

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

ABSTRAL

**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:**

End of Plan Year.

**Other Criteria:**

Member is already taking and is tolerant to around-the-clock opioid therapy. Member is 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 – 2021**

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

ACTEMRA 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:**

RHEUMATOID ARTHRITIS (RA): Prescribed by or in consultation with a rheumatologist. JUVENILE IDIOPATHIC ARTHRITIS (JIA): Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist.

#### **Coverage Duration:**

RA, JIA: End of Plan Year. Cytokine Release Syndrome: 3 months.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Humira, Enbrel, Xeljanz.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ACTEMRA SC

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

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

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

#### **Exclusion Criteria:**

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

SYSTEMIC SCLEROSIS - ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD) (initial authorization only): 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).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

RHEUMATOID ARTHRITIS, GIANT CELL ARTERITIS: Prescribed by or in consultation with a rheumatologist. JUVENILE IDIOPATHIC ARTHRITIS: Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist. SSc-ILD: Prescribed by or in consultation with a pulmonologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR. GIANT CELL ARTERITIS (new starts only): Failure of methotrexate or azathioprine, unless contraindicated or clinically significant adverse effects are experienced. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Humira, Enbrel, Xeljanz. SSc-ILD (new starts only): Failure of cyclophosphamide or mycophenolate mofetil, unless clinically significant adverse effects are experienced or both are contraindicated.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ACTHAR HP

#### **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, nephrologist, rheumatologist, dermatologist, ophthalmologist, or allergist/immunologist as appropriate.

#### **Coverage Duration:**

MS,RA,JUVENILE RA,PSORIATIC ARTHRITIS,ANKYLOSING SPONDYLITIS:1 month.All other indications:3 months.

#### **Other Criteria:**

MULTIPLE SCLEROSIS: Member is being treated with a relapsing remitting multiple sclerosis agent (e.g., Avonex, Betaseron, Copaxone, Gilenya) AND Failure of corticosteroid therapy for acute exacerbations of multiple sclerosis, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ACTIQ

#### **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:**

End of Plan Year.

#### **Other Criteria:**

Member is already taking and is tolerant to around-the-clock opioid therapy. Member is 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 – 2021**

**Prior Authorization Group Description:**

ACYCLOVIR

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ADAKVEO

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

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

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

#### **Exclusion Criteria:**

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

SICKLE CELL DISEASE (initial authorization only): 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 of at least 4 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 2 VOC within the past 12 months. Confirmation of baseline incidence of VOC over the last 12 months. Failure of L-glutamine, unless contraindicated or clinically significant adverse effects are experienced. SICKLE CELL DISEASE (continuation of therapy): Member is responding positively to therapy as evidenced by an improvement in the incidence of VOC from baseline prior to initiating therapy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

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

#### **Coverage Duration:**

6 months.

#### **Other Criteria:**

SICKLE CELL DISEASE: Adakveo is prescribed concurrently with hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced. Adakveo is not prescribed concurrently with Oxbryta.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ADEMPAS

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

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

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

#### **Exclusion Criteria:**

Members on concomitant phosphodiesterase (PDE) inhibitors (e.g., sildenafil, tadalafil, vardenafil, dipyridamole or theophylline) or nitrates (e.g., Nitrodur, Nitrobid, Nitrostat, Isordil, Ismo).

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

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

AFINITOR

#### **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. TUBEROUS SCLEROSIS COMPLEX ASSOCIATED PARTIAL ONSET SEIZURES: Prescribed by or in consultation with an oncologist or neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

AIMOVIG

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

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

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

#### **Exclusion Criteria:**

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

MIGRAINE PROPHYLAXIS (new starts only): One of the following (a or b): a) Member experiences 4 or more migraine days per month for at least 3 months, or b) Diagnosis of chronic migraine and Aimovig is prescribed for prophylaxis. MIGRAINE PROPHYLAXIS (continuation of therapy): Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per month from baseline prior to initiating therapy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

MIGRAINE PROPHYLAXIS: Prescribed by or in consultation with a neurologist, headache, or pain specialist.

#### **Coverage Duration:**

Initial authorization: 3 months. Continuation of therapy: 6 months.

#### **Other Criteria:**

MIGRAINE PROPHYLAXIS (new starts only): Failure of two of the following oral migraine preventative therapies, each from different therapeutic classes, unless contraindicated or clinically significant adverse effects are experienced: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

AJOVY

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

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

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

#### **Exclusion Criteria:**

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

MIGRAINE PROPHYLAXIS (new starts only): One of the following (a or b): a) Member experiences 4 or more migraine days per month for at least 3 months, or b) Diagnosis of chronic migraine and Ajoovy is prescribed for prophylaxis. MIGRAINE PROPHYLAXIS (continuation of therapy): Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per month from baseline prior to initiating therapy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

MIGRAINE PROPHYLAXIS: Prescribed by or in consultation with a neurologist, headache or pain specialist.

#### **Coverage Duration:**

Initial authorization: 3 months. Continuation of therapy: 6 months.

#### **Other Criteria:**

MIGRAINE PROPHYLAXIS (new starts only): Failure of two of the following oral migraine preventative therapies, each from different therapeutic classes, unless contraindicated or clinically significant adverse effects are experienced: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

ALECENSA

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ALPHA1-PROTEINASE INHIBITOR

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

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

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

#### **Exclusion Criteria:**

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

ALPHA-1 ANTITRYPSIN (AAT) DEFICIENCY (initial authorization only): Member meets one of the following (a, b, or c): a) Diagnosis of necrotizing panniculitis, b) Confirmation of plasma AAT level less than 11 micromol/L (50 mg/dL using nephelometry or 80 mg/dL by radial immunodiffusion), OR c) If member has an AAT level greater than 11 micromol/L, then the member must have one of the high-risk phenotypes (i.e. PiZZ, PiZnull, Pi(null, null), or one of a few rare phenotypes [e.g. Pi(Malton, Malton)]). For members without necrotizing panniculitis, member demonstrates clinical evidence of emphysema by one of the following (a or b): a) Pre-treatment post-bronchodilator forced expiratory volume in one second (FEV1) from 30% or greater to 65% or less of predicted, OR b) Pre-treatment post-bronchodilator FEV1 from greater than 65% to less than 80% of predicted and a rapid decline in lung function showing a change in FEV1 greater than 100 mL/year.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

AAT DEFICIENCY: Prescribed by or in consultation with a pulmonologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

ALUNBRIG

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

AMANTADINE

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

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

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

#### **Exclusion Criteria:**

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

PARKINSON'S DISEASE, DRUG INDUCED EXTRAPYRAMIDAL REACTIONS (initial authorization only):  
Member meets one of the following (a or b): a) Medical justification supports inability to use immediate-release amantadine OR b) Failure of immediate-release amantadine unless contraindicated or clinically significant adverse effects are experienced.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

AMBRISENTAN

**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:**

PULMONARY ARTERIAL HYPERTENSION: Prescribed by or in consultation with a cardiologist or pulmonologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

AMITRIPTYLINE

#### **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:**

End of Plan Year.

#### **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 – 2021**

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

AMITRIPTYLINE/CHLORDIAZEPOXIDE

#### **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:**

End of Plan Year.

#### **Other Criteria:**

DEPRESSION ASSOCIATED WITH ANXIETY: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: duloxetine, escitalopram, or venlafaxine XR.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

AMITRIPTYLINE/PERPHENAZINE

#### **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:**

End of Plan Year.

#### **Other Criteria:**

DEPRESSION WITH ANXIETY: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: duloxetine, escitalopram, or venlafaxine XR.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

AMPHOTERICIN B

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ABELCET (initial authorization only): Failure of conventional amphotericin B therapy unless contraindicated or clinically significant adverse effects are experienced. AMBISOME (initial authorization only): For requests when treating patients with Aspergillus species, Candida species and/or Cryptococcus species infections, failure of conventional amphotericin B therapy unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

AMPYRA

**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 (MS): Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ANTI-HISTAMINES

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

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

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

#### **Exclusion Criteria:**

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

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ALLERGIC RHINITIS (new starts only): Failure to two of the following, unless contraindicated or clinically significant adverse effects are experienced: levocetirizine, desloratadine, fluticasone propionate nasal suspension, flunisolide nasal solution or triamcinolone acetonide nasal inhaler.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ANTI-HISTAMINE COMBINATIONS

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

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

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

#### **Exclusion Criteria:**

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

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ALLERGIC RHINITIS (new starts only): Failure to two of the following, unless contraindicated or clinically significant adverse effects are experienced: levocetirizine, desloratadine, fluticasone propionate nasal suspension, flunisolide nasal solution or triamcinolone acetonide nasal inhaler.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

APOKYN

**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:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ARANESP

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

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

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

Anemia due to myelodysplastic syndrome. Myelofibrosis-associated anemia.

#### **Exclusion Criteria:**

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

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

ANEMIA (new starts only): Failure of epoetin alfa-epbx or epoetin alfa, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ARIKAYCE

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

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

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

#### **Exclusion Criteria:**

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

MYCOBACTERIUM AVIUM COMPLEX (new starts only): Positive sputum culture after at least 6 consecutive months of a multidrug background regimen therapy (e.g., clarithromycin or azithromycin, ethambutol, and a rifamycin). MYCOBACTERIUM AVIUM COMPLEX (continuation of therapy): Confirmation of at least 3 consecutive negative monthly sputum cultures in the first 6 months of therapy or at least 2 consecutive negative monthly sputum cultures in the last 2 months of therapy. Member has not received Arikayce treatment for more than 12 months after converting to negative sputum status.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

MYCOBACTERIUM AVIUM COMPLEX: Prescribed by or in consultation with an infectious disease specialist or pulmonologist.

#### **Coverage Duration:**

Initial authorization: 6 months. Continuation of therapy: End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

AUBAGIO

**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:**

End of Plan Year.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2021

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

AUSTEDO

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

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

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

#### **Exclusion Criteria:**

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

TARDIVE DYSKINESIA: 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:**

HUNTINGTON'S DISEASE: Prescribed by or in consultation with a neurologist. TARDIVE DYSKINESIA: Prescribed by or in consultation with a psychiatrist or neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

HUNTINGTON'S DISEASE (initial authorization only): Failure of tetrabenazine, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

AVASTIN

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

All medically accepted indications not otherwise excluded from Part D.

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

#### **Exclusion Criteria:**

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

#### **Age Restrictions:**

Age 18 or older.

#### **Prescriber Restrictions:**

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

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

FOR ALL NON-OPHTHALMOLOGY INDICATIONS: Medical justification supports inability to use Mvasi or Zirabev (e.g., contraindications to the excipients).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

AYVAKIT

#### **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:**

End of Plan Year.

#### **Other Criteria:**

GASTROINTESTINAL STROMAL TUMOR: If disease is positive for a PDGFRA exon 18 mutation other than D842V, failure of imatinib, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

BALVERSA

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

BAXDELA

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

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

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

#### **Exclusion Criteria:**

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

ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION (ABSSSI), COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP): Request is for continuation of therapy initiated in an acute care hospital from which member was discharged OR Both of the following (1 and 2): 1) Current culture and sensitivity (C&S) report shows isolated pathogen is susceptible to delafloxacin, unless provider confirms that obtaining a C&S report is not feasible AND 2) Failure of one fluoroquinolone, unless all are contraindicated or clinically significant adverse effects are experienced, or C&S report shows resistance or lack of susceptibility of the isolated pathogen to all fluoroquinolones.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

ABSSSI: 14 days. CABP: 10 days.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

BELEODAQ

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

BELSOMRA

#### **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:**

End of Plan Year.

