

Prior Authorization Protocol

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

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

Medicare Part D – 2021

Prior Authorization Group Description:

PROCYSBI

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

NEPHROPATHIC CYSTINOSIS (initial authorization only): Diagnosis is confirmed by one of the following (a, b, or c): a) Increased leukocyte cystine concentration (normal concentration: less than 0.2 nmol half-cystine/mg protein). b) Cystinosis, lysosomal cystine transporter gene mutation. c) Corneal crystals on slit lamp examination. NEPHROPATHIC CYSTINOSIS (continuation of therapy): Member is responding positively to therapy as evidenced by improvement in the leukocyte cystine concentration.

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

End of Plan Year.

Other Criteria:

NEPHROPATHIC CYSTINOSIS (initial authorization only): Medical justification supports inability to use Cystagon (e.g., contraindication to excipients in Cystagon).

Prior Authorization Protocol

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

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

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

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

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

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

Medicare Part D – 2021

Prior Authorization Group Description:

QSYMIA

Prior Authorization Indication:

As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m² or greater (obese) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

BMI is greater than or equal to 30 kg/m² OR BMI is greater than or equal to 27 kg/m² with one or more of the following severe co-morbid conditions 1. Coronary artery/heart disease 2. Diabetes 3. Dyslipidemia 4. Hypertension 5. Obstructive sleep apnea. CONTINUATION OF THERAPY: One of the following (a, b, or c): a) Member has received less than 12 weeks of treatment on 7.5 mg/46 mg and request is for a dose escalation, OR b) Member received up to 12 weeks of treatment on 7.5 mg/46 mg and confirmation of a 3% weight loss from baseline prior to initiating therapy, OR c) Confirmation of at least 5% weight loss from baseline body weight prior to initiating therapy. Subsequent authorizations require confirmation of weight maintenance.

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Initial auth:12 weeks. Continuation of therapy: First auth:12 weeks. Subsequent reauth:6 months.

Other Criteria:

Prior Authorization Protocol

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Medicare Part D – 2021

Prior Authorization Group Description:

XENICAL

Prior Authorization Indication:

For obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet or to reduce the risk for weight regain after prior weight loss in obese patients with an initial body mass index (BMI) of 30 kg/m² or greater (obese) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

BMI is greater than or equal to 30 kg/m² OR BMI is greater than or equal to 27 kg/m² with one or more of the following severe co-morbid conditions 1. Coronary artery/heart disease 2. Diabetes 3. Dyslipidemia 4. Hypertension 5. Obstructive sleep apnea. CONTINUATION OF THERAPY: for members that received at least 6 months of treatment, confirmation of a 5-10 pound weight loss from baseline prior to initiating therapy. Subsequent authorizations require confirmation of weight maintenance.

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

6 months.

Other Criteria:

Prior Authorization Protocol

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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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