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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

HETLIOZ

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

HUMAN GROWTH HORMONE

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

CHILDREN AND ADOLESCENTS WITH GROWTH HORMONE DEFICIENCY, SHOX DEFICIENCY IN CHILDREN: Baseline height must be greater than 2 standard deviations below the mean for gender and age. Growth rate is such that the member is unlikely to attain an adult height in the normal range - 59 inches for girls and 63 inches for boys. TURNER SYNDROME: Confirmed by karyotype. PRADER-WILLI or NOONAN SYNDROME: Baseline height must be less than the 5th percentile for gender and age OR 2 or more standard deviations below the mean measured paternal height. Growth rate is such that the member is unlikely to attain an adult height in the normal range - 59 inches for girls and 63 inches for boys.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

Adult Growth Hormone Deficiency: 12 months. HIV Wasting or Cachexia, Children: 6 months.

#### **Other Criteria:**

HIV Wasting or Cachexia: Member is being treated with concomitant antiretroviral therapy.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

HUMIRA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

For the following indications, prescribed by or in consultation with: PSORIATIC ARTHRITIS, PLAQUE PSORIASIS - rheumatologist or dermatologist. CROHN'S DISEASE, ULCERATIVE COLITIS - gastroenterologist. RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS - rheumatologist. HIDRADENITIS SUPPURATIVA - rheumatologist, dermatologist or gastroenterologist. UVEITIS - ophthalmologist or rheumatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, sulfasalazine, hydroxychloroquine, d-penicillamine, azathioprine or auranofin. PLAQUE PSORIASIS: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, cyclosporine or acitretin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

HYDROCODONE

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

3 months initial for non-malignant pain then 12 months. 12 months for cancer pain.

#### **Other Criteria:**

Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: MS Contin, Kadian, Duragesic, Opana ER, Avinza or Oxycontin.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

HYDROXYZINE HCL INJECTION

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

HYDROXYZINE HCL ORAL

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Pruritus: Failure of one of the following topical agents, unless contraindicated or clinically significant adverse effects are experienced: betamethasone, hydrocortisone, triamcinolone, fluticasone, clobetasol, fluocinonide or fluocinolone. Anxiety: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: venlafaxine, buspirone, duloxetine or escitalopram. All other FDA approved indications: Patient is continuing on this medication without adverse effects.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

HYDROXYZINE PAMOATE

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Pruritus: Failure of one of the following topical agents, unless contraindicated or clinically significant adverse effects are experienced: betamethasone, hydrocortisone, triamcinolone, fluticasone, clobetasol, fluocinonide or fluocinolone. Anxiety: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: venlafaxine, buspirone, duloxetine or escitalopram. All other FDA approved indications: Patient is continuing on this medication without adverse effects.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

ICLUSIG

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

ACUTE LYMPHOBLASTIC LEUKEMIA (ALL): disease is Philadelphia chromosome positive (Ph+).

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

IDH1FA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Presence of an isocitrate dehydrogenase-2 (IDH2) mutation.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

For age less than 60 years, disease has relapsed or is refractory following treatment with a first line chemotherapy regimen (e.g., cytarabine, idarubicin, daunorubicin, Vyxeos, cladribine, Rydapt, Mylotarg).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

ILARIS

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Acute gouty arthritis.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Confirmation of current weight.

#### **Age Restrictions:**

Cryopyrin-Associated Periodic Syndromes: 4 years and older. All other covered indications: 2 years and older.

#### **Prescriber Restrictions:**

SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS: Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist. ALL OTHER COVERED INDICATIONS: Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

ILUMYA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a rheumatologist or dermatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of one of the following unless contraindicated or clinically significant adverse effects are experienced: methotrexate, cyclosporine or acitretin. Failure of one of the following unless contraindicated or clinically significant adverse effects are experienced: Cosentyx, Humira, Inflectra, Remicade, Stelara, Taltz, and Tremfya.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

IMATINIB

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

CHRONIC MYELOID LEUKEMIA (CML), ACUTE LYMPHOBLASTIC LEUKEMIA (ALL): disease is Philadelphia chromosome positive. CHRONIC MYELOMONOCYTIC LEUKEMIA: disease is positive for a platelet-derived growth factor receptor (PDGFR) mutation or a 5q3133 mutation.

MYELOYDYSPLASTIC/MYELOPROLIFERATIVE DISEASES: disease is positive for a PDGFR mutation.

AGGRESSIVE SYSTEMIC MASTOCYTOSIS: disease is D816V c-Kit mutation negative or c-Kit mutational status is unknown. MELANOMA: disease is KIT-positive. PIGMENTED VILLOUS NODULAR

SYNOVITIS/TENOSYNOVIAL GIANT CELL TUMOR: Disease is associated with severe morbidity or functional limitations and is not amenable to improvement with surgery.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

IMBRUVICA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

CHRONIC GRAFT-VERSUS-HOST DISEASE: Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist. ALL OTHER INDICATIONS: Prescribed by or in consultation with an oncologist or hematologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

IMIPRAMINE

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Depression: Failure of one of the following generic antidepressants, unless contraindicated or clinically significant adverse effects are experienced: bupropion, bupropion SR, bupropion XL, citalopram, desvenlafaxine succinate, duloxetine, escitalopram, fluoxetine, mirtazapine, sertraline, venlafaxine or venlafaxine XR.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

INDOMETHACIN

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of naproxen and sulindac, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

INFLECTRA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Psoriatic Arthritis/Plaque Psoriasis: Prescribed by or in consultation with a rheumatologist or dermatologist.  
Crohn's Disease/Ulcerative Colitis: Prescribed by or in consultation with a gastroenterologist. Rheumatoid Arthritis/Ankylosing Spondylitis: Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Rheumatoid Arthritis: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, sulfasalazine, hydroxychloroquine, d-penicillamine, azathioprine or auranofin.  
Plaque Psoriasis: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, cyclosporine or acitretin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

INGREZZA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Development of tardive dyskinesia is secondary to a centrally acting dopamine receptor blocking agent (neuroleptic) (e.g., first- or second-generation antipsychotics such as chlorpromazine or aripiprazole, antiemetics such as promethazine or metoclopramide, the tri-cyclic antidepressant amoxapine).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a psychiatrist or neurologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

INLYTA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

RENAL CELL CARCINOMA WITH CLEAR CELL HISTOLOGY: One of the following (a or b): a) prescribed concurrently with Keytruda or Bavencio, OR b) prescribed as monotherapy after failure of one prior therapy (e.g., Votrient, Sutent), unless contraindicated or clinically significant adverse effects are experienced.

DIFFERENTIATED THYROID CARCINOMA: Failure of Lenvima or Nexavar unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

INQOVI

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

ALL ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist or hematologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

INREBIC

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

MYELOFIBROSIS: Confirmation of a recent (within the last 30 days) thiamine level of 70 nmol/L (3 mcg/dL) or greater. Confirmation of a recent (within the last 30 days) platelet count of 50,000/mcL or greater.

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

**Coverage Duration:**

12 months.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

INTERFERON BETA-1A

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

INTERFERON BETA-1B

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

INTUNIV

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Attention Deficit Hyperactivity Disorder: Failure of both of the following, unless contraindicated or clinically significant adverse effects are experienced: amphetamine-based stimulant and methylphenidate based-stimulant.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

JAKAFI

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

STEROID REFRACTORY GRAFT-VERSUS-HOST DISEASE: Member has history of bone marrow or stem cell transplant.

#### **Age Restrictions:**

STEROID REFRACTORY GRAFT-VERSUS-HOST DISEASE: Age greater than or equal to 12 years.

#### **Prescriber Restrictions:**

STEROID REFRACTORY GRAFT-VERSUS-HOST DISEASE: Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist. ALL OTHER INDICATIONS: Prescribed by or in consultation with an oncologist or hematologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

POLYCYTHEMIA VERA: Failure of hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced. STEROID REFRACTORY GRAFT-VERSUS-HOST DISEASE: Failure of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

JUXTAPID

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

Failure of Repatha 420 mg, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

JYNARQUE

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with a nephrologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

KADCYLA

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Kadcyla will be used as a single-agent therapy.

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

KALYDECO

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Presence of one mutation in the CFTR gene that is responsive to ivacaftor. Confirmation that a homozygous F508del mutation in the CFTR gene is not present.

#### **Age Restrictions:**

6 months of age or older.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

KETOROLAC TROMETHAMINE

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

Patients with active peptic ulcer disease. Advanced renal impairment or at risk for renal failure due to volume depletion. Suspected or confirmed cerebrovascular bleeding, hemorrhagic diathesis, incomplete hemostasis and those at high risk for bleeding. Patient currently receiving aspirin or NSAIDs (non-steroidal anti-inflammatory drugs). Patient currently receiving probenecid or pentoxifylline.

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

5 days.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

KEVZARA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, sulfasalazine, hydroxychloroquine, d-penicillamine, azathioprine or auranofin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

KISQALI(Kisqali Femara Co-Pack , Kisqali )

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Breast cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, and advanced or metastatic.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

For Kisqali: Prescribed in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane), fulvestrant, or tamoxifen. If prescribed in combination with tamoxifen: Medical justification supports need to use tamoxifen over an aromatase inhibitor or fulvestrant. For men receiving an aromatase inhibitor: Prescribed in combination with an agent that suppresses testicular steroidogenesis (e.g., gonadotropin-releasing hormone agonists).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

KORLYM

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an endocrinologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

KOSELUGO

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

NEUROFIBROMATOSIS TYPE 1 (NF1): Diagnosis is confirmed by positive genetic testing for NF1 or member has at least one diagnostic criteria for NF1 based on the National Institutes of Health Neurofibromatosis 1 Diagnostic Criterion. Complete resection of plexiform neurofibroma (PN) is not considered to be feasible without substantial risk or morbidity (e.g., due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

NF1: Prescribed by or in consultation with an oncologist or neurologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

KUVAN

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Recent (within 90 days) phenylalanine (Phe) blood level is greater than 360 micromol/L. CONTINUATION OF THERAPY: Confirmation of a reduction in Phe blood levels since initiation of therapy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a metabolic or genetic disease specialist.

#### **Coverage Duration:**

Initial: 3 months. Reauthorization: 12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

LATUDA

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

Failure of two of the following atypical antipsychotics, unless contraindicated or clinically significant adverse effects are experienced: risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

LAZANDA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

##### **Age Restrictions:**

Age 18 or greater

##### **Prescriber Restrictions:**

##### **Coverage Duration:**

Through the end of the Plan contract year.