#### **Other Criteria:**

INSOMNIA (initial authorization only): For patients 65 years of age and older: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: ramelteon, doxepin 6 mg/day or less, or trazodone. For patients under 65 years of age: Failure of zolpidem or zolpidem CR, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

BENLYSTA

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

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

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

#### **Exclusion Criteria:**

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

LUPUS NEPHRITIS (initial authorization only): confirmation that member is positive for an SLE autoantibody (e.g., anti-nuclear antibody (ANA), anti-double-stranded DNA (anti-ds-DNA), anti-Smith (anti-Sm), anti-ribonucleoprotein (anti-RNP), anti-Ro/SSA, anti-La/SSB, antiphospholipid antibody).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

SYSTEMIC LUPUS ERYTHEMATOSUS: Prescribed by or in consultation with a rheumatologist. LUPUS NEPHRITIS: Prescribed by or in consultation with a nephrologist or rheumatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

BENZTROPINE

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

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

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

#### **Exclusion Criteria:**

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

PARKINSONS DISEASE/PARKINSONISM (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

PARKINSONS DISEASE/PARKINSONISM (new starts only): 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 – 2021**

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

BEOVU

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

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

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

#### **Exclusion Criteria:**

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

NEOVASCULAR (WET) AGE-RELATED MACULAR DEGENERATION (AMD) (continuation of therapy): Member is responding positively to therapy as evidenced by one of the following (a, b, c, or d): a) detained neovascularization, b) improvement/stabilization in visual acuity, c) maintenance of corrected visual acuity from prior treatment, or d) supportive findings from optical coherence tomography or fluorescein angiography.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

NEOVASCULAR (WET) AMD: Prescribed by or in consultation with an ophthalmologist.

#### **Coverage Duration:**

NEOVASCULAR (WET) AMD: Initial authorization: 4 months. Continuation of therapy: 6 months.

#### **Other Criteria:**

NEOVASCULAR (WET) AMD (new starts only): member must use bevacizumab intravitreal solution, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

BLEOMYCIN

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

BOSENTAN

**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:**

PULMONARY ARTERIAL HYPERTENSION: Prescribed by or in consultation with a cardiologist or pulmonologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

BOSULIF

**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:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

BOTOX

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

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

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

#### **Exclusion Criteria:**

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

CHRONIC MIGRAINE HEADACHE (new starts only): Persistent history of chronic, debilitating migraine headaches with frequent attacks on more than 15 days per month.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

CHRONIC MIGRAINE HEADACHE: Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

CHRONIC MIGRAINE HEADACHE (new starts only): Failure of prophylactic treatment with ONE of the following, unless contraindicated or clinically significant adverse effects are experienced: divalproex, topiramate, timolol or propranolol AND Failure of abortive therapy with ONE of the following, unless contraindicated or clinically significant adverse effects are experienced: sumatriptan, rizatriptan, zolmitriptan, naratriptan, almotriptan, frovatriptan, Relpax, ergotamine/caffeine or dihydroergotamine. BLEPHAROSPASM, CERVICAL DYSTONIA, UPPER LIMB SPASTICITY (new starts only): For members age 18 or older, failure of Xeomin unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

BRAFTOVI

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

BRIVIACT

#### **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:**

End of Plan Year.

#### **Other Criteria:**

PARTIAL-ONSET SEIZURES: 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 or divalproex sodium.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

BRUKINSA

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

C1 ESTERASE INHIBITOR

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

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

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

#### **Exclusion Criteria:**

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

Member is not using the requested product in combination with another FDA-approved product for the same indication (e.g., using both Cinryze and Haegarda for long-term prophylaxis of HAE attacks).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

HEREDITARY ANGIOEDEMA: Prescribed by or in consultation with an immunologist, allergist, or hematologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

CABLIVI

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

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

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

#### **Exclusion Criteria:**

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

ACQUIRED THROMBOTIC THROMBOCYTOPENIC PURPURA (aTTP) (continuation of therapy): Member has received no more than 58 days of Cablivi therapy after completion of plasma exchange therapy AND member meets one of the following (a or b): a) If request is for a new treatment cycle, member has experienced no more than two recurrences while taking Cablivi and Cablivi is prescribed in combination with plasma exchange and immunosuppressive therapy (i.e., glucocorticoids, rituximab) OR b) If request is for treatment extension, member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters: increase in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers (lactate dehydrogenase, cardiac troponin I, and serum creatinine).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

aTTP: Prescribed by or in consultation with a hematologist.

#### **Coverage Duration:**

Initial authorization: 60 days. Continuation of therapy: 58 days post plasma-exchange.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

CABOMETYX

**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 oncologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

CALQUENCE

**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:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

CAPLYTA

#### **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:**

End of Plan Year.

#### **Other Criteria:**

SCHIZOPHRENIA: 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 – 2021**

**Prior Authorization Group Description:**

CAPRELSA

**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:**

End of Plan Year.

**Other Criteria:**

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 – 2021**

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

CARISOPRODOL/ASPIRIN/CODEINE

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

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

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

#### **Exclusion Criteria:**

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

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

CAYSTON

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

CERDELGA

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

CEREZYME

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

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

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

Type 3 Gaucher disease.

#### **Exclusion Criteria:**

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

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

CHLORPROMAZINE

#### **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:**

End of Plan Year.

#### **Other Criteria:**

Medical justification supports inability to use generic chlorpromazine tablet (e.g., contraindications to excipients). SCHIZOPHRENIA, BIPOLAR DISORDER: Failure of one of the following generic 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 – 2021**

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

CHLORZOAZONE

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

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

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

#### **Exclusion Criteria:**

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

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

CHORIONIC GONADOTROPIN

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

Induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure. Treatment of obesity.

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

CIALIS

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

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

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

#### **Exclusion Criteria:**

Member is on concomitant nitrates (e.g., Nitrodur, Nitrobid, Nitrostat, Isordil, Ismo) or guanylate cyclase stimulators (e.g., Adempas (riociguat)).

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

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

BENIGN PROSTATIC HYPERPLASIA (initial authorization only): Failure of ONE alpha blocker (e.g., terazosin, doxazosin, tamsulosin, alfuzosin, Rapaflo) and ONE 5-alpha reductase inhibitor (finasteride, dutasteride/tamsulosin, or dutasteride), unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

CIMZIA

#### **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:**

CROHN'S DISEASE: Prescribed by or in consultation with a gastroenterologist. PSORIATIC ARTHRITIS, PLAQUE PSORIASIS: Prescribed by or in consultation with a rheumatologist or dermatologist. RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS, NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR. PLAQUE PSORIASIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Skyrizi. PSORIATIC ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Xeljanz/Xeljanz XR. ANKYLOSING SPONDYLITIS (new starts only): Failure of Humira and Enbrel, unless contraindicated or clinically significant adverse effects are experienced. CROHN'S DISEASE (new starts only): Failure of Humira, unless contraindicated or clinically significant adverse effects are experienced.

## Prior Authorization Protocol

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### Medicare Part D – 2021

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

CINQAIR

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

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

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

#### **Exclusion Criteria:**

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

ASTHMA (initial authorization only): Blood eosinophil count of greater than or equal to 400 cells/mcL within the past 3 months. ASTHMA (continuation of therapy): member is responding positively to therapy (examples may include but are not limited to a reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second since baseline prior to initiating therapy, reduction in the use of rescue therapy since baseline prior to initiating therapy).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

ASTHMA: Prescribed by or in consultation with an allergist, pulmonologist, or immunologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

ASTHMA (initial authorization only): Failure of an inhaled corticosteroid used in combination with a long-acting beta-agonist (e.g., fluticasone/salmeterol), unless clinically significant adverse effects are experienced or all are contraindicated. 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.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

CLADRIBINE

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

CLOMIPRAMINE

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

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

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

Autistic disorder.

#### **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:**

End of Plan Year.

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

OBSESSIVE-COMPULSIVE DISORDER, AUTISTIC DISORDER: Failure of one selective serotonin reuptake inhibitor (e.g., fluoxetine, fluvoxamine, sertraline), unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

COMETRIQ

**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:**

End of Plan Year.

**Other Criteria:**

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 – 2021**

**Prior Authorization Group Description:**

COPIKTRA

**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:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

COSENTYX

#### **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. ANKYLOSING SPONDYLITIS, NONRADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

PLAQUE PSORIASIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Skyrizi. PSORIATIC ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Xeljanz/Xeljanz XR. ANKYLOSING SPONDYLITIS (new starts only): Failure of Humira and Enbrel, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

COTELLIC

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

CRINONE

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

All medically accepted indications not otherwise excluded from Part D.

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

#### **Exclusion Criteria:**

Progesterone supplementation or replacement as part of an Assisted Reproductive Technology (ART) treatment for infertile women with progesterone deficiency.

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

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

ALL INDICATIONS (initial authorization only): Crinone 8%: Medical justification supports inability to use Crinone 4% (e.g., contraindications to excipients, inadequate response, standard practice requires initial therapy with Crinone 8%).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

CROFELEMER

#### **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:**

End of Plan Year.

#### **Other Criteria:**

NON-INFECTIOUS DIARRHEA IN HIV/AIDS (initial authorization only): Failure of loperamide or diphenoxylate/atropine, unless contraindicated or clinically significant adverse effects are experienced.

## Prior Authorization Protocol

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### Medicare Part D – 2021

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

CRYSVITA

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

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

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

#### **Exclusion Criteria:**

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

X-LINKED HYPOPHOSPHATEMIA (new starts only): DNA testing results confirm the presence of mutations in the PHEX gene or documentation of elevated serum fibroblast growth factor 23 (FGF23) levels. Current (within the last 30 days) serum phosphorus level is below the reference range for age and gender and member has not received oral phosphate or vitamin D replacement therapy, OR serum phosphorus level is in normal range and member is receiving oral phosphate and/or vitamin D replacement therapy. X-LINKED HYPOPHOSPHATEMIA (continuation of therapy): Member has had an increase in serum phosphorus level from baseline prior to initiating therapy and/or maintenance within the normal range for age and gender, while on Crysvida therapy. TUMOR-INDUCED OSTEOMALACIA (new starts only): Confirmation of elevated serum FGF23 levels. Current (within the last 30 days) serum phosphorus level is below the reference range for age and gender and member has not received oral phosphate or vitamin D replacement therapy, OR serum phosphorus level is in normal range and member is receiving oral phosphate and/or vitamin D replacement therapy. TUMOR-INDUCED OSTEOMALACIA (continuation of therapy): Member has had an increase in serum phosphorus level from baseline prior to initiating therapy and/or maintenance within the normal range for age and gender, while on Crysvida therapy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

TUMOR-INDUCED OSTEOMALACIA and X-LINKED HYPOPHOSPHATEMIA: Prescribed by or in consultation with an endocrinologist or metabolic disease specialist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

CYCLOBENZAPRINE HCL

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

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

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

#### **Exclusion Criteria:**

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

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

CYTARABINE

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

DAURISMO

**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:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

DIACOMIT

**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:**

DRAVET SYNDROME: Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

DRAVET SYNDROME: Will be prescribed as adjunctive therapy with at least one other antiepileptic drug (e.g., clobazam).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

DICLOFENAC GEL

**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:**

ACTINIC KERATOSES: 3 months.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

DIPYRIDAMOLE

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

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

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

#### **Exclusion Criteria:**

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

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

DISOPYRAMIDE

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

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

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

#### **Exclusion Criteria:**

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

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2021

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

DOPTELET

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

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

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

#### **Exclusion Criteria:**

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

THROMBOCYTOPENIA WITH CHRONIC LIVER DISEASE: 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. CHRONIC IMMUNE THROMBOCYTOPENIA (ITP) (new starts only): Recent (within the last 30 days) platelet count is less than  $30 \times 10^9/L$  or member has an active bleed. CHRONIC ITP (continuation of therapy): Member is responding positively to therapy (examples may include but are not limited to an increase in platelet count from baseline, reduction in bleeding events).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

THROMBOCYTOPENIA WITH CHRONIC LIVER DISEASE: Prescribed by or in consultation with a hematologist, hepatologist, or gastroenterologist. CHRONIC ITP: Prescribed by or in consultation with a hematologist.

