOSE

**Other Criteria:**N/A

#### Affected Drugs: Zokinvy

Off-Label Uses:N/A

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

**Required Medical Information:**Documentation of a confirmed diagnosis through genetic testing of one of the following: Hutchinson-Gilford Progeria Syndrome OR Processing deficient progeroid laminopathy with either 1) heterozygous LMNA mutation with progerin-like protein accumulation or 2) homozygous or compound heterozygous ZMPSTE24 mutations.

## Age Restrictions: MUST BE 12 MONTHS OF AGE OR OLDER

## Prescription Order Restrictions:N/A

## Coverage Duration:12 MONTHS

**Other Criteria**:Documentation of body surfate area of at least 0.39m2. Documentation that the requested dose is appropriate based on the patient's body surface area AND documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling to the beneficiary regarding the risks associated with the use of both medications when they interact). Reauthorizations will require documentation that the requested dose continues to be appropriate based on the patient's body surface area AND documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling to the beneficiary regarding the risks associated with the use of both medications when they interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling to the beneficiary regarding the risks associated with the use of both medications when they interaction of the interacting drug, or counseling to the beneficiary regarding the risks associated with the use of both medications when they interact).

Zontivity

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DOCUMENTATION OF MYOCARDIAL INFARCTION (MI) OCCURRING LESS THAN 12 MONTHS PRIOR TO STARTING THERAPY OR DOCUMENTATION OF PERIPHERAL ARTERIAL DISEASE (PAD) AS INDICATED BY A HISTORY OF INTERMITTENT CLAUDICATION AND RESTING ANKLE/BRACHIAL INDEX (ABI) OF LESS THAN 0.85 OR AMPUTATION, PERIPHERAL BYPASS, OR PERIPHERAL ANGIOPLASTY OF THE EXTREMITIES SECONDARY TO ISCHEMIA.

Age Restrictions:N/A

#### Prescription Order Restrictions:N/A

Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**FOR MI AND PAD: DOCUMENTATION OF NO PRIOR HISTORY OF STROKE, TIA, OR ICH AND DOCUMENTATION OF CONCOMITANT THERAPY WITH ASPIRIN ALONE, A THIENOPYRIDINE (CLOPIDOGREL) ALONE, OR A COMBINATION OF ASPIRIN AND CLOPIDOGREL.

## ZORBTIVE

Affected Drugs:

Zorbtive

Off-Label Uses:N/A

**Exclusion Criteria:**DOCUMENTATION OF ACUTE ILLNESS DUE TO COMPLICATIONS FROM OPEN HEART OR ABDOMINAL SURGERY, MULTIPLE ACCIDENT TRAUMA, OR ACUTE RESPIRATORY FAILURE.

**Required Medical Information:**DIAGNOSIS OF SHORT BOWEL SYNDROME and DOCUMENTATION OF CURRENT, DAILY THERAPIES WITH PARENTERAL NUTRITION (TPN OR PPN) AND/OR ENTERAL NUTRITION SUPPORT.

Age Restrictions:N/A

Prescription Order Restrictions: ENDOCRINOLOGIST OR GASTROENTEROLOGIST

Coverage Duration:2 MONTHS

**Other Criteria:**N/A

## ZORTRESS

## Affected Drugs:

Everolimus Zortress

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

Exclusion Criteria:N/A

#### **Required Medical Information**:DOCUMENTED KIDNEY TRANSPLANT NOT COVERED BY MEDICARE OR DOCUMENTED LIVER TRANSPLANT NOT COVERED BY MEDICARE

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

**Prescription Order Restrictions:**PHYSICIAN EXPERIENCED IN IMMUNOSUPPRESSIVE THERAPY AND MANAGEMENT OF TRANSPLANT PATIENTS

#### Coverage Duration: REMAINDER OF CONTRACT YEAR

**Other Criteria:**For kidney transplant: documentation that medication is being administered in combination with basiliximab (Simulect) induction and concurrently with reduced doses of cyclosporine and corticosteroids OR documentation of a therapeutic failure on, contraindication to or intolerance to calcineurin inhibitors. For liver transplant: documentation that medication is not being administered earlier than 30 days post transplant AND one of the following: used in combination with low dose tacrolimus and corticosteroids OR documentation of a therapeutic failure on, contraindication to or intolerance to calcineurin inhibitors.

Affected Drugs: Zulresso

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**Diagnosis of postpartum depression (PPD) as defined by 1) patient experiencing a major depressive episode AND 2) patient experienced onset of symptoms within the third trimester or within 4 weeks of delivery. Documentation that patient is less than or equal to 6 months postpartum AND documentation that current depressive episode is moderate to severe based on a standardized and validated questionnaire/scale (e.g. a score of greater than 10 on the Patient Health Questionnaire (PHQ-9), a score of greater than 20 on the Hamilton Depression Rating Scale (HAM-D), etc.)

#### Age Restrictions:N/A

Prescription Order Restrictions: by or in consultation with a psychiatrist

Coverage Duration: ONE-TIME COURSE OF THERAPY OF 3 DAYS

**Other Criteria:**Additional infusion(s) of Zulresso for future cases of PPD associated with additional pregnancies will be reviewed for medical necessity based on the above criteria. More than one administration of Zulresso per pregnancy/birth is considered investigational and not covered.