##### **Other Criteria:**

Patient is already taking and is tolerant to around-the-clock opioid therapy. Patients are considered opioid tolerant when taking another opioid daily for a week or longer (for example, at least 60 mg of oral morphine per day or an equianalgesic dose of another opioid).



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

LEMTRADA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of TWO of the following, unless contraindicated or clinically significant adverse effects are experienced:  
Aubagio, Tecfidera, Gilenya, Avonex, Betaseron, Plegridy, glatiramer, Copaxone, Glatopa, Extavia or Rebif.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

LENVIMA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

RENAL CELL CARCINOMA: Prescribed in combination with Afinitor AND if histology is clear cell or unknown, failure of a regimen consisting of or including one of the following drugs unless contraindicated or clinically significant adverse effects are experienced: Avastin, Cabometyx, Inlyta, Nexavar, Opdivo, Proleukin, Sutent, Tarceva, Torisel, Votrient, or Yervoy. MEDULLARY THYROID CARCINOMA: Failure of Cometriq or Caprelsa unless contraindicated or clinically significant adverse effects are experienced.

## Prior Authorization Protocol

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### Medicare Part D – 2020

#### **Prior Authorization Group Description:**

LEUKINE

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

AML following induction therapy, Mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation, Following autologous peripheral blood progenitor cell or bone marrow transplantation (BMT) in members with NHL, ALL, HL for acceleration of myeloid reconstitution, Following allogeneic BMT for acceleration of myeloid reconstitution, Acute Radiation Syndrome: Failure of Neupogen, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

LIDODERM

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Diabetic neuropathy. Cancer-related neuropathic pain.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2020

#### **Prior Authorization Group Description:**

LONSURF

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

COLORECTAL CANCER: Confirmation that the patient does or does not have the RAS (KRAS or NRAS) wild type gene. GASTRIC CANCER, GASTROESOPHAGEAL ADENOCARCINOMA: Confirmation that the patient does or does not have a HER2/neu-positive tumor.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

COLORECTAL CANCER: If tumor expresses the RAS wild type gene, failure of Erbitux or Vectibix, unless contraindicated or clinically significant adverse effects are experienced. GASTRIC CANCER, GASTROESOPHAGEAL ADENOCARCINOMA: If tumor is HER2/neu-positive (i.e., HER2-overexpressing), failure of Herceptin, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

LORBRENA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

NON-SMALL CELL LUNG CANCER: Disease is ALK or ROS1 positive.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

NON-SMALL CELL LUNG CANCER: For ALK-positive disease, failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Alecensa, Alunbrig, Xalkori, Zykadia. For ROS1-positive disease, failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Rozlytrek, Xalkori, Zykadia.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

LOTROXEX

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

Male patients.

#### **Required Medical Information:**

Female patient with irritable bowel symptoms persisting for at least 6 months.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

LUCEMYRA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Diagnosis of opioid dependence (may be limited to physiologic dependence/tolerance) or opioid use disorder. Member is currently or will be undergoing abrupt opioid discontinuation within the next seven days and one of the following: member has taken one or more opioids for at least the last three weeks OR an opioid antagonist (e.g., naltrexone) has been or will be administered after a period of opioid use. Medical justification supports why an opioid taper (e.g., with buprenorphine, methadone or other opioid) cannot be used. Lucemyra has not been prescribed for a prior opioid withdrawal event within the last 30 days or medical justification supports retreatment.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a physician specializing in one of the following areas: emergency medicine/inpatient care, pain management, addiction psychiatry.

#### **Coverage Duration:**

14 days per course of treatment.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

LYNPARZA TABLET

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

BREAST CANCER: Mutations in the BRCA genes and confirmation of human epidermal growth factor receptor 2 (HER2)-negative disease. METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: Member does not have a PPP2R2A gene mutation.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

PROSTATE CANCER: Prescribed by or in consultation with an oncologist or urologist. ALL OTHER ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

MAVENCLAD

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

CONTINUATION OF THERAPY: Member has not yet received 2 courses (4 cycles) lifetime total.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

RELAPSING-REMITTING MULTIPLE SCLEROSIS: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Aubagio, Tecfidera, Gilenya, Avonex, Betaseron, Plegridy, glatiramer, Copaxone, Glatopa, Extavia, or Rebif.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

MAVYRET

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

Treatment-experienced patients with both NS3/4A protease inhibitor and NS5A inhibitor.

#### **Required Medical Information:**

If cirrhosis is present, confirmation of Child-Pugh A status. Refer to the document, "Recommendations for Testing, Managing, and Treating Hepatitis C," by AASLD-IDSa available at <http://www.hcvguidelines.org> for drug regimen and duration of treatment based on genotype, treatment status, previous drug regimens used, past medical history and comorbidities.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a gastroenterologist, hepatologist or infectious disease physician.

#### **Coverage Duration:**

8 to 16 weeks based on genotype, cirrhosis status, prior treatment regimen.

#### **Other Criteria:**

If member has been previously treated with an HCV regimen containing NS5A inhibitor or an NS3/4A protease inhibitor, but not both, member has genotype 1.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

MAYZENT

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

CYP2C9\*3/\*3 genotype.

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

RELAPSING-REMITTING MULTIPLE SCLEROSIS: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Aubagio, Tecfidera, Gilenya, Avonex, Betaseron, Plegridy, glatiramer, Copaxone, Glatopa, Extavia, or Rebif.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

MEGACE

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

BREAST CANCER AND ENDOMETRIAL CANCER: Megestrol acetate is being used for palliative treatment.

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

ANOREXIA AND CACHEXIA ASSOCIATED WITH AIDS: Failure of dronabinol and oxandrolone, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

MEGACE ES

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

BREAST CANCER AND ENDOMETRIAL CANCER: Megestrol acetate is being used for palliative treatment.

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

ANOREXIA AND CACHEXIA ASSOCIATED WITH AIDS: Failure of dronabinol and oxandrolone, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

MEKINIST

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

MELANOMA: Positive for BRAF V600E or V600K mutation. NON-SMALL CELL LUNG CANCER, ANAPLASTIC THYROID CANCER: Positive for BRAF V600E mutation.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

NON-SMALL CELL LUNG CANCER, ANAPLASTIC THYROID CANCER: Prescribed in combination with Tafinlar.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

MEKTOVI

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Positive for BRAF V600E or V600K mutation.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

MELANOMA: Prescribed in combination with Braftovi. COLON CANCER, RECTAL CANCER: Prescribed in combination with Braftovi and either Erbitux or Vectibix.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

METAXALONE

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

METHAMPHETAMINE

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

Treatment of obesity.

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

METHOCARBAMOL

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

METHOTREXATE INJ

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS, RHEUMATOID ARTHRITIS: Prescribed by or in consultation with a rheumatologist. PSORIASIS: Prescribed by or in consultation with a rheumatologist or a dermatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of generic methotrexate injection, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

MIRVASO

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

Erythema of rosacea with papules or pustules: Failure of topical metronidazole, oral doxycycline or Finacea, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

MOZOBIL

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Member is scheduled to receive autologous stem cell transplantation.

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

Prescribed in combination with a granulocyte-colony stimulating factor (G-CSF) (i.e., Neupogen, Zarxio, Granix, or Nivestym).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

MULPLETA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Recent (within the past 14 days) platelet count is less than  $50 \times 10^9/L$ . Member is scheduled to undergo a medical or dental procedure within the next 30 days.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a hematologist, hepatologist, or gastroenterologist.

#### **Coverage Duration:**

4 weeks.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

NAMENDA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Vascular dementia.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 59 years and younger. Prior authorization is not required for patients 60 years and older.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

NATPARA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Recent (dated within the last 30 days) serum calcium level is greater than 7.5 mg/dL. Recent (dated within the last 30 days) lab result shows sufficient 25-hydroxyvitamin D stores (at least 50 nmol/L or 20 ng/mL).

CONTINUATION OF THERAPY: Maintained on therapy with positive response as evidenced by a recent (dated within the last 90 days) serum calcium level within 8-9 mg/dL.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an endocrinologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of an active form of vitamin D (e.g., calcitriol) unless contraindicated or clinically significant adverse events are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

NAYZILAM

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Member is currently on a stable regimen of antiepileptic drugs.

**Age Restrictions:**

Age greater than or equal to 12 years.

**Prescriber Restrictions:**

Prescribed by or in consultation with neurologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

NERLYNX

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Human epidermal growth factor receptor 2 (HER2)-positive breast cancer.

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

NEULASTA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Mobilization of peripheral-blood progenitor cells prior to autologous transplantation. Supportive care post autologous hematopoietic cell transplantation.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

NEUPOGEN

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Myelodysplastic syndrome. Neutropenia in patients with HIV/AIDS.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

NINLARO

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

MULTIPLE MYELOMA: Prescribed in combination with dexamethasone.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

NIVESTYM

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Myelodysplastic syndrome. Neutropenia in patients with HIV/AIDS. Hematopoietic syndrome of acute radiation syndrome.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

NONPREFERRED

**Prior Authorization Indication:**

Refer to Preferred Drug List Criteria Guide on Texas Vendor Drug Program website.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

Refer to Preferred Drug List Criteria Guide on Texas Vendor Drug Program website.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

NORTHERA

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

NUBEQA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Concurrent use of a gonadotropin-releasing hormone (GnRH) analog (e.g., Zoladex, Vantas, leuprolide/Lupron Depot, Eligard, Trelstar, Firmagon) or past bilateral orchiectomy. Disease is not metastatic.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or urologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2020

#### **Prior Authorization Group Description:**

NUCALA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

ASTHMA OR EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS: Blood eosinophil count of greater than or equal to 150 cells/mcL within the past 3 months.

#### **Age Restrictions:**

ASTHMA: 6 years of age or older.

#### **Prescriber Restrictions:**

ASTHMA: Prescribed by or in consultation with an allergist, pulmonologist, or immunologist. EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS: Prescribed by or in consultation with a pulmonologist, immunologist, rheumatologist, or nephrologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

ASTHMA: Prescribed in combination with ONE inhaled corticosteroid (e.g., beclomethasone, budesonide, flunisolide, fluticasone, mometasone, ciclesonide), unless contraindicated or clinically significant adverse effects are experienced AND Prescribed in combination with ONE long-acting beta-agonist (e.g., salmeterol, formoterol, vilanterol), unless contraindicated or clinically significant adverse effects are experienced. EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS: Failure of ONE glucocorticoid, unless contraindicated or clinically significant adverse events are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

NUEDEXTA

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

NUPLAZID

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2020

#### **Prior Authorization Group Description:**

NUZYRA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Request is for continuation of therapy initiated in an acute care hospital from which member was discharged OR Culture and sensitivity (C&S) report for the current infection shows isolated pathogen is an organism susceptible to omadacycline, unless provider confirms that obtaining a C&S report is not feasible.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

14 days.