#### **Coverage Duration:**

THROMBOCYTOPENIA WITH CHRONIC LIVER DISEASE: 4 weeks. CHRONIC ITP: End of Plan Year.

#### **Other Criteria:**

THROMBOCYTOPENIA WITH CHRONIC LIVER DISEASE (new starts only): For members with platelet count less than  $40 \times 10^9/L$ , failure of Mulpleta unless contraindicated or clinically significant adverse effects are experienced. CHRONIC ITP (new starts only): 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 – 2021**

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

DOXEPIIN

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

DOXEPIN CREAM

#### **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:**

4 weeks.

#### **Other Criteria:**

PRURITUS (initial authorization only): Failure of two 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 – 2021**

**Prior Authorization Group Description:**

DRIZALMA SPRINKLE

**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:**

End of Plan Year.

**Other Criteria:**

ALL INDICATIONS: Medical justification supports inability to use generic duloxetine capsules (e.g., contraindications to excipients).



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

DUEXIS

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ALL INDICATIONS (initial authorization only): Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: pantoprazole, lansoprazole or omeprazole AND Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: ibuprofen, diclofenac sodium or potassium, etodolac, ketoprofen, meloxicam, naproxen, oxaprozin, piroxicam, sulindac, tolmetin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ELIDEL

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ATOPIC DERMATITIS (initial authorization only): 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 – 2021**

**Prior Authorization Group Description:**

EMEND 40 MG

**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:**

4 weeks.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

EMFLAZA

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

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

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

#### **Exclusion Criteria:**

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

DUCHENNE MUSCULAR DYSTROPHY (initial authorization only): Diagnosis of Duchenne muscular dystrophy (DMD) confirmed by one of the following: Genetic testing (e.g., dystrophin deletion or duplication mutation found) OR if genetic studies are negative (i.e., no mutation identified), positive muscle biopsy (e.g., absence of dystrophin protein).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

DUCHENNE MUSCULAR DYSTROPHY: Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

DUCHENNE MUSCULAR DYSTROPHY (initial authorization only): Failure of prednisone, unless contraindicated or clinically significant adverse effects are experienced.

## Prior Authorization Protocol

### Medicare Part D – 2021

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

EMGALITY

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

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

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

#### **Exclusion Criteria:**

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

MIGRAINE PROPHYLAXIS (new starts only): One of the following (a or b): a) Member experiences 4 or more migraine days per month for at least 3 months, or b) Diagnosis of chronic migraine and Emgality is prescribed for prophylaxis. MIGRAINE PROPHYLAXIS (continuation of therapy): Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per month from baseline prior to initiating therapy. EPISODIC CLUSTER HEADACHE (new starts only): Member has a history of at least 2 cluster headache attack periods which lasted from 7 days to 1 year each and were separated by at least 3 months. EPISODIC CLUSTER HEADACHE (continuation of therapy): Member has experienced and maintained positive response to therapy as evidenced by a reduction in cluster headache attack frequency. Member has not received more than 12 months of consecutive treatment OR it has been at least 3 months since the member last received Emgality.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

MIGRAINE PROPHYLAXIS, EPISODIC CLUSTER HEADACHE: Prescribed by or in consultation with a neurologist, headache or pain specialist.

#### **Coverage Duration:**

Initial authorization: 3 months. Continuation of therapy: 6 months.

#### **Other Criteria:**

MIGRAINE PROPHYLAXIS (new starts only): Failure of two of the following oral migraine preventative therapies, each from different therapeutic classes, unless contraindicated or clinically significant adverse effects are experienced: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine).

## Prior Authorization Protocol

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### Medicare Part D – 2021

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

ENBREL

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

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

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

Hidradenitis suppurativa.

#### **Exclusion Criteria:**

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

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

PSORIATIC ARTHRITIS, PLAQUE PSORIASIS: Prescribed by or in consultation with a rheumatologist or dermatologist. RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist. HIDRADENITIS SUPPURATIVA: Prescribed by or in consultation with a rheumatologist, dermatologist or gastroenterologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): 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 (new starts only): 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 – 2021**

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

ENDARI

#### **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:**

End of Plan Year.

#### **Other Criteria:**

SICKLE CELL DISEASE (initial authorization only): Failure of hydroxyurea, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

ENTRESTO

**Prior Authorization Indication:**

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

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

HEART FAILURE (new starts only): Left ventricular ejection fraction less than or equal to 40%.

**Age Restrictions:**

**Prescriber Restrictions:**

HEART FAILURE: Prescribed by or in consultation with a cardiologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ENTYVIO

#### **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:**

ULCERATIVE COLITIS, CROHN'S DISEASE: Prescribed by or in consultation with a gastroenterologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

CROHN'S DISEASE (new starts only): Failure of Humira and infliximab/infliximab biosimilar, unless contraindicated or clinically significant adverse effects are experienced. ULCERATIVE COLITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Humira, Xeljanz/Xeljanz XR, infliximab/infliximab biosimilar.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

EPCLUSA

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

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

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

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

#### **Exclusion Criteria:**

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

CHRONIC HEPATITIS C INFECTION: 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:**

CHRONIC HEPATITIS C INFECTION: Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or provider who has expertise in treating HCV based on a certified training program.

#### **Coverage Duration:**

12 to 24 weeks based on cirrhosis status, genotype, prior treatment, or ribavirin eligibility.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

EPIDIOLEX

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

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

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

#### **Exclusion Criteria:**

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

DRAVET SYNDROME, LENNOX-GASTAUT SYNDROME, SEIZURES ASSOCIATED WITH TUBEROUS SCLEROSIS COMPLEX (TSC): will be used as adjunctive therapy with other antiepileptic drugs.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

DRAVET SYNDROME, LENNOX-GASTAUT SYNDROME, SEIZURES ASSOCIATED WITH TSC:  
Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

LENNOX-GASTAUT SYNDROME: Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Banzel, clobazam, clonazepam, felbamate, lamotrigine, topiramate.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

EPOETIN

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

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

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

Anemia due to myelodysplastic syndrome. Anemia associated with myelofibrosis. Anemia secondary to combination ribavirin and interferon-alfa therapy in patients infected with hepatitis C virus.

#### **Exclusion Criteria:**

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

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ERGOLOID MESYLATES

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

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

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

#### **Exclusion Criteria:**

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

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ALZHEIMER'S DISEASE (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: donepezil, memantine, rivastigmine or galantamine.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ERLEADA

#### **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:**

PROSTATE CANCER: Prescribed by or in consultation with an oncologist or urologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ESBRIET

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

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

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

#### **Exclusion Criteria:**

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

IDIOPATHIC PULMONARY FIBROSIS (initial authorization only): Pulmonary fibrosis on high resolution computed tomography (HRCT). Known causes of pulmonary fibrosis have been ruled out (examples may include but are not limited to domestic and occupational environmental exposures, connective tissue disease, drug toxicity).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

IDIOPATHIC PULMONARY FIBROSIS: Prescribed by or in consultation with pulmonologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ESTROGENS(Lopreeza , Femhrt , Menostar , Mimvey Lo , Mimvey , Prempro , Amabelz , Combipatch , Climara Pro , Evamist , Estrace , Activella , Duavee , Divigel , Climara , Elestrin , Premarin , Premphase , Fyavolv , Dotti )

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

All medically accepted indications not otherwise excluded from Part D.

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

#### **Exclusion Criteria:**

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

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ATROPHIC VAGINITIS AND KRAUROSIS VULVAE (new starts only): Failure to one of the following, unless contraindicated or clinically significant adverse effects are experienced: Estradiol vaginal tablet, Femring or Premarin vaginal cream.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

EVENITY

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

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

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

#### **Exclusion Criteria:**

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

POSTMENOPAUSAL OSTEOPOROSIS (PMO): Total duration of Evenity therapy has not exceeded 12 months of cumulative use.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

PMO (initial authorization only): Member meets one of the following (a, b, or c): a) Failure of bisphosphonate therapy (e.g., alendronate) unless contraindicated or clinically significant adverse effects are experienced to both intravenous and oral formulations. 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 – 2021**

**Prior Authorization Group Description:**

EXKIVITY

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

EXONDYS 51

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

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

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

#### **Exclusion Criteria:**

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

DUCHENNE MUSCULAR DYSTROPHY: Duchenne muscular dystrophy with mutation amenable to exon 51 skipping confirmed by genetic testing.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

DUCHENNE MUSCULAR DYSTROPHY: Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

6 months.

#### **Other Criteria:**

DUCHENNE MUSCULAR DYSTROPHY: 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 – 2021**

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

EYLEA

#### **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:**

NEOVASCULAR (WET) AGE-RELATED MACULAR DEGENERATION (AMD), RETINAL VEIN OCCLUSION (RVO), DIABETIC MACULAR EDEMA (DME), DIABETIC RETINOPATHY (DR): Prescribed by or in consultation with an ophthalmologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

NEOVASCULAR (WET) AMD, RVO, DME, DR (new starts only): For all indications, except for DME in members with baseline visual acuity worse than 20/50: member must use bevacizumab intravitreal solution, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

FARYDAK

**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 a hematologist or oncologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

FASENRA

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

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

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

#### **Exclusion Criteria:**

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

ASTHMA (initial authorization only): Blood eosinophil count of greater than or equal to 150 cells/mcL within the past 3 months. ASTHMA (continuation of therapy): member is responding positively to therapy (examples may include but are not limited to a reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second since baseline prior to initiating therapy, reduction in the use of rescue therapy since baseline prior to initiating therapy).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

ASTHMA: Prescribed by or in consultation with an allergist, pulmonologist, or immunologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

ASTHMA (initial authorization only): 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.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

FENTORA

**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:**

End of Plan Year.

**Other Criteria:**

Member is already taking and is tolerant to around-the-clock opioid therapy. Member is 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 – 2021**

**Prior Authorization Group Description:**

FERRIPROX

**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:**

End of Plan Year.