## ZYDELIG

Affected Drugs: Zydelig

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DIAGNOSIS OF RELAPSED CHRONIC LYMPHOCYTIC LEUKEMIA (CLL), RELAPSED FOLLICULAR B-CELL NON-HODGKIN LYMPHOMA (FL), OR RELPASED SMALL LYMPHOCYTIC LYMPHOMA (SLL)

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions:ONCOLOGIST OR HEMATOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**FOR CLL - DOCUMENTATION OF CONCURRENT USE WITH RITUXIMAB. FOR FL OR SLL - DOCUMENTATION OF FAILURE ON, INTOLERANCE TO, OR CONTRAINDICATION TO AT LEAST TWO PRIOR THERAPIES INCLUDING BUT NOT LIMITED TO (FOR FL: BENDAMUSTINE + RITUXIMAB, RCHOP, RCVP, RITUXIMAB, FCMR, FLUDARABINE + RITUXIMAB, OR RFND) (FOR SLL: OBINUTUZUMAB + CHLORAMBUCIL, RITUXIMAB + CHLORAMBUCIL, BENDAMUSTINE +/- RITUXIMAB, RITUXIMAB, CYCLOPHOSPHAMIDE + PREDNISONE +/-RITUXIMAB, CHLORAMBUCIL). REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## ZYKADIA

# Affected Drugs:

Zykadia

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) THAT IS ANAPLASTIC LYMPHOMA KINASE (ALK) POSITIVE AS DETECTED BY AN FDA APPROVED TEST

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**FOR ALK-POSITIVE, METASTATIC NON-SMALL CELL LUNG CANCER: DOCUMENTATION OF RATIONALE FOR NOT TREATING WITH ALECENSA IF CLINICALLY APPROPRIATE. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION **Affected Drugs:** Zynlonta

Off-Label Uses:N/A

**Exclusion Criteria:**N/A

**Required Medical Information:**DOCUMENTATION OF RELAPSED OR REFRACTORY LARGE B-CELL LYMPHOMA INCLUDING DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL) NOT OTHERWISE SPECIFIED, DLBCL ARISING FROM LOW GRADE LYMPHOMA, AND HIGH-GRADE B-CELL LYMPHOMA AND DOCUMENTATION OF PRIOR TREATMENT WITH TWO OR MORE LINES OF SYSTEMIC THERAPY.

Age Restrictions: MUST BE 18 YEARS OF AGE OR OLDER

Prescription Order Restrictions: HEMATOLOGIST OR ONCOLOGIST

Coverage Duration: 6 MONTHS INITIAL, 12 MONTHS REAUTH

**Other Criteria**: REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

## ZYTIGA

#### **Affected Drugs:**

Abiraterone Acetate Zytiga

Off-Label Uses:N/A

Exclusion Criteria:N/A

**Required Medical Information:**DIAGNOSIS OF PROSTATE CANCER WITH EVIDENCE OF METASTATIC DISEASE. DOCUMENTATION OF EITHER MEMBER IS NO LONGER RESPONDING TO CASTRATION OR IS HORMONE RESISTANT or THAT THE MEMBER HAS HIGH-RISK, CASTRATION SENSITIVE DISEASE.

Age Restrictions:N/A

Prescription Order Restrictions:ONCOLOGIST OR UROLOGIST

Coverage Duration:12 MONTHS

**Other Criteria:**DOCUMENTATION THAT PREDNISONE WILL BE ADMINISTERED CONCOMITANTLY WITH ABIRATERONE. REAUTHORIZATIONS WILL REQUIRE DOCUMENTATION OF CONTINUED DISEASE IMPROVEMENT OR LACK OF DISEASE PROGRESSION

# Drugs that may be covered under Medicare Part B or Part D

Abelcet IV	Acetylcysteine INH
Acyclovir Sodium IV	Adrucil IV
Albuterol Sulfate INH	AmBisome IV
Aminosyn IV	Aminosyn II IV
Aminosyn II/Electrolytes IV	Aminosyn M IV
Aminosyn/Electrolytes IV	Aminosyn-PF IV
Aminosyn-RF IV	Amphotericin B IV
Azasan Oral Tab	azaTHIOprine Oral Tab
azaTHIOprine Sodium INJ	Bleomycin Sulfate INJ
Budesonide INH	Cladribine IV
Clinisol SF IV	Clinolipid IV
Cromolyn Sodium INH	Cyclophosphamide Oral Cap
cycloSPORINE IV	cycloSPORINE Modified Oral Cap
Cytarabine INJ	Cytarabine (PF) INJ
Deltasone Oral Tab	Dextrose IV
DOBUTamine HCI IV	DOBUTamine in D5W IV
DOXOrubicin HCI IV	Engerix-B INJ
Envarsus XR Oral Tab ER 24H	Floxuridine INJ
Fluorouracil IV	Foscarnet Sodium IV
Ganciclovir Sodium IV	Gengraf Oral Cap

Granisetron HCI Oral Tab	Heparin Sodium (Porcine)
Heparin Sodium (Porcine) PF INJ	Herceptin IV
Ifosfamide IV	Imovax Rabies IM
Intralipid IV	Ipratropium Bromide INH
Ipratropium-Albuterol INH	Levalbuterol HCI INH
Methotrexate Sodium INJ	Milrinone Lactate IV
Milrinone Lactate in Dextrose IV	mitoMYcin IV
Mycophenolate Mofetil IV	Mycophenolate Mofetil HCI IV
Mycophenolate Sodium Oral Tab	Nebupent INH
Nutrilipid IV	Ogivri IV
Ondansetron	Ondansetron HCI Oral Soln
Pentamidine Isethionate INH	prednisoLONE Oral Soln
prednisoLONE Sodium Phosphate Oral Soln	predniSONE Oral Soln
Premasol IV	Prograf IV
Prosol IV	RabAvert IM
Recombivax HB INJ	Simulect IV
Sirolimus Oral Soln	Tacrolimus Oral Cap
Travasol IV	TrophAmine IV
vinBLAStine Sulfate IV	Vincasar PFS IV
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Aminosyn-RF	466
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Ribavirin	
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RisperDAL Consta	
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