#### **Other Criteria:**

For members initiating Nuzyra therapy outside of an acute care hospital, one of the following (a, b, or c): a) If a C&S report is available: Failure of 2 antibiotics to which the isolated pathogen is susceptible (if available) per C&S report, unless all are contraindicated or clinically significant adverse effects are experienced. b) C&S report shows resistance or lack of susceptibility of the isolated pathogen to all antibiotics FDA-approved for member's diagnosis. c) If provider confirms that obtaining a C&S report is not feasible: Failure of 2 antibiotics indicated for member's diagnosis (if available), unless all are contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

OCALIVA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a hepatologist or gastroenterologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Prescribed in combination with ursodeoxycholic acid unless contraindicated or clinically significant adverse effects are experienced to ursodeoxycholic acid.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

OCREVUS

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

RELAPSING-REMITTING MULTIPLE SCLEROSIS: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Aubagio, Tecfidera, Gilenya, Avonex, Betaseron, Plegridy, glatiramer, Copaxone, Glatopa, Extavia or Rebif.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

ODOMZO

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2020

#### **Prior Authorization Group Description:**

OFEV

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

SYSTEMIC SCLEROSIS (SSc) ASSOCIATED INTERSTITIAL LUNG DISEASE: Pulmonary fibrosis on high resolution computed tomography (HRCT). Additional signs of SSc are identified (examples may include but are not limited to skin thickening of the fingers, fingertip lesions, telangiectasia, abnormal nailfold capillaries, Raynaud's phenomenon, pulmonary arterial hypertension, SSc-related autoantibodies - anticentromere, anti-topoisomerase I [anti-Scl-70], anti-RNA polymerase III). CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE WITH A PROGRESSIVE PHENOTYPE: For new starts only: confirmation of both of the following within the past 24 months (a and b): a) pulmonary fibrosis affecting more than 10% of lung volume on HRCT and b) confirmation of one of the following (i or ii): i) a relative decline in the forced vital capacity (FVC) of 10% or more of the predicted value, or ii) a relative decline in the FVC of 5% to less than 10% of the predicted value plus either worsening of respiratory symptoms or an increased extent of fibrosis on HRCT.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

SYSTEMIC SCLEROSIS ASSOCIATED INTERSTITIAL LUNG DISEASE, CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE WITH A PROGRESSIVE PHENOTYPE: Prescribed by or in consultation with pulmonologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

OLUMIANT

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of one of the following agents, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, sulfasalazine, hydroxychloroquine, d-penicillamine, azathioprine, or auranofin. Failure of at least one TNF inhibitor unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

ONUREG

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

ACUTE MYELOID LEUKEMIA (AML): Prescribed by or in consultation with an oncologist or hematologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

AML: Medical justification supports inability to use subcutaneous or intravenous azacitidine (e.g., contraindication to excipients).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

OPSUMIT

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

ORENITRAM

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2020

#### **Prior Authorization Group Description:**

ORLISSA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

For 200 mg twice daily requests, members with osteoporosis.

#### **Required Medical Information:**

Continuation of therapy: improvement in dysmenorrhea, dyspareunia, pelvic pain/induration/tenderness, or size of endometrial lesions. Total duration of therapy has not exceeded 6 months for 200 mg twice daily or 24 months for 150 mg once daily dosing.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a gynecologist.

#### **Coverage Duration:**

200 mg twice daily: 6 months. 150 mg once daily: 12 months.

#### **Other Criteria:**

Failure of ONE non-steroidal anti-inflammatory drug (e.g., ibuprofen, naproxen, fenoprofen, ketoprofen, mefenamic acid, meclofenamate, indomethacin, tolmetin, diclofenac, etodolac, diflunisal, meloxicam, piroxicam) or ONE progestin-containing agent (e.g., norethindrone, ethinyl estradiol with (desogestrel, ethynodiol diacetate, drospirenone, etonogestrel, levonorgestrel, norelgestromin, norethindrone, norgestimate, or norgestrel), estradiol valerate/dienogest, mestranol/norethindrone, depot injectable medroxyprogesterone acetate), unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

ORKAMBI

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Presence of homozygous F508del mutation in an FDA-cleared cystic fibrosis mutation test.

#### **Age Restrictions:**

2 years of age or older.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

OXBRYTA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

**SICKLE CELL DISEASE:** Disease is associated with one of the following genotypes: Homozygous hemoglobin S, Hemoglobin S beta 0-thalassemia, Hemoglobin S beta+ thalassemia, Hemoglobin SC. Member has a hemoglobin level between 5.5 and 10.5 g/dL. Member meets one of the following (a or b): a) Member experienced at least 1 vaso-occlusive crisis (VOC) within the past 6 months while on hydroxyurea, OR b) Member has intolerance or contraindication to hydroxyurea and has experienced at least 1 VOC within the past 12 months. Oxbryta is prescribed concurrently with hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced. Oxbryta is not prescribed concurrently with Adakveo. **CONTINUATION OF THERAPY, SICKLE CELL DISEASE:** Member is responding positively to therapy as evidenced by an increase in Hb level from baseline of at least 1 g/dL. Oxbryta is prescribed concurrently with hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced. Oxbryta is not prescribed concurrently with Adakveo.

#### **Age Restrictions:**

**SICKLE CELL DISEASE:** Age greater than or equal to 12 years.

#### **Prescriber Restrictions:**

**SICKLE CELL DISEASE:** Prescribed by or in consultation with a hematologist.

#### **Coverage Duration:**

6 months.

#### **Other Criteria:**

**SICKLE CELL DISEASE:** Failure of L-glutamine, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

OXERVATE

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an ophthalmologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

PALYNZIQ

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Recent (within 90 days) phenylalanine (Phe) blood level is greater than 600 micromol/L. CONTINUATION OF THERAPY: Positive response as evidenced by one of the following (a, b, or c): a) Blood Phe level has decreased by at least 20% from pre-treatment baseline, b) Blood Phe level is less than or equal to 600 micromol/L, c) Member has been using 20 mg per day for at least 6 months, but a dose titration to 40 mg per day is being requested after failure to meet therapeutic targets (a or b above).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an endocrinologist, metabolic disease specialist, or genetic disease specialist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

PEMAZYRE

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

ALL ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

PENNSAID

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of ONE oral non-steroidal anti-inflammatory drug (e.g., ibuprofen, naproxen, fenoprofen, ketoprofen, mefenamic acid, meclofenamate, indomethacin, tolmetin, diclofenac, etodolac, diflunisal, meloxicam, piroxicam), unless all are contraindicated or clinically significant adverse effects are experienced. Failure of either diclofenac 1.5% topical solution or diclofenac 1% topical gel, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

PERSERIS

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Member meets one of the following (a or b): a) therapy was initiated in an inpatient setting during a recent (within 60 days) hospital admission, OR b) failure of TWO of the following atypical antipsychotics, unless contraindicated or clinically significant adverse effects are experienced: aripiprazole, ziprasidone, quetiapine, olanzapine, risperidone, asenapine, iloperidone, paliperidone.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

PHENOBARBITAL

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Partial seizures: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: carbamazepine, phenytoin, topiramate, tiagabine, levetiracetam, gabapentin, lamotrigine, oxcarbazepine, primidone or divalproex. Generalized seizures: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: carbamazepine, phenytoin, topiramate, levetiracetam, primidone or lamotrigine.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

PIQRAY

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Hormone receptor (HR)-positive (i.e., estrogen or progesterone receptor [ER/PR]-positive), HER2-negative, advanced (locally recurrent) or metastatic, and positive for PIK3CA-mutation.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Prescribed in combination with fulvestrant after disease progression on or after an endocrine therapy (e.g., anastrozole, exemestane, fulvestrant, toremifene, letrozole, tamoxifen, or megestrol acetate).



## Prior Authorization Protocol

### Medicare Part D – 2020

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#### Prior Authorization Group Description:

PRALUENT

#### Prior Authorization Indication:

All FDA-approved indications not otherwise excluded from Part D.

#### Off Label Uses:

#### Exclusion Criteria:

#### Required Medical Information:

GENETICALLY MEDIATED PRIMARY HYPERLIPIDEMIA (INCLUDING HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA): Confirmation (e.g., medical records, chart notes, laboratory values) of LDL level suggestive of a diagnosis of familial hypercholesterolemia (e.g., adults: LDL of 190 mg/dL or greater). NON-GENETICALLY MEDIATED PRIMARY HYPERLIPIDEMIA: Request meets both of the following (a and b): a) Confirmation of a LDL of 100 mg/dL or greater AND b) a diagnosis of secondary hyperlipidemia has been ruled out with confirmation of absence of all of the following potential causes of elevated cholesterol (a-e): a) hypothyroidism, b) obstructive liver disease, c) renal disease, d) nephrosis, e) medications which can increase lipid levels including, but not limited to: glucocorticoids, sex hormones, antipsychotics, antiretrovirals, immunosuppressive agents, retinoic acid derivatives. HYPERCHOLESTEROLEMIA WITH HISTORY OF CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD): Confirmation of an LDL of 70 mg/dL or greater AND history of clinical ASCVD defined as one of the following: Acute coronary syndromes, Myocardial infarction, Stable or unstable angina, Coronary or other arterial revascularization (e.g., percutaneous coronary intervention or coronary artery bypass graft surgery), Stroke, Peripheral artery disease presumed to be of atherosclerotic origin, Transient ischemic attack (TIA), Clinically significant coronary heart disease (CHD) diagnosed by invasive or noninvasive testing (such as coronary angiography, stress test using treadmill, stress echocardiography, or nuclear imaging), Carotid artery occlusion greater than 50% without symptoms, Renal artery stenosis or renal artery stent procedure. CONTINUATION OF THERAPY: Confirmation of LDL reduction while on Praluent therapy AND, if tolerated, confirmation of continued statin therapy at the maximally tolerated dose.

#### Age Restrictions:

#### Prescriber Restrictions:

Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.

#### Coverage Duration:

6 months.