**Other Criteria:**

TRANSFUSIONAL IRON OVERLOAD (initial authorization only): Failure of Exjade or Jadenu, unless contraindicated or clinically significant adverse effects are experienced.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

FINTEPLA

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

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

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

#### **Exclusion Criteria:**

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

DRAVET SYNDROME: Will be prescribed as adjunctive therapy with at least one other antiepileptic drug (e.g., Diacomit, clobazam, valproic acid, Epidiolex, topiramate, levetiracetam, clonazepam, zonisamide, ethosuximide, phenobarbital).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

DRAVET SYNDROME: Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

FIORICET WITH CODEINE

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

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

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

#### **Exclusion Criteria:**

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

TENSION HEADACHE (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

TENSION HEADACHE (new starts only): Failure of naproxen and ibuprofen, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

FIORINAL WITH CODEINE

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

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

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

#### **Exclusion Criteria:**

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

TENSION HEADACHE (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

TENSION HEADACHE (new starts only): Failure of naproxen and ibuprofen, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

FIRAZYR

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

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

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

#### **Exclusion Criteria:**

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

HEREDITARY ANGIOEDEMA: Member is not using icatibant in combination with another FDA-approved product for treatment of acute HAE attacks [e.g., C1 esterase inhibitor (Berinert, Ruconest), ecallantide (Kalbitor)].

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

HEREDITARY ANGIOEDEMA: Prescribed by or in consultation with an immunologist, allergist, or hematologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

FIRDAPSE

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

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

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

#### **Exclusion Criteria:**

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

LAMBERT-EATON MYASTHENIC SYNDROME (LEMS) (initial authorization only): 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)). LEMS (continuation of therapy): Member is responding positively to therapy as evidenced by clinical muscle strength assessments.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

LEMS: Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

LEMS (initial authorization only): Medical justification supports inability to use Ruzurgi (e.g., contraindications to excipients).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

FLECTOR

**Prior Authorization Indication:**

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

**Off Label Uses:**

Cancer pain.

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

Acute Pain: 4 weeks. Cancer pain: End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

FLUOROURACIL

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

FORTEO

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

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

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

#### **Exclusion Criteria:**

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

OSTEOPOROSIS: For requests to continue therapy after having had a total of 2 years duration with any parathyroid hormone (PTH) analog (e.g., abaloparatide, teriparatide), confirmation that member remains at or has returned to having a high risk for fracture.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

OSTEOPOROSIS (initial authorization only): Member meets one of the following (a, b, or c): a) Failure of bisphosphonate therapy (e.g., alendronate) unless contraindicated or clinically significant adverse effects are experienced to both intravenous and oral formulations. 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 – 2021**

**Prior Authorization Group Description:**

FOTIVDA

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

GALAFOLD

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

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

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

#### **Exclusion Criteria:**

FABRY DISEASE: Amenable GLA variants (mutations) associated with benign phenotypes (i.e., phenotypes known not to cause Fabry disease), including the following GLA mutation: c.937G to T, (p.(D313Y)).

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

FABRY DISEASE (initial authorization only): Presence of at least one amenable GLA variant (mutation) as confirmed by one of the following resources: Galafold Prescribing Information brochure (package insert - Section 12, Table 2), Amicus Fabry GLA Gene Variant Search Tool: <http://www.fabrygenevariantsearch.com/hcp>, or Amicus Medical Information at 1-877-4AMICUS or [medinfousa@amicusrx.com](mailto:medinfousa@amicusrx.com).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

FABRY DISEASE: Prescribed by or in consultation with a clinical geneticist or nephrologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

GANCICLOVIR

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

GATTEX

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

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

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

#### **Exclusion Criteria:**

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

SHORT BOWEL SYNDROME (SBS) (initial authorization only): Member has been dependent on parenteral nutrition or other intravenous support for at least 12 months. SBS (continuation of therapy): Requirement for parenteral nutrition or other intravenous support has decreased since initiation of Gattex therapy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

SBS: Prescribed by or in consultation with a gastroenterologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

GAVRETO

**Prior Authorization Indication:**

All medically accepted indications not otherwise excluded from Part D.

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

ALL ONCOLOGY INDICATIONS: Gavreto is not prescribed concurrently with Retevmo. Member has not received prior RET targeted therapy (e.g., Retevmo).

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

GILENYA

**Prior Authorization Indication:**

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

**Off Label Uses:**

**Exclusion Criteria:**

Baseline QTc interval greater than or equal to 500 msec.

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

MULTIPLE SCLEROSIS: Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

GILOTRIF

**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:**

End of Plan Year.

**Other Criteria:**

## Prior Authorization Protocol

### Medicare Part D – 2021

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

GIVLAARI

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

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

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

#### **Exclusion Criteria:**

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

ACUTE HEPATIC PORPHYRIA (AHP): Diagnosis of one of the following AHP subtypes and corresponding gene mutation (a, b, c, or d): a. ALA dehydratase-deficiency (ALAD) porphyria: ALAD mutation. b. Acute intermittent porphyria (AIP): HMBS or PBGD mutation. c. Hereditary coproporphyrin (HCP): CPOX mutation. d. Variegate porphyria (VP): PPOX mutation. Panhematin, as a prophylactic treatment, is not prescribed concurrently with Givlaari (note: use of Panhematin for treatment of acute porphyria attacks while taking Givlaari is appropriate). AHP (new starts only): History of at least a four-fold increase of 5-aminolevulinic acid (ALA) or porphobilinogen (PBG) using a random urine sample. History of two or more porphyria attacks in a 6-month period requiring hospitalization, urgent healthcare visit, or intravenous Panhematin (hemin for injection) administration at home, and one of the following (a or b): a. The porphyria attacks occurred within the last 6 months, b. The porphyria attacks occurred in any 6-month period and member is currently receiving prophylactic Panhematin therapy (e.g., once or twice a week on a regular basis). AHP (continuation of therapy): Member is responding positively to therapy as evidenced by one of the following (a or b): a. Decreased number of porphyria attacks requiring hospitalization, urgent healthcare visit, or intravenous Panhematin administration at home, OR b. No increase in porphyria attacks requiring hospitalization, urgent healthcare visit, or intravenous Panhematin administration at home if member was receiving prophylactic Panhematin prior to Givlaari initiation.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

AHP: Prescribed by or in consultation with a gastroenterologist, hematologist, or neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

GLATIRAMER

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

GLIMEPIRIDE

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

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

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

#### **Exclusion Criteria:**

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

TYPE 2 DIABETES MELLITUS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

TYPE 2 DIABETES MELLITUS (new starts only): Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: glipizide or glipizide/metformin combination product.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

GLYBURIDE

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

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

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

#### **Exclusion Criteria:**

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

TYPE 2 DIABETES MELLITUS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

TYPE 2 DIABETES MELLITUS (new starts only): Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: glipizide or glipizide/metformin combination product.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

GLYBURIDE/METFORMIN

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

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

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

#### **Exclusion Criteria:**

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

TYPE 2 DIABETES MELLITUS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

TYPE 2 DIABETES MELLITUS (new starts only): Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: glipizide or glipizide/metformin combination product.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

GRASTEK

**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:**

ALLERGIC RHINITIS: Prescribed by or in consultation with an allergist or immunologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

ALLERGIC RHINITIS (initial authorization only): Failure of both of the following, unless contraindicated or clinically significant adverse effects are experienced: oral antihistamines and intranasal corticosteroids.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

GUANFACINE

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

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

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

#### **Exclusion Criteria:**

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

HYPERTENSION (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

HYPERTENSION (new starts only): 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 – 2021**

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

HARVONI

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

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

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

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

#### **Exclusion Criteria:**

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

CHRONIC HEPATITIS C INFECTION: 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:**

CHRONIC HEPATITIS C INFECTION: Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or provider who has expertise in treating HCV based on a certified training program.

#### **Coverage Duration:**

8 to 24 weeks based on cirrhosis status, genotype, prior treatment, or ribavirin eligibility.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

HERCEPTIN

**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:**

End of Plan Year.

**Other Criteria:**

ALL INDICATIONS: Medical justification supports inability to use Ogivri or Trazimera (e.g., contraindications to excipients).



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

HERCEPTIN HYLECTA

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ALL INDICATIONS: Medical justification supports inability to use Ogivri or Trazimera (e.g., contraindications to excipients).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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 (initial authorization only): Baseline height prior to initiating therapy 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 (initial authorization only): Confirmed by karyotype. PRADER-WILLI or NOONAN SYNDROME (initial authorization only): Baseline height prior to initiating therapy 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: End of Plan Year. 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 – 2021**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): 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 (new starts only): 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 – 2021**

#### **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:**

CANCER PAIN: Plan Year. NON-MALIGNANT PAIN: Initial auth: 3 months, cont. of therapy: Plan Year.

#### **Other Criteria:**

CANCER PAIN, NON-MALIGNANT PAIN (initial authorization only): 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 – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

PRURITUS (new starts only): 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 (new starts only): Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: venlafaxine, buspirone, duloxetine or escitalopram.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

PRURITUS (new starts only): 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 (new starts only): Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: venlafaxine, buspirone, duloxetine or escitalopram.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

IDHIFA

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ILARIS

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

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

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

Acute gouty arthritis.

#### **Exclusion Criteria:**

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

ALL INDICATIONS: Confirmation of current weight.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS: Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist. ADULT ONSET STILL'S DISEASE: Prescribed by or in consultation with a rheumatologist or hematologist. ALL OTHER COVERED INDICATIONS: Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

PLAQUE PSORIASIS: Prescribed by or in consultation with a rheumatologist or dermatologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

PLAQUE PSORIASIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Skyrizi.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

End of Plan Year.

#### **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 – 2021**

#### **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:**

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ALL INDICATIONS (new starts only): Failure of naproxen and sulindac, unless contraindicated or clinically significant adverse effects are experienced.



## Prior Authorization Protocol

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### Medicare Part D – 2021

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

INFLECTRA

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

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

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

Granulomatosis with polyangiitis (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:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): 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 (new starts only): 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 – 2021**

#### **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:**

TARDIVE DYSKINESIA: 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:**

TARDIVE DYSKINESIA: Prescribed by or in consultation with a psychiatrist or neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

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 – 2021**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

MYELOYDYSPLASTIC SYNDROMES: Medical justification supports inability to use decitabine (e.g., contraindications or clinically significant adverse effects to excipients).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

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

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

MYELOFIBROSIS: Failure of Jakafi, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

MULTIPLE SCLEROSIS: Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

MULTIPLE SCLEROSIS: Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

ATTENTION DEFICIT HYPERACTIVITY DISORDER (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ATTENTION DEFICIT HYPERACTIVITY DISORDER (new starts only): 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 – 2021**

#### **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:**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

JUBLIA

**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:**

End of Plan Year.

**Other Criteria:**

ONYCHOMYCOSIS (initial authorization only): Failure of terbinafine tablets, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (new starts only): Failure of Repatha 420 mg, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE: Prescribed by or in consultation with a nephrologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

CYSTIC FIBROSIS (new starts only): Diagnosis of CF confirmed by all of the following (a, b, c, and d): 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) Elevated sweat chloride that is 60 mmol/L or greater, OR ii) Genetic testing confirming the presence of two disease-causing mutations in the CFTR gene, one from each parental allele, AND c) Presence of one mutation in the CFTR gene that is responsive to Kalydeco based on clinical and/or in vitro assay data, AND d) Confirmation that a homozygous F508del mutation in the CFTR gene is not present.

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%. CYSTIC FIBROSIS (continuation of therapy): Member is responding positively to therapy as evidenced by a stabilization in ppFEV1 if baseline prior to initiating therapy was 70% or greater or increase in ppFEV1 if baseline prior to initiating therapy was less than 70%.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

Kalydeco is not prescribed concurrently with other CFTR modulators (e.g., Orkambi, Symdeko, Trikafta).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

KANJINTI

**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:**

End of Plan Year.

**Other Criteria:**

ALL INDICATIONS: Medical justification supports inability to use Ogivri or Trazimera (e.g., contraindications to excipients).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

KAZANO

#### **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:**

End of Plan Year.

#### **Other Criteria:**

TYPE 2 DIABETES MELLITUS (initial authorization only): Failure of Tradjenta or Jentadueto, unless contraindicated or clinically significant adverse effects are experienced AND Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Januvia, Janumet, Janumet XR.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

KERYDIN

**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:**

End of Plan Year.

**Other Criteria:**

ONYCHOMYCOSIS (initial authorization only): Failure of terbinafine tablets, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

ACUTE PAIN (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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 – 2021**

**Prior Authorization Group Description:**

KEVEYIS

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

RHEUMATOID ARTHRITIS: Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

KEYTRUDA

#### **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:**

CLASSICAL HODGKIN LYMPHOMA, PRIMARY MEDIASTINAL LARGE B-CELL LYMPHOMA: Prescribed by or in consultation with an oncologist or hematologist. UROTHELIAL CARCINOMA: Prescribed by or in consultation with an oncologist or urologist. ALL OTHER ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

KINERET

#### **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, DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST: Prescribed by or in consultation with a rheumatologist. NEONATAL-ONSET MULTISYSTEM INFLAMMATORY DISEASE (NOMID): Prescribed by or in consultation with a rheumatologist, neonatologist, or pediatrician.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

KISQALI(Kisqali , Kisqali Femara Co-Pack )

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

KOMBIGLYZE XR

#### **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:**

End of Plan Year.

#### **Other Criteria:**

TYPE 2 DIABETES MELLITUS (initial authorization only): Failure of Tradjenta or Jentadueto, unless contraindicated or clinically significant adverse effects are experienced AND Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Januvia, Janumet, Janumet XR.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

CUSHING'S SYNDROME: Prescribed by or in consultation with an endocrinologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2021

#### **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. Presence of at least one plexiform neurofibroma (PN) with lesion measuring 3 cm or greater in one dimension. Complete resection of 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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

PHENYLKETONURIA (PKU) (new starts only): Recent (within 90 days) phenylalanine (Phe) blood level is greater than 360 micromol/L. PKU (continuation of therapy): Confirmation of a reduction in Phe blood levels since initiation of therapy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

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

#### **Coverage Duration:**

Initial authorization: 3 months. Continuation of therapy: End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

BIPOLAR I DISORDER, SCHIZOPHRENIA: 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 – 2021**

#### **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:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

Member is already taking and is tolerant to around-the-clock opioid therapy. Member is 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 – 2021**

#### **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:**

MULTIPLE SCLEROSIS (MS): Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

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

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

LIDODERM

**Prior Authorization Indication:**

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

**Off Label Uses:**

Diabetic neuropathy. Cancer-related neuropathic pain.

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

LOTRONEX

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

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

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

#### **Exclusion Criteria:**

Male patients.

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

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2021

#### **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:**

OPIOID WITHDRAWAL: 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 meets 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:**

OPIOID WITHDRAWAL: 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:**

OPIOID WITHDRAWAL: 14 days per course of treatment.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

LUMAKRAS

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

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:**

End of Plan Year.

#### **Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2021

**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:**

Member has not yet received 2 courses (4 cycles) lifetime total.

**Age Restrictions:**

**Prescriber Restrictions:**

MULTIPLE SCLEROSIS (MS): Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

RELAPSING-REMITTING MS (initial authorization only): Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Aubagio, Tecfidera, Gilenya, Avonex, Betaseron, Plegridy, glatiramer, Copaxone, Glatopa, Extavia, Rebif.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

CHRONIC HEPATITIS C INFECTION: 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:**

CHRONIC HEPATITIS C INFECTION: Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or provider who has expertise in treating HCV based on a certified training program.

#### **Coverage Duration:**

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

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

MULTIPLE SCLEROSIS (MS): Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

RELAPSING-REMITTING MS (new starts only): Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Aubagio, Tecfidera, Gilenya, Avonex, Betaseron, Plegridy, glatiramer, Copaxone, Glatopa, Extavia, Rebif.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

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

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

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

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

MEPROBAMATE

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

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

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

#### **Exclusion Criteria:**

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

ANXIETY (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ANXIETY (new starts only): Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: venlafaxine, buspirone, duloxetine or escitalopram.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ALL INDICATIONS (initial authorization only): Failure of generic methotrexate injection, unless contraindicated or clinically significant adverse effects are experienced.

## Prior Authorization Protocol

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### Medicare Part D – 2021

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

METHYLDOPA

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

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

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

#### **Exclusion Criteria:**

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

HYPERTENSION (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

HYPERTENSION (new starts only): 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 – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

ERYTHEMA OF ROSACEA WITH PAPULES OR PUSTULES (initial authorization only): 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 – 2021**

**Prior Authorization Group Description:**

MORPHINE SULFATE ER

**Prior Authorization Indication:**

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

**Off Label Uses:**

**Exclusion Criteria:**

**Required Medical Information:**

PAIN (initial authorization only): Medical justification as to why patient cannot take an equivalent daily dose of an alternative generically available extended-release morphine sulfate product.

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

MOBILIZATION OF HEMATOPOIETIC STEM CELLS: Prescribed by or in consultation with an oncologist or hematologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

THROMBOCYTOPENIA: 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:**

THROMBOCYTOPENIA: 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 – 2021**

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

NAMENDA

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

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

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

HYPOPARATHYROIDISM (new starts only): 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). HYPOPARATHYROIDISM (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:**

HYPOPARATHYROIDISM: Prescribed by or in consultation with an endocrinologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

HYPOPARATHYROIDISM (new starts only): 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 – 2021**

**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:**

EPILEPSY: Member is currently on a stable regimen of antiepileptic drugs.

**Age Restrictions:**

**Prescriber Restrictions:**

EPILEPSY: Prescribed by or in consultation with neurologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

NESINA

#### **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:**

End of Plan Year.

#### **Other Criteria:**

TYPE 2 DIABETES MELLITUS (initial authorization only): Failure of Tradjenta or Jentadueto, unless contraindicated or clinically significant adverse effects are experienced AND Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Januvia, Janumet, Janumet XR.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

PROSTATE CANCER: Concurrent use of a gonadotropin-releasing hormone (GnRH) analog or past bilateral orchiectomy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

PROSTATE CANCER: Prescribed by or in consultation with an oncologist or urologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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 (initial authorization only): Blood eosinophil count of greater than or equal to 150 cells/mcL within the past 3 months. ASTHMA (continuation of therapy): member is responding positively to therapy (examples may include but are not limited to a reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second since baseline prior to initiating therapy, reduction in the use of rescue therapy since baseline prior to initiating therapy).

EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (continuation of therapy): Member is responding positively to therapy (examples may include but are not limited to: reduction of relapses or reduction in glucocorticoid dose). HYPEREOSINOPHILIC SYNDROME (HES) (initial authorization only): Diagnosis of FIP1L1-PDGFR-alpha negative HES without a non-hematologic secondary cause. HES is uncontrolled, defined as a history of at least 2 flares within the past 12 months. Blood eosinophil count of greater than or equal to 1,000 cells/mcL within the past 3 months. Failure of a corticosteroid, unless contraindicated or clinically significant adverse events are experienced. HYPEREOSINOPHILIC SYNDROME (continuation of therapy): Member is responding positively to therapy with reduction in flares from baseline or reduction in maintenance HES therapy dose from baseline.

#### **Age Restrictions:**

#### **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. HYPEREOSINOPHILIC SYNDROME: Prescribed by or in consultation with hematologist, dermatologist, or immunologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

ASTHMA (initial authorization only): 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 (initial authorization only): Failure of ONE glucocorticoid, unless contraindicated or clinically significant adverse events are experienced. HYPEREOSINOPHILIC SYNDROME: Prescribed concurrently with baseline HES maintenance therapy (e.g., oral corticosteroids, immunosuppressive therapy).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

PSEUDOBULBAR AFFECT: Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

NUVIGIL

**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 or sleep medicine specialist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION (ABSSSI), COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP): 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:**

ABSSSI, CABP: 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 – 2021**

#### **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:**

PRIMARY BILIARY CHOLANGITIS (continuation of therapy): Member is responding positively to therapy as evidenced by a reduction in alkaline phosphatase (ALP) level from pretreatment level or maintenance of initial reduction in ALP level.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

PRIMARY BILIARY CHOLANGITIS: Prescribed by or in consultation with a hepatologist or gastroenterologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

MULTIPLE SCLEROSIS (MS): Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

RELAPSING-REMITTING MS (new starts only): Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Aubagio, Tecfidera, Gilenya, Avonex, Betaseron, Plegridy, glatiramer, Copaxone, Glatopa, Extavia, Rebif.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2021

#### **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 (initial authorization only): 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). IDIOPATHIC PULMONARY FIBROSIS (initial authorization only): Pulmonary fibrosis on HRCT. Known causes of pulmonary fibrosis have been ruled out (examples may include but are not limited to domestic and occupational environmental exposures, connective tissue disease, drug toxicity). CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE WITH A PROGRESSIVE PHENOTYPE (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:**

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

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

RHEUMATOID ARTHRITIS: Prescribed by or in consultation with a rheumatologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ONGLYZA

#### **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:**

End of Plan Year.

#### **Other Criteria:**

TYPE 2 DIABETES MELLITUS (initial authorization only): Failure of Tradjenta or Jentadueto, unless contraindicated or clinically significant adverse effects are experienced AND Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Januvia, Janumet, Janumet XR.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

PULMONARY ARTERIAL HYPERTENSION: Prescribed by or in consultation with a cardiologist or pulmonologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ORALAIR

#### **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:**

ALLERGIC RHINITIS: Prescribed by or in consultation with an allergist or immunologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

ALLERGIC RHINITIS (initial authorization only): Failure of both of the following, unless contraindicated or clinically significant adverse effects are experienced: oral antihistamines and intranasal corticosteroids.

## Prior Authorization Protocol

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### Medicare Part D – 2021

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

ORENCIA

#### **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, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist. PSORIATIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist or dermatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR. PSORIATIC ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Xeljanz/Xeljanz XR. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Humira, Enbrel, Xeljanz.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

ORGOVYX

**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:**

PROSTATE CANCER: Prescribed by or in consultation with an oncologist or urologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2021

#### **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:**

ENDOMETRIOSIS PAIN (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:**

ENDOMETRIOSIS PAIN: Prescribed by or in consultation with a gynecologist.

#### **Coverage Duration:**

200 mg twice daily: 6 months. 150 mg once daily: End of Plan Year.

#### **Other Criteria:**

ENDOMETRIOSIS PAIN (initial authorization only): Failure of ONE non-steroidal anti-inflammatory drug (e.g., ibuprofen, naproxen, ketoprofen, mefenamic acid, meclofenamate, 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 – 2021**

#### **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:**

CYSTIC FIBROSIS: (new starts only): Diagnosis of CF confirmed by all of the following (a, b, and c): 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) Elevated sweat chloride that is 60 mmol/L or greater, OR ii) Genetic testing confirming the presence of two disease-causing mutations in the CFTR gene, one from each parental allele, AND c) Confirmation that member is homozygous for the F508del mutation in the CFTR gene. 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%. CYSTIC FIBROSIS (continuation of therapy): Member is responding positively to therapy as evidenced by a stabilization in ppFEV1 if baseline prior to initiating therapy was 70% or greater or increase in ppFEV1 if baseline prior to initiating therapy was less than 70%.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

CYSTIC FIBROSIS: Prescribed by or in consultation with a pulmonologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

Orkambi is not prescribed concurrently with other CFTR modulators (e.g., Kalydeco, Symdeko, Trikafta).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ORPHENADRINE

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

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

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

#### **Exclusion Criteria:**

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

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

OSENI

#### **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:**

End of Plan Year.