#### Other Criteria:

Failure of two of the following at maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced: atorvastatin, rosuvastatin, simvastatin, ezetimibe/simvastatin, pitavastatin, pravastatin, fluvastatin, or lovastatin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

PRETOMANID

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Confirmed resistance to fluoroquinolones, unless contraindicated or clinically significant adverse effects are experienced. CONTINUATION OF THERAPY: Confirmation of delayed culture conversion and total duration of pretomanid therapy has not exceeded 9 months.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an expert in the treatment of tuberculosis.

#### **Coverage Duration:**

Initial: 6 months. Reauthorization: 3 months.

#### **Other Criteria:**

Prescribed in combination with bedaquiline and linezolid. CONTINUATION OF THERAPY: Member meets one of the following (a or b): a) Prescribed in combination with bedaquiline and linezolid OR b) If member has completed at least 4 weeks of linezolid therapy, member continues to receive pretomanid in combination with bedaquiline.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

PREVYMIS

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

Member is receiving pimozide or ergot alkaloids. Member is receiving cyclosporine co-administered with pitavastatin or simvastatin.

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncology, hematology, infectious disease, or transplant specialist.

#### **Coverage Duration:**

Through day 100 post-transplantation.

#### **Other Criteria:**

Failure of generic valacyclovir or generic ganciclovir, unless contraindicated, clinically significant adverse effects are experienced, or member is at high risk for CMV.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

PROLASTIN C

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with a pulmonologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

PROLIA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

PROSTATE CANCER: Receiving or has received androgen deprivation therapy [e.g., leuprolide (Lupron), bicalutamide (Casodex) or Nilandron]. BREAST CANCER: Receiving or has received adjuvant endocrine therapy [e.g., tamoxifen or aromatase inhibitors such as anastrozole (Arimidex), exemestane (Aromasin) or letrozole (Femara)].

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

PROMACTA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Thrombocytopenia in Chronic Hepatitis C: Confirmation of current or planned interferon-based treatment of chronic hepatitis C.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

CHRONIC IMMUNE THROMBOCYTOPENIA, SEVERE APLASTIC ANEMIA: Prescribed by or in consultation with a hematologist. THROMBOCYTOPENIA IN CHRONIC HEPATITIS C: Prescribed by or in consultation with a hematologist, gastroenterologist, or an infectious disease specialist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Chronic Immune (Idiopathic) Thrombocytopenia: Failure of a corticosteroid (e.g., prednisone, methylprednisolone, or dexamethasone), unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

PROTOPIC

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

##### **Age Restrictions:**

Tacrolimus 0.1%: 16 years and older.

##### **Prescriber Restrictions:**

##### **Coverage Duration:**

12 months.

##### **Other Criteria:**

Failure of two medium to high potency topical corticosteroids (e.g., amcinonide, fluticasone propionate, triamcinolone acetonide, betamethasone valerate, fluocinolone acetonide, hydrocortisone butyrate, mometasone furoate, desoximetasone, fluocinonide or betamethasone dipropionate), unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

PROVIGIL

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Multiple sclerosis-related fatigue.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

PURIXAN

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with oncologist or hematologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

One of the following: Failure of mercaptopurine tablets, unless contraindicated or clinically significant adverse effects are experienced OR member has a swallowing disorder or an inability to swallow tablets or capsules..

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

QINLOCK

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

ALL ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

GASTROINTESTINAL STROMAL TUMOR: For members with PDGFRA exon 18 mutation, failure of Ayvakit, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

QUALAQUIN

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Babesiosis. Plasmodium vivax malaria.

#### **Exclusion Criteria:**

For the treatment or prevention of nocturnal leg cramps.

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

Malaria: 7 days. Babesiosis: 7-10 days.

#### **Other Criteria:**

Plasmodium vivax malaria: Infection is chloroquine-resistant.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

RADICAVA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Forced vital capacity greater than or equal to 80%, disease duration of less than or equal to 2 years, functionally retains most activities of daily living (defined as a baseline revised ALS Functional Rating Scale (ALSFRS-R) score with greater than or equal to 2 points in each of the 12 items, meets diagnostic criteria of definite or probable amyotrophic lateral sclerosis (ALS) based on El Escorial revised criteria. CONTINUATION OF THERAPY: Member continues to retain most activities of daily living, forced vital capacity greater than or equal to 80%, and ALSFRS-R score with greater than or equal to 2 points in each of the 12 items.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

6 months.

#### **Other Criteria:**

Prescribed in combination with riluzole unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

RAYALDEE

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Patient has stage 3 or 4 chronic kidney disease (CKD) and serum total 25-hydroxyvitamin D level less than 30 ng/mL.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

REBLOZYL

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

TRANSFUSION DEPENDENT BETA-THALASSEMIA: Total volume of transfusions exceeds 6 red blood cell units within the last 6 months. No transfusion free period for greater than or equal to 35 days within the last 6 months. CONTINUATION OF THERAPY, TRANSFUSION DEPENDENT BETA THALASSEMIA: Member meets one of the following (a or b): a) Member is responding positively to therapy as evidenced by at least a 33% reduction in transfusion burden from baseline, b) Request is for a dose increase. MYELODYSPLASTIC SYNDROMES (MDS): Member requires 2 or more RBC units per 8 weeks confirmed for at least the last 16 weeks. Member has either a ring sideroblast of at least 15% of erythroid precursors in bone marrow or ring sideroblast of at least 5% if SF3B1 mutation is present. Member does not have del(5q) cytogenetic abnormality. CONTINUATION OF THERAPY, MDS: Member meets one of the following (a or b): a) Member is responding positively to therapy as evidenced by a decreased transfusion burden, b) Request is for a dose increase.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

TRANSFUSION DEPENDENT BETA-THALASSEMIA: Prescribed by or in consultation with a hematologist.  
MDS: Prescribed by or in consultation with a hematologist or oncologist.

#### **Coverage Duration:**

TRANSFUSION DEPENDENT BETA-THALASSEMIA, MDS: Initial: 2 months. Reauthorization: 6 months.

#### **Other Criteria:**

MDS: Failure of an erythropoiesis-stimulating agent used in combination with a granulocyte colony stimulating factor, unless clinically significant adverse effects are experienced, all are contraindicated, or confirmation of current serum erythropoietin greater than 500 mU/mL.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

REMICADE

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Wegener's Granulomatosis.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Psoriatic Arthritis/Plaque Psoriasis: Prescribed by or in consultation with a rheumatologist or dermatologist.  
Crohn's Disease/Ulcerative Colitis: Prescribed by or in consultation with a gastroenterologist. Rheumatoid Arthritis/Ankylosing Spondylitis: Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Rheumatoid Arthritis: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, sulfasalazine, hydroxychloroquine, d-penicillamine, azathioprine or auranofin.  
Plaque Psoriasis: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, cyclosporine or acitretin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

RENFLEXIS

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Psoriatic Arthritis/Plaque Psoriasis: Prescribed by or in consultation with a rheumatologist or dermatologist.  
Crohn's Disease/Ulcerative Colitis: Prescribed by or in consultation with a gastroenterologist. Rheumatoid Arthritis/Ankylosing Spondylitis: Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Rheumatoid Arthritis: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, sulfasalazine, hydroxychloroquine, d-penicillamine, azathioprine or auranofin.  
Plaque Psoriasis: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, cyclosporine or acitretin.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

REPATHA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

GENETICALLY MEDIATED PRIMARY HYPERLIPIDEMIA (INCLUDING HETEROZYGOUS OR HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA): Confirmation (e.g., medical records, chart notes, laboratory values) of LDL level suggestive of a diagnosis of familial hypercholesterolemia (e.g., adults: LDL 190 mg/dL or greater). NON-GENETICALLY MEDIATED PRIMARY HYPERLIPIDEMIA: Request meets both of the following (a and b): a) Confirmation of a LDL of 100 mg/dL or greater AND b) a diagnosis of secondary hyperlipidemia has been ruled out with confirmation of absence of all of the following potential causes of elevated cholesterol (a-e): a) hypothyroidism, b) obstructive liver disease, c) renal disease, d) nephrosis, e) medications which can increase lipid levels including, but not limited to: glucocorticoids, sex hormones, antipsychotics, antiretrovirals, immunosuppressive agents, retinoic acid derivatives. HYPERCHOLESTEROLEMIA WITH HISTORY OF CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD): Confirmation of an LDL of 70 mg/dL or greater AND history of clinical ASCVD defined as one of the following: Acute coronary syndromes, Myocardial infarction, Stable or unstable angina, Coronary or other arterial revascularization (e.g., percutaneous coronary intervention or coronary artery bypass graft surgery), Stroke, Peripheral artery disease presumed to be of atherosclerotic origin, Transient ischemic attack (TIA), Clinically significant coronary heart disease (CHD) diagnosed by invasive or noninvasive testing (such as coronary angiography, stress test using treadmill, stress echocardiography, or nuclear imaging), Carotid artery occlusion greater than 50% without symptoms, Renal artery stenosis or renal artery stent procedure. CONTINUATION OF THERAPY: Confirmation of LDL reduction while on Repatha therapy AND, if tolerated, confirmation of continued statin therapy at the maximally tolerated dose.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.

#### **Coverage Duration:**

6 months.

#### **Other Criteria:**

Failure of two of the following at maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced: atorvastatin, rosuvastatin, simvastatin, ezetimibe/simvastatin, pitavastatin, pravastatin, fluvastatin, or lovastatin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

RETEVMO

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

ALL ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

REVATIO

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

Members on concomitant nitrates (e.g., Nitrodur, Nitrobid, Nitrostat, Isordil, Ismo). Members on concomitant guanylate cyclase stimulator, such as riociguat (Adempas).

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

REVC0VI

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an immunologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

REVLIMID

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

REXULTI

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

Failure of aripiprazole and one of the following generic atypical antipsychotics, unless contraindicated or clinically significant adverse effects are experienced: risperidone, olanzapine, quetiapine, ziprasidone.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

RINVOQ

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, sulfasalazine, hydroxychloroquine, d-penicillamine, azathioprine or auranofin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

ROZLYTREK

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

ROS1-POSITIVE NON-SMALL CELL LUNG CANCER: Confirmation of a ROS1 mutation. Member has not received prior ROS1 targeted therapy (e.g., Xalkori, Zykadia, Lorbrena). NTRK FUSION-POSITIVE SOLID TUMOR: Confirmation of an NTRK gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1). Member has not received prior NTRK targeted therapy (e.g., Vitrakvi).