#### **Other Criteria:**

TYPE 2 DIABETES MELLITUS (initial authorization only): Failure of Tradjenta or Jentadueto, unless contraindicated or clinically significant adverse effects are experienced AND Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Januvia, Janumet, Janumet XR.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

OTEZLA

#### **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, ORAL ULCERS ASSOCIATED WITH BEHCET'S DISEASE:  
Prescribed by or in consultation with a rheumatologist or dermatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

PLAQUE PSORIASIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Skyrizi. PSORIATIC ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Xeljanz/Xeljanz XR.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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 (initial authorization only): Disease is associated with one of the following genotypes: Homozygous hemoglobin S, Hemoglobin S beta 0-thalassemia, Hemoglobin S beta+ thalassemia, Hemoglobin SC, or other genotypic variants of sickle cell disease. 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. Failure of L-glutamine, unless contraindicated or clinically significant adverse effects are experienced. SICKLE CELL DISEASE (continuation of therapy): Member is responding positively to therapy as evidenced by an increase in Hb level from baseline prior to initiating therapy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

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

#### **Coverage Duration:**

6 months.

#### **Other Criteria:**

SICKLE CELL DISEASE: Oxbryta is not prescribed concurrently with Adakveo.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

NEUROTROPHIC KERATITIS: Prescribed by or in consultation with an ophthalmologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

PHENYLKETONURIA (new starts only): Recent (within 90 days) phenylalanine (Phe) blood level is greater than 600 micromol/L. PHENYLKETONURIA (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:**

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

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

OSTEOARTHRITIS PAIN (initial authorization only): Failure of diclofenac 1.5% topical solution and diclofenac 1% topical gel, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

SCHIZOPHRENIA: 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) Confirmation of established tolerability to oral risperidone AND 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 – 2021

#### **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:**

End of Plan Year.

#### **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 – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

PLEGRIDY

**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:**

End of Plan Year.

**Other Criteria:**

## Prior Authorization Protocol

### Medicare Part D – 2021

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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 OR HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA) (initial authorization only): 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 (initial authorization only): 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 that have had a clinically relevant contributory effect on the current degree of this member's elevated 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) (initial authorization only): 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, Stroke, Peripheral arterial 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). ALL HYPERLIPIDEMIA AND HYPERCHOLESTEROLEMIA INDICATIONS (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:**

ALL HYPERLIPIDEMIA AND HYPERCHOLESTEROLEMIA INDICATIONS: Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.

#### **Coverage Duration:**

6 months.

#### **Other Criteria:**

ALL HYPERLIPIDEMIA AND HYPERCHOLESTEROLEMIA INDICATIONS (initial authorization only): One of the following (a, b, or c): a) Member has a contraindication to statins. OR b) For members currently on statin therapy, inadequate response to two of the following at maximally tolerated doses, unless clinically significant adverse effects are experienced: atorvastatin, rosuvastatin, simvastatin, ezetimibe/simvastatin, pitavastatin, pravastatin, fluvastatin, or lovastatin. OR c) For members not on statin therapy, member is statin intolerant as

demonstrated by both of the following (1 and 2): 1) member has tried at least two statins, 1 of which must be hydrophilic statin (pravastatin, fluvastatin, or rosuvastatin), AND 2) One of the following (i or ii): i) member has a statin risk factor that increases the likelihood of experiencing an adverse effect to statin therapy (i.e., multiple or serious comorbidities, including impaired renal or hepatic function, unexplained alanine transaminase (ALT) elevations greater than 3 times upper limit of normal or active liver disease, concomitant use of drugs adversely affecting statin metabolism, age greater than 75 years or history of hemorrhagic stroke, Asian ancestry) OR ii) confirmation that member has experienced intolerable statin-associated muscle symptoms persisting for at least two weeks, which disappeared with discontinuing the statin therapy and recurred with a statin re-challenge (statin re-challenge may be initiated with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly)).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

TUBERCULOSIS (new starts only): Confirmed resistance to fluoroquinolones, unless contraindicated or clinically significant adverse effects are experienced. Prescribed in combination with bedaquiline and linezolid.

TUBERCULOSIS (continuation of therapy): Confirmation of delayed culture conversion and total duration of pretomanid therapy has not exceeded 9 months. 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.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

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

#### **Coverage Duration:**

Initial authorization: 6 months. Continuation of therapy: 3 months.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

PROPHYLAXIS OF CMV INFECTION: Prescribed by or in consultation with an oncology, hematology, infectious disease, or transplant specialist.

#### **Coverage Duration:**

Through day 100 post-transplantation.

#### **Other Criteria:**

PROPHYLAXIS OF CMV INFECTION (new starts only): Failure of generic valacyclovir, 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 – 2021**

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

PROCARDIA CAPSULES

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

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

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

#### **Exclusion Criteria:**

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

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

CHRONIC STABLE ANGINA (new starts only): Failure of ONE of the following, unless contraindicated or clinically significant adverse effects are experienced: nifedipine SR, amlodipine or nicardipine. VASOSPASTIC ANGINA (new starts only): Failure of ONE of the following, unless contraindicated or clinically significant adverse effects are experienced: nifedipine SR or amlodipine.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

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

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

OSTEOPOROSIS (initial authorization only): Member meets one of the following (a, b, or c): a) Failure of bisphosphonate therapy (e.g., alendronate) unless contraindicated or clinically significant adverse effects are experienced to both intravenous and oral formulations. 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 – 2021

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

PROMACTA

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

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

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

Myelodysplastic Syndromes.

#### **Exclusion Criteria:**

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

THROMBOCYTOPENIA IN CHRONIC HEPATITIS C: Confirmation of current or planned interferon-based treatment of chronic hepatitis C. MYELODYSPLASTIC SYNDROMES (new starts only): Member has lower-risk MDS (IPSS-R (Very Low, Low, Intermediate), IPSS (Low/Intermediate-1), WPSS (Very Low, Low, Intermediate). Member has severe or refractory thrombocytopenia following disease progression or no response to hypomethylating agents (e.g., azacitadine, decitabine), immunosuppressive therapy (e.g., Atgam, cyclosporine), or clinical trial.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

PERSISTENT/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. MYELODYSPLASTIC SYNDROMES: Prescribed by or in consultation with an oncologist or hematologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

End of Plan Year.

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

ATOPIC DERMATITIS (initial authorization only): 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 – 2021**

**Prior Authorization Group Description:**

PROVIGIL

**Prior Authorization Indication:**

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

**Off Label Uses:**

Multiple sclerosis-related fatigue.

**Exclusion Criteria:**

**Required Medical Information:**

**Age Restrictions:**

**Prescriber Restrictions:**

NARCOLEPSY: Prescribed by or in consultation with a neurologist or sleep medicine specialist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**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 – 2021**

#### **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:**

End of Plan Year.

#### **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 – 2021**

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

QUALAQUIN

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

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

#### **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 – 2021**

#### **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:**

AMYOTROPHIC LATERAL SCLEROSIS (ALS): Confirmation of definite or probable ALS diagnosis based on El Escorial revised criteria. Forced vital capacity greater than or equal to 80%. 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. Prescribed in combination with riluzole unless contraindicated or clinically significant adverse effects are experienced.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

ALS: Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

6 months.

#### **Other Criteria:**

ALS (new starts only): Disease duration of less than or equal to 2 years.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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 (new starts only): 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. TRANSFUSION DEPENDENT BETA THALASSEMIA (continuation of therapy): 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) (new starts only): 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. MDS (continuation of therapy): 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:**

TD BETA-THALASSEMIA, MDS: Initial: 2 months. Continuation of therapy: 6 months.

#### **Other Criteria:**

MDS (new starts only): 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 – 2021**

**Prior Authorization Group Description:**

RELISTOR

**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:**

End of Plan Year.

**Other Criteria:**

OPIOID-INDUCED CONSTIPATION (initial authorization only): Failure of Amitiza and Movantik, unless contraindicated or clinically significant adverse effects are experienced.

## Prior Authorization Protocol

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### Medicare Part D – 2021

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

REMICADE

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

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

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

Granulomatosis with polyangiitis (Wegener's granulomatosis).

#### **Exclusion Criteria:**

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

ALL INDICATIONS (initial authorization only): Medical justification supports inability to use Inflectra and Renflexis (e.g., contraindications to the excipients).

#### **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:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): 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 (new starts only): 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 – 2021**

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

RENFLEXIS

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

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

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

Granulomatosis with polyangiitis (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:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): 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 (new starts only): Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, cyclosporine or acitretin.

## Prior Authorization Protocol

### Medicare Part D – 2021

#### 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) (initial authorization only): 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 (initial authorization only): 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 that have had a clinically relevant contributory effect on the current degree of this member's elevated 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) (initial authorization only): 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, 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). ALL HYPERLIPIDEMIA AND HYPERCHOLESTEROLEMIA INDICATIONS (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:

ALL HYPERLIPIDEMIA AND HYPERCHOLESTEROLEMIA INDICATIONS: Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.

#### Coverage Duration:

6 months.

#### Other Criteria:

ALL HYPERLIPIDEMIA AND HYPERCHOLESTEROLEMIA INDICATIONS (initial authorization only): One of the following (a, b, or c): a) Member has a contraindication to statins. OR b) For members currently on statin therapy, inadequate response to two of the following at maximally tolerated doses, unless clinically significant adverse effects are experienced: atorvastatin, rosuvastatin, simvastatin, ezetimibe/simvastatin, pitavastatin, pravastatin, fluvastatin, or lovastatin. OR c) For members not on statin therapy, member is statin intolerant as



demonstrated by both of the following (1 and 2): 1) member has tried at least two statins, 1 of which must be hydrophilic statin (pravastatin, fluvastatin, or rosuvastatin), AND 2) One of the following (i or ii): i) member has a statin risk factor that increases the likelihood of experiencing an adverse effect to statin therapy (i.e., multiple or serious comorbidities, including impaired renal or hepatic function, unexplained alanine transaminase (ALT) elevations greater than 3 times upper limit of normal or active liver disease, concomitant use of drugs adversely affecting statin metabolism, age greater than 75 years or history of hemorrhagic stroke, Asian ancestry) OR ii) confirmation that member has experienced intolerable statin-associated muscle symptoms persisting for at least two weeks, which disappeared with discontinuing the statin therapy and recurred with a statin re-challenge (statin re-challenge may be initiated with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly)).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

ADENOSINE DEAMINASE SEVERE COMBINED IMMUNODEFICIENCY DISEASE (ADA-SCID):  
Prescribed by or in consultation with an immunologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

SCHIZOPHRENIA, MAJOR DEPRESSIVE DISORDER: 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 – 2021**

#### **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:**

RHEUMATOID ARTHRITIS: Prescribed by or in consultation with a rheumatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): 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 – 2021

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

RITUXAN

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

All medically accepted indications not otherwise excluded from Part D.

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

#### **Exclusion Criteria:**

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

RHEUMATOID ARTHRITIS (initial authorization only): Prescribed in combination with methotrexate, unless contraindicated or clinically significant adverse effects were experienced with prior methotrexate therapy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

ALL ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist or hematologist.  
RHEUMATOID ARTHRITIS, GRANULOMATOSIS WITH POLYANGIITIS, MICROSCOPIC POLYANGIITIS: Prescribed by or in consultation with a rheumatologist. PEMPFIGUS VULGARIS: Prescribed by or in consultation with a dermatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

ALL INDICATIONS (initial authorization only): Medical justification supports inability to use Ruxience (e.g., contraindications to excipients in Ruxience). RHEUMATOID ARTHRITIS (new starts only): Failure of infliximab, unless contraindicated or clinically significant adverse effects are experienced.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

RITUXAN HYCELA

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

All medically accepted indications not otherwise excluded from Part D.

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

#### **Exclusion Criteria:**

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

ALL INDICATIONS: Member has received at least one full dose of a rituximab product (e.g., Rituxan, Ruxience, or Truxima).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

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

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

ALL INDICATIONS: Medical justification supports inability to use Ruxience (e.g., contraindications to excipients in Ruxience).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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: Member has not received prior ROS1 targeted therapy (e.g., Xalkori, Zykadia, Lorbrena). NTRK FUSION-POSITIVE SOLID TUMOR: Member has not received prior NTRK targeted therapy (e.g., Vitrakvi).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

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

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

LAMBERT-EATON MYASTHENIC SYNDROME (LEMS) (initial authorization only): 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)). LEMS (continuation of therapy): Member is responding positively to therapy as evidenced by clinical muscle strength assessments.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

LEMS: Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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 (AML): Positive for the FLT3 mutation.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

ADVANCED SYSTEMIC MASTOCYTOSIS: Prescribed by or in consultation with an oncologist, allergist, or immunologist. ALL OTHER ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist or hematologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

SAVELLA

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

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

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

Depression.

#### **Exclusion Criteria:**

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

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

FIBROMYALGIA (new starts only): Failure of duloxetine or Lyrica, unless contraindicated or clinically significant adverse effects are experienced. DEPRESSION (new starts only): 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 – 2021**

**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:**

End of Plan Year.

**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 – 2021**

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

SEROQUEL XR

#### **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:**

End of Plan Year.

#### **Other Criteria:**

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



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

PLAQUE PSORIASIS: Prescribed by or in consultation with a rheumatologist or dermatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

PLAQUE PSORIASIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Skyrizi.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

SIMPONI(auto-injector, prefilled syringe)

#### **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:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR. PSORIATIC ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Xeljanz/Xeljanz XR. ANKYLOSING SPONDYLITIS (new starts only): Failure of Humira and Enbrel, unless contraindicated or clinically significant adverse effects are experienced. ULCERATIVE COLITIS (new starts only): Failure of Humira and Xeljanz/Xeljanz XR, unless contraindicated or clinically significant adverse effects are experienced.

## Prior Authorization Protocol

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### Medicare Part D – 2021

#### 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, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist.

#### Coverage Duration:

End of Plan Year.

#### Other Criteria:

RHEUMATOID ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR. PSORIATIC ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Xeljanz/Xeljanz XR. ANKYLOSING SPONDYLITIS (new starts only): Failure of Humira and Enbrel, unless contraindicated or clinically significant adverse effects are experienced. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Humira, Enbrel, Xeljanz.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

PLAQUE PSORIASIS: Prescribed by or in consultation with a dermatologist or rheumatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

PLAQUE PSORIASIS (new starts only): 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 – 2021**

#### **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:**

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

ACROMEGALY: Prescribed by or in consultation with an endocrinologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

SOVALDI

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

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

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

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

#### **Exclusion Criteria:**

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

CHRONIC HEPATITIS C INFECTION: 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:**

CHRONIC HEPATITIS C INFECTION: Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or provider who has expertise in treating HCV based on a certified training program.

#### **Coverage Duration:**

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

#### **Other Criteria:**

CHRONIC HEPATITIS C INFECTION (new starts only): 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 – 2021

#### **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:**

TREATMENT-RESISTANT DEPRESSION (TRD): Currently on an oral antidepressant (must not be an agent previously tried and failed). Spravato is prescribed in combination with an oral antidepressant. MAJOR DEPRESSIVE DISORDER WITH SUICIDAL IDEATION OR BEHAVIOR: Prescribed in combination with another oral antidepressant.

#### **Age Restrictions:**

TRD: Age is 18 to 64 years.

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

TRD: 6 months. MAJOR DEPRESSIVE DISORDER WITH SUICIDAL IDEATION OR BEHAVIOR: 4 weeks.

#### **Other Criteria:**

TRD: 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 – 2021**

**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:**

End of Plan Year.

**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 – 2021**

#### **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:**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

CROHN'S DISEASE, ULCERATIVE COLITIS: Prescribed by or in consultation with a gastroenterologist.

#### **Coverage Duration:**

4 weeks.

#### **Other Criteria:**

CROHN'S DISEASE (new starts only): Failure of Humira, unless contraindicated or clinically significant adverse effects are experienced. ULCERATIVE COLITIS(new starts only): Failure of Humira and Xeljanz/Xeljanz XR, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

PLAQUE PSORIASIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Skyrizi. PSORIATIC ARTHRITIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Xeljanz/Xeljanz XR. CROHN'S DISEASE (new starts only): Failure of Humira, unless contraindicated or clinically significant adverse effects are experienced. ULCERATIVE COLITIS (new starts only): Failure of Humira and Xeljanz/Xeljanz XR, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

HYPOPHOSPHATASIA: Prescribed by or in consultation with an endocrinologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Prescriber Restrictions:**

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

Member is already taking and is tolerant to around-the-clock opioid therapy. Member is 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 – 2021**

**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 or sleep medicine specialist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

NARCOLEPSY, OBSTRUCTIVE SLEEP APNEA (initial authorization only): 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 – 2021**

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

SURMONTIL

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

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

#### **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:**

End of Plan Year.

#### **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 – 2021

#### 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:

CYSTIC FIBROSIS (new starts only): Diagnosis of CF confirmed by all of the following (a, b, and c): 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) Elevated sweat chloride that is 60 mmol/L or greater, ii) Genetic testing confirming the presence of two disease-causing mutations in CFTR gene, one from each parental allele, AND c) One of the following (i or ii): i) Member is homozygous for the F508del mutation in the CFTR gene, OR ii) Presence of at least one mutation in the CFTR gene that is responsive to Symdeko. 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%. CYSTIC FIBROSIS (continuation of therapy): Member is responding positively to therapy as evidenced by a stabilization in ppFEV1 if baseline prior to initiating therapy was 70% or greater or increase in ppFEV1 if baseline prior to initiating therapy was less than 70%.

#### Age Restrictions:

#### Prescriber Restrictions:

CYSTIC FIBROSIS: Prescribed by or in consultation with a pulmonologist.

#### Coverage Duration:

End of Plan Year.

#### Other Criteria:

Symdeko is not prescribed concurrently with other CFTR modulators (e.g., Kalydeco, Orkambi, Trikafta).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

TYPE I OR TYPE 2 DIABETES MELLITUS (initial authorization only): Previous use of mealtime insulin therapy or an insulin pump.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

LENNOX-GASTAUT SYNDROME: Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

LENNOX-GASTAUT SYNDROME: 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 – 2021**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

TADALAFIL

#### **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:**

End of Plan Year.

#### **Other Criteria:**

## Prior Authorization Protocol

### Medicare Part D – 2021

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#### **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) (initial authorization only): Diagnosis is supported by one of the following (a or b): a) Tissue biopsy amyloid protein is identified as transthyretin via mass spectrometry or immunohistochemistry, AND (i or ii): i) Tissue biopsy is of endomyocardial origin OR ii) Tissue biopsy is of extra-cardiac origin and echocardiography (Echo), cardiac magnetic resonance imaging (CMR), or positron emission tomography (PET) findings are consistent with cardiac amyloidosis. OR 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 (a, b, or c): a) 99m technetium (Tc)-labeled 3,3-diphosphono-1,2-propanodicarboxylic acid (DPD), b) 99mTc-labeled pyrophosphate (PYP), or c) 99mTc-labeled hydroxymethylene diphosphonate (HMDP), AND iii) Each of the following laboratory tests is negative for monoclonal protein (a, b, and c): a) Serum kappa/lambda free light chain ratio analysis, b) Serum protein immunofixation, c) Urine protein immunofixation. ATTR-CM (continuation of therapy): 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:**

ATTR-CM: Prescribed by or in consultation with a cardiologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

TAGRISSE

**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:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Prescriber Restrictions:**

HEREDITARY ANGIOEDEMA: Prescribed by or in consultation with an immunologist, allergist, or hematologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2021

#### Prior Authorization Group Description:

TALTZ

#### 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:

PLAQUE PSORIASIS, PSORIATIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist or dermatologist. ANKYLOSING SPONDYLITIS, NONRADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: Prescribed by or in consultation with a rheumatologist.

#### Coverage Duration:

End of Plan Year.

#### Other Criteria:

PLAQUE PSORIASIS (new starts only): Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Skyrizi. PSORIATIC ARTHRITIS (new starts only): Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Xeljanz/Xeljanz XR. ANKYLOSING SPONDYLITIS (new starts only): Failure of Humira or Enbrel, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

TARGRETIN GEL

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

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

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

CHRONIC IMMUNE THROMBOCYTOPENIA (initial authorization only): 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 – 2021**

#### **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:**

#### **Prescriber Restrictions:**

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

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

MULTIPLE SCLEROSIS: Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (hATTR) (initial authorization only): 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.  
hATTR (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:**

hATTR: Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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) (initial authorization only): 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. Failure of a systemic corticosteroid, unless clinically significant adverse effects are experienced or all are contraindicated. TED (continuation of therapy): 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.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

TED: Prescribed by or in consultation with an ophthalmologist.

#### **Coverage Duration:**

6 months.

#### **Other Criteria:**

TED: 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).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

TEPMETKO

#### **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. Member does not have symptomatic CNS metastases.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

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

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

HUNTINGTON'S DISEASE CHOREA: Prescribed by or in consultation with a neurologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2021

**Prior Authorization Group Description:**

TOLSURA

**Prior Authorization Indication:**

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

**Off Label Uses:**

Hematologic malignancy for prophylaxis of aspergillosis.

**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 (new starts only): Failure of generic itraconazole capsule, unless contraindicated or clinically significant adverse effects are experienced. ASPERGILLOSIS (new starts only): Failure of voriconazole, unless contraindicated or clinically significant adverse effects are experienced.



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

PLAQUE PSORIASIS and PSORIATIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist or dermatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

PLAQUE PSORIASIS (new starts only): Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: Enbrel, Humira, Skyrizi. PSORIATIC ARTHRITIS (new starts only): Failure of two of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Enbrel, Humira, Xeljanz/Xeljanz XR.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

ALL INDICATIONS (continuation of therapy): Prescriber has documented all of the following (a, b, and c): a) Medical justification outlining the specific benefit for continued therapy that outweighs the potential risk, b) Patient counseling has occurred outlining the potential risks of the medication, c) Ongoing monitoring plan.

#### **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:**

End of Plan Year.