#### **Age Restrictions:**

NTRK FUSION-POSITIVE SOLID TUMOR: Age greater than or equal to 12 years.

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

RUBRACA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

OVARIAN CANCER: Mutations in the BRCA genes OR member has a complete or partial response to two or more platinum-based chemotherapy regimens.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

PROSTATE CANCER: Prescribed by or in consultation with an oncologist or urologist. ALL OTHER ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

RUZURGI

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Confirmation of a baseline clinical muscle strength assessment (examples may include but are not limited to the Quantitative Myasthenia Gravis (QMG) score, triple-timed up-and-go test (3TUG), Timed 25-foot Walk test (T25FW)). CONTINUATION OF THERAPY: Member is responding positively to therapy as evidenced by clinical muscle strength assessments.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

RYDAPT

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Acute Myeloid Leukemia: Positive for the FLT3 mutation.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Acute Myeloid Leukemia: Prescribed by or in consultation with an oncologist or hematologist. Advanced Systemic Mastocytosis: Prescribed by or in consultation with an oncologist, allergist, or immunologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Acute Myeloid Leukemia: for induction therapy, prescribed in combination with cytarabine and daunorubicin OR for consolidation therapy, prescribed in combination with cytarabine.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

SECUADO

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Medical justification supports inability to use Saphris (asenapine sublingual tablets) (e.g., contraindications to excipients).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

SILIQ

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a rheumatologist or dermatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced:  
methotrexate, cyclosporine or acitretin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

SIMPONI(prefilled syringe, auto-injector)

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

PSORIATIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist or dermatologist. ULCERATIVE COLITIS: Prescribed by or in consultation with a gastroenterologist. RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS: Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, sulfasalazine, hydroxychloroquine, d-penicillamine, azathioprine or auranofin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

SIMPONI ARIA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

PSORIATIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist or dermatologist.  
RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS: Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, sulfasalazine, hydroxychloroquine, d-penicillamine, azathioprine or auranofin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

SKYRIZI

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a dermatologist or rheumatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, cyclosporine, or acitretin.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

SOMA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

SOMAVERT

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an endocrinologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Inadequate response to surgery or radiation therapy, unless surgery or radiation therapy is not appropriate for the patient.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

SOVALDI

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Criteria will be applied consistent with current AASLD-IDSA guidance.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Refer to the document, "Recommendations for Testing, Managing, and Treating Hepatitis C," by AASLD-IDSA available at <http://www.hcvguidelines.org> for drug regimen and duration of treatment based on genotype, treatment status, previous drug regimens used, past medical history and comorbidities.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a gastroenterologist, hepatologist or infectious disease physician.

#### **Coverage Duration:**

Criteria will be applied consistent with current AASLD-IDSA guidance.

#### **Other Criteria:**

Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Mavyret, Harvoni, Epclusa, Vosevi, and Zepatier for applicable genotypes.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

SPRAVATO

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Currently on an oral antidepressant (must not be an agent previously tried and failed). CONTINUATION OF THERAPY: Member is responding positively to therapy and is using Spravato in combination with an oral antidepressant.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

Initial: 4 weeks. Reauthorization: 6 months.

#### **Other Criteria:**

Failure of two antidepressants (e.g., selective serotonin reuptake inhibitor [SSRI], serotonin-norepinephrine reuptake inhibitor [SNRI], tricyclic antidepressant [TCA], bupropion, mirtazapine) from two different classes, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

SPRITAM

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

Medical justification must be provided why patient cannot take generic levetiracetam tablets or liquid.

## Prior Authorization Protocol

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### Medicare Part D – 2020

#### **Prior Authorization Group Description:**

SPRYCEL

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

CHRONIC MYELOGENOUS LEUKEMIA, ACUTE LYMPHOBLASTIC LEUKEMIA: Confirmation that the member has Philadelphia chromosome positive disease.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

CHRONIC MYELOGENOUS LEUKEMIA, ACUTE LYMPHOBLASTIC LEUKEMIA: Prescribed by or in consultation with an oncologist or hematologist. ALL OTHER COVERED ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

GASTROINTESTINAL STROMAL TUMOR: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: imatinib, Sutent or Stivarga.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

STELARA IV

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a gastroenterologist.

#### **Coverage Duration:**

4 weeks.

#### **Other Criteria:**

CROHN'S DISEASE: Failure of Humira or Remicade and one of the following, unless contraindicated or clinically significant adverse effects are experienced: 6-mercaptopurine, azathioprine or methotrexate.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

STELARA SC

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

PSORIATIC ARTHRITIS, PLAQUE PSORIASIS: Prescribed by or in consultation with a rheumatologist or dermatologist. CROHN'S DISEASE, ULCERATIVE COLITIS: Prescribed by or in consultation with a gastroenterologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

PLAQUE PSORIASIS: Failure of ONE of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, cyclosporine, or acitretin. PSORIATIC ARTHRITIS: Failure of one TNF inhibitor (e.g., Humira, Enbrel, Cimzia, Simponi, Simponi Aria, Remicade, Inflectra), unless contraindicated or clinically significant adverse effects are experienced.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

STIVARGA

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

STRENSIQ

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2020

**Prior Authorization Group Description:**

SUBSYS

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

Age 18 or greater.

**Prescriber Restrictions:**

**Coverage Duration:**

Through the end of the Plan contract year.

**Other Criteria:**

Patient is already taking and is tolerant to around-the-clock opioid therapy. Patients are considered opioid tolerant when taking another opioid daily for a week or longer (for example, at least 60 mg of oral morphine per day or an equianalgesic dose of another opioid).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

SUNOSI

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

NARCOLEPSY: Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

Failure of armodafinil (Nuvigil) or modafinil (Provigil), unless contraindicated or clinically significant side effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

SURMONTIL

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Irritable bowel syndrome.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

##### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

##### **Prescriber Restrictions:**

##### **Coverage Duration:**

12 months.

##### **Other Criteria:**

Depression: Failure of one of the following generic antidepressants, unless contraindicated or clinically significant adverse effects are experienced: bupropion, bupropion SR, bupropion XL, citalopram, desvenlafaxine succinate, duloxetine, escitalopram, fluoxetine, mirtazapine, sertraline, venlafaxine, or venlafaxine XR.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

SYMDEKO

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Presence of homozygous F508del mutation or at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor.

#### **Age Restrictions:**

Age greater than or equal to 6 years.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

SYMLINPEN

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

Previous use of mealtime insulin therapy or an insulin pump.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

SYMPAZAN

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Medical justification supports inability to use clobazam tablets and oral suspension (e.g., contraindications to excipients).



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TABRECTA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

NON-SMALL CELL LUNG CANCER: Disease is epidermal growth factor receptor (EGFR) wild-type and anaplastic lymphoma kinase (ALK) negative.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

ALL ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2020

#### **Prior Authorization Group Description:**

TAFAMIDIS

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

TRANSTHYRETIN AMYLOID CARDIOMYOPATHY (ATTR-CM): Member has not had a liver transplant. Diagnosis is supported by (a or b): a) Confirmation of amyloid deposition on biopsy and either transthyretin (TTR) precursor protein (e.g., by immunohistochemistry, scintigraphy, mass spectrometry) or a TTR mutation by genetic testing. b) Member meets all of the following (i, ii, and iii): i) Echo, CMR, or PET findings are consistent with cardiac amyloidosis, AND ii) Cardiac uptake is Grade 2 or 3 on a radionuclide scan utilizing one of the following radiotracers (1, 2, or 3): 1) 99m technetium (Tc)-labeled 3,3-diphosphono-1,2-propanodicarboxylic acid (DPD), 2) 99mTc-labeled pyrophosphate (PYP), or 3) 99mTc-labeled hydroxymethylene diphosphonate (HMDP), AND iii) Each of the following laboratory tests is negative for monoclonal protein (1, 2, and 3): 1) Serum kappa/lambda free light chain ratio analysis, 2) Serum protein immunofixation, 3) Urine protein immunofixation. CONTINUATION OF THERAPY, ATTR-CM: Maintained on therapy with positive response, including but not limited to, improvement or stabilization in any of the following parameters: 1) walking ability, 2) nutrition (e.g., body mass index), 3) cardiac related hospitalization, 4) cardiac procedures or laboratory tests (e.g., Holter monitoring, echocardiography, electrocardiogram, plasma BNP or NT-proBNP, serum troponin).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a cardiologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TAGRISSO

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

NON-SMALL CELL LUNG CANCER: Disease is positive for either of the following (a or b): a) sensitizing EGFR mutation (e.g., exon 19 deletion or insertion, exon 21 point mutation (L858R, L861Q), exon 18 point mutation (G719X), exon 20 point mutation (S768I)), OR b) T790M mutation.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

TAKHZYRO

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

Age greater than or equal to 12 years.

**Prescriber Restrictions:**

Prescribed by or in consultation with an immunologist, allergist, hematologist, or rheumatologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TALZENNA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Confirmation of human epidermal growth factor receptor 2 (HER2)-negative disease and mutation in the BRCA genes.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TARCEVA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

NON-SMALL CELL LUNG CANCER: Disease is positive for a sensitizing EGFR mutation (e.g., exon 19 deletion or insertion, exon 21 point mutation (L858R, L861Q), exon 18 point mutation (G719X), exon 20 point mutation (S768I)). RENAL CELL CARCINOMA: Confirmation of non-clear cell histology.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

PANCREATIC CANCER: Prescribed in combination with gemcitabine.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TARGRETIN GEL

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D. Some medically-accepted indications.

#### **Off Label Uses:**

Primary cutaneous B-cell lymphoma types: primary cutaneous marginal zone lymphoma and primary cutaneous follicle center lymphoma.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

ALL ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TASIGNA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

CHRONIC MYELOGENOUS LEUKEMIA, ACUTE LYMPHOBLASTIC LEUKEMIA: Confirmation that the member has Philadelphia chromosome positive disease.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

CHRONIC MYELOGENOUS LEUKEMIA, ACUTE LYMPHOBLASTIC LEUKEMIA: Prescribed by or in consultation with an oncologist or hematologist. GASTROINTESTINAL STROMAL TUMOR: Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

GASTROINTESTINAL STROMAL TUMOR: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: imatinib, Sutent or Stivarga.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TAVALISSE

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of a corticosteroid (e.g., prednisone, methylprednisolone, or dexamethasone), unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TAZVERIK

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

EPITHELIOID SARCOMA: Tumor demonstrates loss of INI1 expression through inactivation, deletion, or mutation of the INI1 (SMARCB-1) gene.

#### **Age Restrictions:**

EPITHELIOID SARCOMA: Age 16 years or older.

#### **Prescriber Restrictions:**

FOLLICULAR LYMPHOMA: Prescribed by or in consultation with an oncologist or hematologist. EPITHELIOID SARCOMA: Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TECENTRIQ

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

EXTENSIVE-STAGE SMALL CELL LUNG CANCER: Prescribed in combination with carboplatin and etoposide. TRIPLE NEGATIVE BREAST CANCER: Hormone-receptor (HR)-negative, estrogen-receptor (ER)-negative, and human epidermal growth factor receptor 2 (HER2)-negative disease. Prescribed in combination with protein-bound paclitaxel (nab-paclitaxel). Tumor expresses PD-L1.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

NON-SMALL CELL LUNG CANCER: If a known epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberration exists, then for ALK+ disease: prior trial of Xalkori, Alecensa, or Zykadia OR for EGFR+ disease: prior trial of Tarceva, Gilotrif, or Iressa.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

TECFIDERA

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2020

#### **Prior Authorization Group Description:**

TEGSEDI

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Confirmation of transthyretin (TTR) mutation. Confirmation of amyloid deposition on biopsy or medical justification is provided as to why treatment should be initiated in the presence of a negative biopsy or no biopsy. Member has not had a liver transplant. CONTINUATION OF THERAPY: Maintained on therapy with positive response, including but not limited to improvement in any of the following parameters: 1) neuropathy (motor function, sensation, reflexes, walking ability), 2) nutrition (body mass index), 3) cardiac parameters (Holter monitoring, echocardiography, electrocardiogram, plasma BNP or NT-proBNP, serum troponin), 4) renal parameters (creatinine clearance, urine albumin), 5) ophthalmic parameters (eye exam).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2020

#### **Prior Authorization Group Description:**

TENEX

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: amlodipine/benazepril, benazepril, benazepril/hydrochlorothiazide, captopril, captopril/hydrochlorothiazide, fosinopril, fosinopril/hydrochlorothiazide, lisinopril, lisinopril/hydrochlorothiazide, quinapril, quinapril/hydrochlorothiazide, losartan, losartan/hydrochlorothiazide, valsartan, valsartan/hydrochlorothiazide, irbesartan, irbesartan/hydrochlorothiazide, candesartan, candesartan/hydrochlorothiazide, carvedilol, labetalol, acebutolol, atenolol, bisoprolol, bisoprolol/hydrochlorothiazide, timolol, nadolol, propranolol, metoprolol, metoprolol/hydrochlorothiazide, pindolol, nifedipine SR, amlodipine, nicardipine.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TEPEZZA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

THYROID EYE DISEASE (TED): Member has active TED with a clinical activity score (CAS) of at least 4 or greater. Member is euthyroid with confirmation of a recent (within the last 30 days) free thyroxine (FT4) and free triiodothyronine (FT3) levels within the laboratory defined reference range. Member has not had previous surgical intervention for TED. Member does not require surgical ophthalmological intervention. Member has not received 8 or more infusions lifetime (including the initial 10 mg/kg first infusion). CONTINUATION OF THERAPY, TED: Member is responding positively to therapy as evidenced by both of the following (a and b): a) at least a 2 mm or greater reduction in proptosis AND b) at least a 2 point or greater reduction in CAS from baseline. Member does not require surgical ophthalmological intervention. Member has not received 8 or more infusions lifetime (including the initial 10 mg/kg first infusion).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

TED: Prescribed by or in consultation with an ophthalmologist.

#### **Coverage Duration:**

6 months.

#### **Other Criteria:**

TED: Failure of a systemic corticosteroid, unless clinically significant adverse effects are experienced or all are contraindicated.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

TETRABENAZINE

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

12 months.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TIBSOVO

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Presence of an isocitrate dehydrogenase-1 (IDH1) mutation. For newly diagnosed acute myeloid leukemia (AML), member is age 60 years or older OR medical justification supports inability to use intensive induction therapy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

For age less than 60 years where medical justification does not support inability to use intensive induction therapy, disease has relapsed or is refractory following treatment with standard antineoplastic induction agents (e.g., cytarabine, idarubicin, daunorubicin, cladribine, midostaurin).

## Prior Authorization Protocol

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### Medicare Part D – 2020

**Prior Authorization Group Description:**

TOLSURA

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

Hematologic malignancy for prophylaxis of aspergillosis or candidiasis.

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

HISTOPLASMOSIS: 6 weeks. ASPERGILLOSIS: 3 months. BLASTOMYCOSIS, HEMATOLOGIC MALIGNANCY: 6 months.

**Other Criteria:**

ALL INDICATIONS: Failure of generic itraconazole capsule, unless contraindicated or clinically significant adverse effects are experienced. ASPERGILLOSIS: Failure of voriconazole, unless contraindicated or clinically significant adverse effects are experienced. HEMATOLOGIC MALIGNANCY: For candidiasis prophylaxis, failure of fluconazole, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TREMFYA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a rheumatologist or dermatologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of ONE of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, cyclosporine, or acitretin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TRIHEXYPHENIDYL

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

Prior authorization is required for patients 65 years and older. Prior authorization is not required for patients 64 years and younger.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Parkinsons disease/Parkinsonism: Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: amantadine, levodopa/carbidopa, entacapone, pramipexole, ropinirole, selegiline.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TRIKAFTA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

CYSTIC FIBROSIS: Diagnosis of cystic fibrosis (CF) confirmed by both of the following (a and b): a) Clinical symptoms consistent with CF in at least one organ system, or positive newborn screen or genetic testing for siblings of patients with CF, AND b) Evidence of cystic fibrosis transmembrane conductance regulator (CFTR) dysfunction confirmed by one of the following (i or ii): i) Evidence of clinical severity as defined by an average sweat chloride greater than 60 mmol/L, OR ii) Genetic testing confirming the presence of two disease-causing mutations in CFTR gene, one from each parent allele, and one of which is a F508del mutation. Confirmation that pulmonary function tests, performed within the last 90 days, show a percent predicted forced expiratory volume in 1 second (ppFEV1) that is between 40-90%. Trikafta is not prescribed concurrently with other CFTR modulators (e.g., Orkambi, Kalydeco, Symdeko). CONTINUATION OF THERAPY, CYSTIC FIBROSIS: For members that received at least 12 weeks of therapy, member is responding positively to therapy as evidenced by stabilization in ppFEV1 if baseline was 70% or greater or increase in ppFEV1 if baseline was less than 70%.

#### **Age Restrictions:**

CYSTIC FIBROSIS: Age greater than or equal to 12 years.

#### **Prescriber Restrictions:**

CYSTIC FIBROSIS: Prescribed by or in consultation with a pulmonologist.

#### **Coverage Duration:**

Initial: 4 months. Reauthorization: 12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

TUKYSA

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

ALL ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

TURALIO

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TYMLOS

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Total duration of therapy on parathyroid hormone (PTH) analogs (e.g., Tymlos, Forteo) has not exceeded 2 years.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Member meets one of the following (a, b, or c): a) Failure of a bisphosphonate (e.g., alendronate) unless contraindicated or clinically significant adverse effects are experienced. OR b) Bone mineral density T-score at hip or spine is -3.5 or less. OR c) Bone mineral density T-score at hip or spine is -2.5 or less with a history of major osteoporotic fracture of the hip, spine, forearm, wrist, or humerus.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

TYSABRI

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

MULTIPLE SCLEROSIS: Prescribed by or in consultation with a neurologist. CROHN'S DISEASE: Prescribed by or in consultation with a gastroenterologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

RELAPSING-REMITTING MULTIPLE SCLEROSIS: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Aubagio, Tecfidera, Gilenya, Avonex, Betaseron, Plegridy, glatiramer, Copaxone, Glatopa, Extavia or Rebif. CROHN'S DISEASE: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Humira or Remicade.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

UPTRAVI

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

VALCHLOR

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of one of the following skin-directed therapies unless contraindicated or clinically significant adverse effects are experienced: topical corticosteroid (e.g., betamethasone, clobetasol), topical retinoid (e.g., Targretin, Avage, Fabior, Tazorac), topical imiquimod (Aldara).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

VALTOCO

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Diagnosis of partial or generalized epilepsy.

#### **Age Restrictions:**

6 years of age or older.

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Medical justification supports inability to use diazepam rectal gel (e.g., contraindications to excipients).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

VANCOGIN

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

C. Diff diarrhea: 14 days. Staph enterocolitis: 10 days. Recurrent C. Diff: 12 weeks.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

VENCLEXTA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

AML: Age 60 years or greater, OR medical justification supports inability to use intensive induction chemotherapy. Prescribed in combination with azacitidine, decitabine, or low-dose cytarabine.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

MANTLE CELL LYMPHOMA: Failure of at least one previous therapy (e.g., a Rituxan based regimen), unless contraindicated or clinically significant adverse effects are experienced. CLL/SLL: Request meets one of the following (a or b): a) Prescribed in combination with Gazyva as first-line therapy OR b) Failure of at least one previous therapy (e.g., Imbruvica, Campath, or high-dose methylprednisolone with Rituxan), unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

VERSACLOZ

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Psychotic disorder associated with Parkinson's disease.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of clozapine (Clozaril) or FazaClo, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

VERZENIO

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Prescribed as a single agent or in combination with an aromatase inhibitor (e.g., letrozole, anastrozole or exemestane) or fulvestrant. For men receiving an aromatase inhibitor: Prescribed in combination with an agent that suppresses testicular steroidogenesis (e.g., gonadotropin-releasing hormone agonists).



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

VINBLASTINE

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Confirmation that vinblastine is being used as palliative therapy.

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

VINCRIStINE

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

Patients with the demyelinating form of Charcot-Marie-Tooth syndrome.

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

VITRAKVI

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

Known acquired tropomyosin receptor kinase resistance mutation.

**Required Medical Information:**

Confirmation of positive neurotrophic receptor tyrosine kinase gene fusion mutation.

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

VIZIMPRO

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Disease is positive for a sensitizing EGFR mutation (e.g., exon 19 deletion or insertion, exon 21 point mutation (L858R, L861Q), exon 18 point mutation (G719X), exon 20 point mutation (S768I)).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

VOSEVI

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

If cirrhosis is present, confirmation of Child-Pugh A status. Refer to the document, "Recommendations for Testing, Managing, and Treating Hepatitis C," by AASLD-IDSAs available at <http://www.hcvguidelines.org> for drug regimen and duration of treatment based on genotype, treatment status, previous drug regimens used, past medical history and comorbidities.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a gastroenterologist, hepatologist or infectious disease physician.