#### **Other Criteria:**

PARKINSON'S DISEASE/PARKINSONISM (new starts only): 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 – 2021

#### **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 (new starts only): Diagnosis of cystic fibrosis (CF) confirmed by all of the following (a, b, and c): 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. c) Confirmation of one of the following (i or ii): i) Member has at least one F508del mutation in the CFTR gene, OR ii) Member has a mutation in the CFTR gene that is responsive to Trikafta. 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%. CYSTIC FIBROSIS (continuation of therapy): For members that received at least 12 weeks of therapy, member is responding positively to therapy as evidenced by stabilization in ppFEV1 if baseline prior to initiating therapy was 70% or greater or increase in ppFEV1 if baseline prior to initiating therapy was less than 70%.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

CYSTIC FIBROSIS: Prescribed by or in consultation with a pulmonologist.

#### **Coverage Duration:**

Initial: 4 months. Continuation of therapy: End of Plan Year.

#### **Other Criteria:**

Trikafta is not prescribed concurrently with other CFTR modulators (e.g., Orkambi, Kalydeco, Symdeko).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

TRUSELTIQ

**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:**

End of Plan Year.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2021

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

TRUXIMA

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

All medically accepted indications not otherwise excluded from Part D.

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

#### **Exclusion Criteria:**

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

RHEUMATOID ARTHRITIS (initial authorization only): Prescribed in combination with methotrexate, unless contraindicated or clinically significant adverse effects were experienced with prior methotrexate therapy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

ALL ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist or hematologist.  
RHEUMATOID ARTHRITIS, GRANULOMATOSIS WITH POLYANGIITIS, MICROSCOPIC  
POLYANGIITIS: Prescribed by or in consultation with a rheumatologist. PEMPFIGUS VULGARIS: Prescribed  
by or in consultation with a dermatologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

ALL INDICATIONS (initial authorization only): Medical justification supports inability to use Ruxience (e.g., contraindications to excipients in Ruxience). RHEUMATOID ARTHRITIS (new starts only): Failure of infliximab, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## Prior Authorization Protocol

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### Medicare Part D – 2021

#### **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:**

POSTMENOPAUSAL OSTEOPOROSIS (PMO): Total duration of therapy on parathyroid hormone (PTH) analogs (e.g., Tymlos, Forteo) has not exceeded 2 years.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

PMO (initial authorization only): Member meets one of the following (a, b, or c): a) Failure of bisphosphonate therapy (e.g., alendronate) unless contraindicated or clinically significant adverse effects are experienced to both intravenous and oral formulations. 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 – 2021**

#### **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 (MS): Prescribed by or in consultation with a neurologist. CROHN'S DISEASE (CD): Prescribed by or in consultation with a gastroenterologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

RELAPSING-REMITTING MS (new starts only): Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: Aubagio, Tecfidera, Gilenya, Avonex, Betaseron, Plegridy, glatiramer, Copaxone, Glatopa, Extavia, Rebif. CD (new starts only): Failure of Humira and infliximab/infliximab biosimilar, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

UKONIQ

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ULTRAVATE LOTION

#### **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:**

End of Plan Year.

#### **Other Criteria:**

PLAQUE PSORIASIS (initial authorization only): Failure of generic halobetasol propionate and generic clobetasol propionate, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

PULMONARY ARTERIAL HYPERTENSION: Prescribed by or in consultation with a cardiologist or pulmonologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

EPILEPSY: Diagnosis of partial or generalized epilepsy.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

EPILEPSY: Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

EPILEPSY: Medical justification supports inability to use diazepam rectal gel (e.g., contraindications to excipients).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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 – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

VERSACLOZ

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

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

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

Psychotic disorder associated with Parkinson's disease.

#### **Exclusion Criteria:**

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

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

ALL INDICATIONS: Medical justification supports inability to use clozapine tablets (generic Clozaril or FazaClo) (e.g., contraindications to excipients).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

VIBERZI

#### **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:**

End of Plan Year.

#### **Other Criteria:**

IRRITABLE BOWEL SYNDROME WITH DIARRHEA (initial authorization only): Failure of loperamide unless contraindicated or clinically significant adverse effects are experienced AND For members 64 years and younger, failure of diphenoxylate-atropine (Lomotil) or dicyclomine, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

VIMOVO

#### **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:**

End of Plan Year.

#### **Other Criteria:**

ALL INDICATIONS (initial authorization only): Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: pantoprazole, lansoprazole or omeprazole AND For osteoarthritis or rheumatoid arthritis (initial authorization only): Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: ibuprofen, diclofenac sodium or potassium, etodolac, ketoprofen, meloxicam, naproxen, oxaprozin, piroxicam, sulindac, tolmetin OR For ankylosing spondylitis (initial authorization only): Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: diclofenac sodium, naproxen or sulindac OR For juvenile idiopathic arthritis (initial authorization only): Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: etodolac, ibuprofen, meloxicam, naproxen, oxaprozin, tolmetin.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

NTRK FUSION-POSITIVE SOLID TUMOR: Failure of Rozlytrek, unless contraindicated or clinically significant adverse effects are experienced

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

VORICONAZOLE 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:**

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

CHRONIC HEPATITIS C INFECTION: 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:**

CHRONIC HEPATITIS C INFECTION: Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or provider who has expertise in treating HCV based on a certified training program.

#### **Coverage Duration:**

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

#### **Other Criteria:**

CHRONIC HEPATITIS C INFECTION: Criteria will be applied consistent with current AASLD-IDSA guidance.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

End of Plan Year.

#### **Other Criteria:**

BIPOLAR I DISORDER, SCHIZOPHRENIA: 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 – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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) (initial authorization only): 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 – 2021**

#### **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 WITH CATAPLEXY OR NARCOLEPSY WITH EXCESSIVE DAYTIME SLEEPINESS:  
Prescribed by or in consultation with a neurologist or sleep medicine specialist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

NARCOLEPSY WITH EXCESSIVE DAYTIME SLEEPINESS (initial authorization only): Failure of Sunosi, unless contraindicated or clinically significant adverse effects are experienced. NARCOLEPSY WITH CATAPLEXY (initial authorizations only): Failure of two antidepressants from the following classes, unless clinically significant adverse effects are experienced or all are contraindicated: selective serotonin reuptake inhibitors (SSRI), serotonin-norepinephrine reuptake inhibitors (SNRI), tricyclic antidepressants (TCA).

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**Prior Authorization Group Description:**

WELIREG

**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:**

End of Plan Year.

**Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

ALL ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist or hematologist.  
POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist.

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

End of Plan Year.

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

ALL INDICATIONS: Medical justification as to why member cannot use methotrexate tablets.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

PARTIAL-ONSET SEIZURES: Prescribed by or in consultation with a neurologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

PARTIAL-ONSET SEIZURES: 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 – 2021**

#### **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:**

POLYARTICULAR COURSE JUVENILE IDIOPATHIC ARTHRITIS AND RHEUMATOID ARTHRITIS: Prescribed by or in consultation with a rheumatologist. PSORIATIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist or dermatologist. ULCERATIVE COLITIS: Prescribed by or in consultation with a gastroenterologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

RHEUMATOID ARTHRITIS (new starts only): 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 – 2021

#### **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:**

COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP): 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:**

CABP: 7 days.

#### **Other Criteria:**

CABP: 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 – 2021**

**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:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

XGEVA

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

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

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

Systemic mastocytosis related osteopenia or osteoporosis.

#### **Exclusion Criteria:**

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

HYPERCALCEMIA OF MALIGNANCY (new starts only): albumin-corrected calcium greater than 12.5 mg/dL despite intravenous (IV) bisphosphonate therapy in the last 30 days.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

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

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

SYSTEMIC MASTOCYTOSIS (initial authorization only): failure of a bisphosphonate (e.g., zoledronic acid), unless contraindicated or clinically significant adverse effects are experienced.



## Prior Authorization Protocol

### Medicare Part D – 2021

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#### **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 (initial authorization only): Positive skin test or in vitro reactivity to a perennial aeroallergen AND immunoglobulin E (IgE) level greater than or equal to 30 IU/mL. ASTHMA (continuation of therapy): member is responding positively to therapy (examples may include but are not limited to a reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second since baseline prior to initiating therapy, reduction in the use of rescue therapy since baseline prior to initiating therapy). CHRONIC IDIOPATHIC URTICARIA (continuation of therapy): member is responding positively to therapy (e.g., improved symptoms). NASAL POLYPS: Diagnosis of chronic rhinosinusitis with nasal polyps. Xolair is prescribed concurrently with an intranasal corticosteroid, unless contraindicated or clinically significant adverse effects are experienced. NASAL POLYPS (initial authorization only): Disease is bilateral, and member has experienced signs and symptoms (e.g., nasal congestion/blockage/obstruction, loss of smell, rhinorrhea) for at least 12 weeks. NASAL POLYPS (continuation of therapy): Member is responding positively to therapy (examples may include but are not limited to: reduced nasal polyp size, reduced need for systemic corticosteroids, improved sense of smell, improved quality of life).

#### **Age Restrictions:**

#### **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. NASAL POLYPS: Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist.

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

ASTHMA (initial authorization only): 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 (initial authorization only): Failure of one H1 Antihistamine (e.g., levocetirizine or desloratadine), unless contraindicated or clinically significant adverse effects are experienced. NASAL POLYPS (initial authorization only): Failure of maintenance therapy with an intranasal corticosteroid, unless contraindicated or clinically significant adverse effects are experienced.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

---

### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

---

### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

PROSTATE CANCER: Prescribed by or in consultation with an oncologist or urologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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: Member has not had previous treatment with a checkpoint inhibitor (e.g., Opdivo, Keytruda, Tecentriq, Imfinzi). NON-SMALL CELL LUNG CANCER: Member has not previously progressed on a PD-1/PD-L1 inhibitor (e.g., Opdivo, Keytruda, Tecentriq, Imfinzi).

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

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

#### **Coverage Duration:**

End of Plan Year.

#### **Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

PROSTATE CANCER: Prescribed by or in consultation with an oncologist or urologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

PROSTATE CANCER: Medical justification supports inability to use Zytiga (e.g., contraindications to excipients).  
Member has not had disease progression after prior treatment with Zytiga.

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

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

ZARXIO

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

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

#### **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:**

End of Plan Year.

#### **Other Criteria:**



## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

ERDHEIM-CHESTER DISEASE, HAIRY CELL LEUKEMIA: Prescribed by or in consultation with an oncologist or hematologist. ALL OTHER ONCOLOGY INDICATIONS: Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

#### **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:**

CHRONIC HEPATITIS C INFECTION: 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-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:**

CHRONIC HEPATITIS C INFECTION: Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or provider who has expertise in treating HCV based on a certified training program.

#### **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 – 2021**

#### **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:**

CLOSTRIDIUM DIFFICILE INFECTION (CDI): Confirmation of positive Clostridium difficile test.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

4 weeks.

#### **Other Criteria:**

CDI: 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 – 2021**

#### **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:**

POSTPARTUM DEPRESSION: No more than 6 months have passed since member has given birth.

#### **Age Restrictions:**

#### **Prescriber Restrictions:**

#### **Coverage Duration:**

POSTPARTUM DEPRESSION: 4 weeks.

#### **Other Criteria:**

POSTPARTUM DEPRESSION: 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 – 2021**

**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:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

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### **Medicare Part D – 2021**

**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:**

**Age Restrictions:**

**Prescriber Restrictions:**

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

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**

## **Prior Authorization Protocol**

---

### **Medicare Part D – 2021**

**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:**

PROSTATE CANCER: Prescribed by or in consultation with an oncologist or urologist.

**Coverage Duration:**

End of Plan Year.

**Other Criteria:**



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