#### **Coverage Duration:**

12 weeks.

#### **Other Criteria:**

Criteria will be applied consistent with current AASLD-IDSAs guidance.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

VOTRIENT

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

VRAYLAR

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of TWO of the following atypical antipsychotics, unless contraindicated or clinically significant adverse effects are experienced: aripiprazole, ziprasidone, quetiapine, olanzapine, risperidone.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

VUMERITY

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

MULTIPLE SCLEROSIS: Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

12 months.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

VYONDYS 53

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

DUCHENNE MUSCULAR DYSTROPHY (DMD): DMD with mutation amenable to exon 53 skipping confirmed by genetic testing.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

DMD: Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

6 months.

#### **Other Criteria:**

DMD: Currently stable on an oral corticosteroid regimen (e.g., prednisone), unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

WAKIX

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

NARCOLEPSY: Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

NARCOLEPSY: Failure of Sunosi, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

XALKORI

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

NON-SMALL CELL LUNG CANCER: Disease is ALK, ROS1, or MET positive. INFLAMMATORY MYOFIBROBLASTIC TUMOR, ANAPLASTIC LARGE CELL LYMPHOMA: Disease is ALK-positive.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

XATMEP

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

##### **Age Restrictions:**

Less than 18 years of age.

##### **Prescriber Restrictions:**

ACUTE LYMPHOCYTIC LEUKEMIA: Prescribed by or in consultation with an oncologist or hematologist.  
POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist.

##### **Coverage Duration:**

12 months.

##### **Other Criteria:**

Medical justification as to why member cannot use methotrexate tablets.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

XCOPRI

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of two of the following generic antiepileptic drugs, unless contraindicated or clinically significant adverse effects are experienced: lamotrigine, topiramate, oxcarbazepine, carbamazepine, phenytoin, valproic acid, divalproex sodium, felbamate, gabapentin, levetiracetam, pregabalin, tiagabine, zonisamide.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

XELJANZ

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

RHEUMATOID ARTHRITIS: Prescribed by or in consultation with a rheumatologist. PSORIATIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist or dermatologist. ULCERATIVE COLITIS (IMMEDIATE-RELEASE ONLY): Prescribed by or in consultation with a gastroenterologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, sulfasalazine, hydroxychloroquine, d-penicillamine, azathioprine or auranofin. PSORIATIC ARTHRITIS: Failure of one TNF inhibitor (e.g., Humira, Enbrel, Cimzia, Simponi, Simponi Aria, Remicade, Inflectra), unless predominantly axial disease, contraindicated, or clinically significant adverse effects are experienced.

## Prior Authorization Protocol

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### Medicare Part D – 2020

#### **Prior Authorization Group Description:**

XENLETA

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Request is for continuation of therapy initiated in an acute care hospital from which member was discharged OR culture and sensitivity (C&S) report for the current infection shows isolated pathogen is an organism susceptible to Xenleta, unless provider confirms that obtaining a C&S report is not feasible.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

7 days.

#### **Other Criteria:**

For members initiating Xenleta therapy outside of an acute care hospital, one of the following (a, b, or c): a) If a C&S report is available: Failure of 2 antibiotics to which the isolated pathogen is susceptible (if available) per C&S report, unless all are contraindicated or clinically significant adverse effects are experienced. b) C&S report shows resistance or lack of susceptibility of the isolated pathogen to all formulary antibiotics FDA-approved for member's diagnosis. c) If provider confirms that obtaining a C&S report is not feasible: Failure of 2 antibiotics indicated for member's diagnosis (if available), unless all are contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

XEOMIN

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

12 months.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

XERMELO

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

Prescribed in combination with a somatostatin analog (e.g., octreotide, lanreotide) unless contraindicated or clinically significant adverse effects are experienced.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Failure of a somatostatin analog (e.g., octreotide, lanreotide) unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

XOLAIR

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

ASTHMA: Positive skin test or in vitro reactivity to a perennial aeroallergen AND immunoglobulin E (IgE) level greater than or equal to 30 IU/mL.

#### **Age Restrictions:**

ASTHMA: 6 years of age or older. CHRONIC IDIOPATHIC URTICARIA: 12 years of age or older.

#### **Prescriber Restrictions:**

ASTHMA: Prescribed by or in consultation with a pulmonologist, immunologist, or allergist. CHRONIC IDIOPATHIC URTICARIA: Prescribed by or in consultation with an allergist, dermatologist, or immunologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

ASTHMA: Failure of one inhaled corticosteroid (e.g., beclomethasone, budesonide, flunisolide, fluticasone, mometasone, ciclesonide), unless contraindicated or clinically significant adverse effects are experienced.  
CHRONIC IDIOPATHIC URTICARIA: Failure of one H1 Antihistamine (e.g., levocetirizine or desloratadine), unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

XOSPATA

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Confirmation of the presence of a FLT3 mutation.

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

XPOVIO

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

MULTIPLE MYELOMA: Member has received at least 4 prior lines of therapy that include all of the following (a, b, and c): a) Two proteasome inhibitors (e.g., bortezomib, Kyprolis, Ninlaro), b) Two immunomodulatory agents (e.g., Revlimid, pomalidomide, Thalomid), c) One anti-CD38 monoclonal antibody (e.g., Darzalex).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or hematologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

---

### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

XTANDI

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

PROSTATE CANCER: Concurrent use of a gonadotropin-releasing hormone (GnRH) analog or past bilateral orchiectomy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or urologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

YERVOY

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

HEPATOCELLULAR CARCINOMA (new starts only): Member has not had previous treatment with a checkpoint inhibitor (e.g., Opdivo, Keytruda, Tecentriq, Imfinzi). NON-SMALL CELL LUNG CANCER (new starts only): Member has not previously progressed on a PD-1/PD-L1 inhibitor (e.g., Opdivo, Keytruda, Tecentriq, Imfinzi).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

SMALL CELL LUNG CANCER, MALIGNANT PLEURAL MESOTHELIOMA: Failure of a platinum-containing regimen (e.g., cisplatin, carboplatin), unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

YONSA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or urologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Medical justification supports inability to use Zytiga. Prescribed in combination with methylprednisolone. Member has previously had bilateral orchiectomy, failed androgen deprivation therapy (ADT) or will use ADT concurrently with Yonsa.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

ZALTRAP

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Prescribed in combination with irinotecan or FOLFIRI (5-fluorouracil, leucovorin, and irinotecan). Previous treatment with one of the following: oxaliplatin-containing regimen (e.g., FOLFIRI, FOLFOX [leucovorin, 5-fluorouracil, oxaliplatin], CapeOX [capecitabine, oxaliplatin]) OR 5-fluorouracil and leucovorin containing regimen OR capecitabine containing regimen.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

ZARXIO

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

Myelodysplastic syndrome. Neutropenia in patients with HIV/AIDS. Hematopoietic syndrome of acute radiation syndrome.

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

## **Prior Authorization Protocol**

---

### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

ZEJULA

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

OVARIAN, FALLOPIAN, OR PRIMARY PERITONEAL CANCER: Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2020

#### **Prior Authorization Group Description:**

ZELBORAF

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

MELANOMA, ERDHEIM-CHESTER DISEASE: Positive for the BRAF V600 mutation. NON-SMALL CELL LUNG CANCER, COLORECTAL CANCER: Positive for the BRAF V600E mutation. DIFFERENTIATED THYROID CARCINOMA: Positive for the BRAF mutation.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

ERDHEIM-CHESTER DISEASE, HAIRY CELL LEUKEMIA: Prescribed by or in consultation with an oncologist or hematologist. ALL OTHER ONCOLOGY INDICATION: Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

NON-SMALL CELL LUNG CANCER: Failure of Tafenlar or Mekinist, unless contraindicated or clinically significant adverse effects are experienced. COLORECTAL CANCER: Failure of irinotecan or platinum-based therapy (e.g., oxaliplatin), unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

ZEPATIER

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

If cirrhosis is present, confirmation of Child-Pugh A status. For genotype 1a, confirmation of presence or absence of NS5A resistance-associated polymorphisms. Refer to the document, "Recommendations for Testing, Managing, and Treating Hepatitis C," by AASLD-IDSA available at <http://www.hcvguidelines.org> for drug regimen and duration of treatment based on genotype, treatment status, previous drug regimens used, past medical history and comorbidities.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with a gastroenterologist, hepatologist or infectious disease physician.

#### **Coverage Duration:**

12 to 16 wks based on genotype,presence of NS5A resistance-associated polymorphisms,prior treatment.

#### **Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2020

**Prior Authorization Group Description:**

ZINPLAVA

**Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

Confirmation of positive Clostridium difficile test.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

4 weeks.

**Other Criteria:**

Will receive or is currently receiving antibacterial drug treatment for Clostridium difficile infection (e.g., metronidazole, vancomycin, fidaxomicin) concomitantly with Zinplava. Has received appropriate treatment for past CDI recurrences, including a pulsed vancomycin regimen.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

ZULRESSO

#### **Prior Authorization Indication:**

All FDA-approved indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

No more than 6 months have passed since member has given birth.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

4 weeks.

#### **Other Criteria:**

Failure of one of the following oral antidepressants, unless contraindicated or clinically significant adverse effects are experienced: selective serotonin reuptake inhibitor (SSRI), serotonin-norepinephrine reuptake inhibitor (SNRI), tricyclic antidepressant (TCA), bupropion, mirtazapine.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

ZYDELIG

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with a hematologist or oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

**Prior Authorization Group Description:**

ZYKADIA

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

NON-SMALL CELL LUNG CANCER: Disease is ALK or ROS1 positive. If disease is ROS1 positive, Zykadia is prescribed as first-line therapy. INFLAMMATORY MYOFIBROBLASTIC TUMOR: Disease is ALK-positive.

**Age Restrictions:**

**Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

12 months.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2020**

#### **Prior Authorization Group Description:**

ZYTIGA

#### **Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

#### **Off Label Uses:**

#### **Exclusion Criteria:**

#### **Required Medical Information:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

Prescribed by or in consultation with an oncologist or urologist.

#### **Coverage Duration:**

12 months.

#### **Other Criteria:**

Prescribed in combination with prednisone. Member has previously had bilateral orchiectomy, failed androgen deprivation therapy (ADT) or will use ADT concurrently with abiraterone.

ACTEMRA SC	1	CLADRIBINE	48
ACTIQ	2	CLOMIPRAMINE	49
ACYCLOVIR	3	COMETRIQ	50
ADAKVEO	4	COPIKTRA	51
ADCIRCA	5	COTELLIC	52
ADEMPAS	6	CRYSVITA	53
AFINITOR	7	CYCLOBENZAPRINE HCL	54
AIMOVIG	8	CYTARABINE	55
AJOVY	9	DAURISMO	56
ALECENSA	10	DICLOFENAC GEL	57
ALUNBRIG	11	DIPYRIDAMOLE	58
AMITRIPTYLINE	12	DISOPYRAMIDE	59
AMITRIPTYLINE/CHLORDIAZEPOXIDE	13	DOPTELET	60
AMITRIPTYLINE/PERPHENAZINE	14	DOXEPIN	61
AMPHOTERICIN B	15	DOXEPIN CREAM	62
AMPYRA	16	ELIDEL	63
ANTI-HISTAMINES	17	EMEND 40 MG	64
ANTI-HISTAMINE COMBINATIONS	18	EMFLAZA	65
ARANESP	19	EMGALITY	66
ARIKAYCE	20	ENBREL	67
AUBAGIO	21	ENDARI	68
AYVAKIT	22	ENTYVIO	69
BALVERSA	23	EPCLUSA	70
BAXDELA	24	EPIDIOLEX	71
BELEODAQ	25	EPOETIN	72
BELSOMRA	26	ERGOLOID MESYLATES	73
BENLYSTA	27	ERLEADA	74
BENZTROPINE	28	ESBRIET	75
BEOVU	29	ESTROGENS(Divigel , Climara , Mimvey , Prempro , Amabelz , Estrace , Activella , Femhrt , Mimvey Lo , Lopreeza , Premarin , Premphase )	76
BLEOMYCIN	30	EXONDYS 51	77
BOSULIF	31	FARYDAK	78
BOTOX	32	FASENRA	79
BRAFTOVI	33	FERRIPROX	80
BRIVIACT	34	FINTEPLA	81
BRUKINSA	35	FIORINAL WITH CODEINE	82
C1 ESTERASE INHIBITOR	36	FIRAZYR	83
CABLIVI	37	FIRDAPSE	84
CABOMETYX	38	FLECTOR	85
CALQUENCE	39	FLUOROURACIL	86
CAPLYTA	40	FORTEO	87
CAPRELSA	41	GALAFOLD	88
CAYSTON	42	GANCICLOVIR	89
CERDELGA	43	GATTEX	90
CEREZYME	44	GAVRETO	91
CHLORZOXAZONE	45	GILENYA	92
CHORIONIC GONADOTROPIN	46		
CINQAIR	47		

GILOTRIF . . . . .	93	LIDODERM . . . . .	140
GLATIRAMER . . . . .	94	LONSURF . . . . .	141
GLIMEPIRIDE . . . . .	95	LORBRENA . . . . .	142
GLYBURIDE . . . . .	96	LOTRONEX . . . . .	143
GLYBURIDE/METFORMIN . . . . .	97	LUCEMYRA . . . . .	144
GRANIX . . . . .	98	LYNPARZA TABLET . . . . .	145
HARVONI . . . . .	99	MAVENCLAD . . . . .	146
HERCEPTIN . . . . .	100	MAVYRET . . . . .	147
HETLIOZ . . . . .	101	MAYZENT . . . . .	148
HUMAN GROWTH HORMONE . . . . .	102	MEGACE . . . . .	149
HUMIRA . . . . .	103	MEGACE ES . . . . .	150
HYDROCODONE . . . . .	104	MEKINIST . . . . .	151
HYDROXYZINE HCL INJECTION . . . . .	105	MEKTOVI . . . . .	152
HYDROXYZINE HCL ORAL . . . . .	106	METAXALONE . . . . .	153
HYDROXYZINE PAMOATE . . . . .	107	METHAMPHETAMINE . . . . .	154
ICLUSIG . . . . .	108	METHOCARBAMOL . . . . .	155
IDHIFA . . . . .	109	METHOTREXATE INJ . . . . .	156
ILARIS . . . . .	110	MIRVASO . . . . .	157
ILUMYA . . . . .	111	MOZOBIL . . . . .	158
IMATINIB . . . . .	112	MULPLETA . . . . .	159
IMBRUVICA . . . . .	113	NAMENDA . . . . .	160
IMIPRAMINE . . . . .	114	NATPARA . . . . .	161
INDOMETHACIN . . . . .	115	NAYZILAM . . . . .	162
INFLECTRA . . . . .	116	NERLYNX . . . . .	163
INGREZZA . . . . .	117	NEULASTA . . . . .	164
INLYTA . . . . .	118	NEUPOGEN . . . . .	165
INQOVI . . . . .	119	NINLARO . . . . .	166
INREBIC . . . . .	120	NIVESTYM . . . . .	167
INTERFERON BETA-1A . . . . .	121	NONPREFERRED . . . . .	168
INTERFERON BETA-1B . . . . .	122	NORTHERA . . . . .	169
INTUNIV . . . . .	123	NUBEQA . . . . .	170
JAKAFI . . . . .	124	NUCALA . . . . .	171
JUXTAPID . . . . .	125	NUEDEXTA . . . . .	172
JYNARQUE . . . . .	126	NUPLAZID . . . . .	173
KADCYLA . . . . .	127	NUZYRA . . . . .	174
KALYDECO . . . . .	128	OCALIVA . . . . .	175
KETOROLAC TROMETHAMINE . . . . .	129	OCREVUS . . . . .	176
KEVZARA . . . . .	130	ODOMZO . . . . .	177
KISQALI(Kisqali Femara Co-Pack , Kisqali ) . . . . .	131	OFEV . . . . .	178
KORLYM . . . . .	132	OLUMIANT . . . . .	179
KOSELUGO . . . . .	133	ONUREG . . . . .	180
KUVAN . . . . .	134	OPSUMIT . . . . .	181
LATUDA . . . . .	135	ORENITRAM . . . . .	182
LAZANDA . . . . .	136	ORILISSA . . . . .	183
LEMTRADA . . . . .	137	ORKAMBI . . . . .	184
LENVIMA . . . . .	138	OXBRYTA . . . . .	185
LEUKINE . . . . .	139	OXERVATE . . . . .	186

PALYNZIQ . . . . .	187	STRENSIQ . . . . .	234
PEMAZYRE . . . . .	188	SUBSYS . . . . .	235
PENNSAID . . . . .	189	SUNOSI . . . . .	236
PERSERIS . . . . .	190	SURMONTIL . . . . .	237
PHENOBARBITAL . . . . .	191	SYMDEKO . . . . .	238
PIQRAY . . . . .	192	SYMLINPEN . . . . .	239
PRALUENT . . . . .	193	SYMPAZAN . . . . .	240
PRETOMANID . . . . .	194	TABRECTA . . . . .	241
PREVYMIS . . . . .	195	TAFAMIDIS . . . . .	242
PROLASTIN C . . . . .	196	TAGRISSE . . . . .	243
PROLIA . . . . .	197	TAKHZYRO . . . . .	244
PROMACTA . . . . .	198	TALZENNA . . . . .	245
PROTOPIC . . . . .	199	TARCEVA . . . . .	246
PROVIGIL . . . . .	200	TARGRETIN GEL . . . . .	247
PURIXAN . . . . .	201	TASIGNA . . . . .	248
QINLOCK . . . . .	202	TAVALISSE . . . . .	249
QUALAQUIN . . . . .	203	TAZVERIK . . . . .	250
RADICAVA . . . . .	204	TECENTRIQ . . . . .	251
RAYALDEE . . . . .	205	TECFIDERA . . . . .	252
REBLOZYL . . . . .	206	TEGSEDI . . . . .	253
REMICADE . . . . .	207	TENEX . . . . .	254
RENFLEXIS . . . . .	208	TEPEZZA . . . . .	255
REPATHA . . . . .	209	TETRABENAZINE . . . . .	256
RETEVMO . . . . .	210	TIBSOVO . . . . .	257
REVATIO . . . . .	211	TOLSURA . . . . .	258
REVCIVI . . . . .	212	TREMFYA . . . . .	259
REVLIMID . . . . .	213	TRIHENXYPHENIDYL . . . . .	260
REXULTI . . . . .	214	TRIKAFTA . . . . .	261
RINVOQ . . . . .	215	TUKYSA . . . . .	262
ROZLYTREK . . . . .	216	TURALIO . . . . .	263
RUBRACA . . . . .	217	TYMLOS . . . . .	264
RUZURGI . . . . .	218	TYSABRI . . . . .	265
RYDAPT . . . . .	219	UPTRAVI . . . . .	266
SECUADO . . . . .	220	VALCHLOR . . . . .	267
SILIQ . . . . .	221	VALTOCO . . . . .	268
SIMPONI(prefilled syringe, auto-injector) . . . . .	222	VANCOCIN . . . . .	269
SIMPONI ARIA . . . . .	223	VENCLEXTA . . . . .	270
SKYRIZI . . . . .	224	VERSACLOZ . . . . .	271
SOMA . . . . .	225	VERZENIO . . . . .	272
SOMAVERT . . . . .	226	VINBLASTINE . . . . .	273
SOVALDI . . . . .	227	VINCRISTINE . . . . .	274
SPRAVATO . . . . .	228	VITRAKVI . . . . .	275
SPRITAM . . . . .	229	VIZIMPRO . . . . .	276
SPRYCEL . . . . .	230	VOSEVI . . . . .	277
STELARA IV . . . . .	231	VOTRIENT . . . . .	278
STELARA SC . . . . .	232	VRAYLAR . . . . .	279
STIVARGA . . . . .	233	VUMERITY . . . . .	280

VYONDYS 53	281
WAKIX	282
XALKORI	283
XATMEP	284
XCOPRI	285
XELJANZ	286
XENLETA	287
XEOMIN	288
XERMELO	289
XOLAIR	290
XOSPATA	291
XPOVIO	292
XTANDI	293
YERVOY	294
YONSA	295
ZALTRAP	296
ZARXIO	297
ZEJULA	298
ZELBORAF	299
ZEPATIER	300
ZINPLAVA	301
ZULRESSO	302
ZYDELIG	303
ZYKADIA	304
ZYTIGA	305