

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

ORKAMBI

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

2 years of age or older.

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

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:

Age Restrictions:

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

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

OXBRYTA

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

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

Prescriber Restrictions:

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

Coverage Duration:

6 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

OXERVATE

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an ophthalmologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PALYNZIQ

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PEMAZYRE

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PENNSAID

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PENTAZOCINE/NALOXONE

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

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

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: codeine, hydromorphone, morphine, oxymorphone, hydrocodone/acetaminophen or oxycodone.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PERSERIS

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PHENOBARBITAL

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

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

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PIQRAY

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PRALUENT

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

6 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PRETOMANID

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

Initial: 6 months. Reauthorization: 3 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PREVYMIS

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

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

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

Through day 100 post-transplantation.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

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:

Age Restrictions:

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

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PROLASTIN C

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a pulmonologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PROLIA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PROMACTA

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PROTOPIC

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Tacrolimus 0.1%: 16 years and older.

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PROVIGIL

Prior Authorization Indication:

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

Off Label Uses:

Multiple sclerosis-related fatigue.

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

PURIXAN

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with oncologist or hematologist.

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

QINLOCK

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

QUALAQUIN

Prior Authorization Indication:

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

Off Label Uses:

Babesiosis. Plasmodium vivax malaria.

Exclusion Criteria:

For the treatment or prevention of nocturnal leg cramps.

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

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

Other Criteria:

Plasmodium vivax malaria: Infection is chloroquine-resistant.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

RADICAVA

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a neurologist.

Coverage Duration:

6 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

RAYALDEE

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

REBLOZYL

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

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

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

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:

12 months.

Other Criteria:

Failure of Amitiza and Movantik, unless contraindicated or clinically significant adverse effects are experienced.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

REMICADE

Prior Authorization Indication:

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

Off Label Uses:

Wegener's Granulomatosis.

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

RENFLEXIS

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

REPATHA

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

6 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

RETEVMO

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

REVATIO

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

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

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

REVC0VI

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an immunologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

REVLIMID

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist or hematologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

REXULTI

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

RINVOQ

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a rheumatologist.

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

RITUXIMAB

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. Rheumatoid arthritis, granulomatosis with polyangiitis, microscopic polyangiitis: Prescribed by or in consultation with a rheumatologist. Pemphigus vulgaris: Prescribed by or in consultation with a dermatologist.

Coverage Duration:

12 months.

Other Criteria:

Rheumatoid Arthritis: Prescribed in combination with methotrexate, unless contraindicated or clinically significant adverse effects were experienced with prior methotrexate therapy AND failure of Enbrel or Humira, unless contraindicated or clinically significant adverse effects are experienced. Granulomatosis with polyangiitis, Microscopic polyangiitis: Prescribed in combination with a glucocorticoid (e.g. prednisone, prednisolone, dexamethasone).

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

ROZLYTREK

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

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

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

RUBRACA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

RUZURGI

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a neurologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

RYDAPT

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Acute Myeloid Leukemia: Positive for the FLT3 mutation.

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SAVELLA

Prior Authorization Indication:

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

Off Label Uses:

Depression.

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Fibromyalgia: Failure of duloxetine or Lyrica, unless contraindicated or clinically significant adverse effects are experienced. 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 – 2020

Prior Authorization Group Description:

SECUADO

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

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:

12 months.

Other Criteria:

Schizophrenia: 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

Medicare Part D – 2020

Prior Authorization Group Description:

SILIQ

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a rheumatologist or dermatologist.

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

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:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SIMPONI ARIA

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SKYRIZI

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a dermatologist or rheumatologist.

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SOMA

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

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

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SOMAVERT

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an endocrinologist.

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SOVALDI

Prior Authorization Indication:

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

Off Label Uses:

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

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

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

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SPRAVATO

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

Initial: 4 weeks. Reauthorization: 6 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SPRITAM

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SPRYCEL

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

STELARA IV

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a gastroenterologist.

Coverage Duration:

4 weeks.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

STELARA SC

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

STIVARGA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

STRENSIQ

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SUBSYS

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Age 18 or greater.

Prescriber Restrictions:

Coverage Duration:

Through the end of the Plan contract year.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SUNOSI

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

NARCOLEPSY: Prescribed by or in consultation with a neurologist.

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SURMONTIL

Prior Authorization Indication:

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

Off Label Uses:

Irritable bowel syndrome.

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

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

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SYMDEKO

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Age greater than or equal to 6 years.

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SYMLINPEN

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Previous use of mealtime insulin therapy or an insulin pump.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

SYMPAZAN

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a neurologist.

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TABRECTA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TAFAMIDIS

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a cardiologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TAGRISSO

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TAKHZYRO

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Age greater than or equal to 12 years.

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TALZENNA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TARCEVA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

PANCREATIC CANCER: Prescribed in combination with gemcitabine.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TARGRETIN GEL

Prior Authorization Indication:

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

Off Label Uses:

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

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TASIGNA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TAVALISSE

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TAZVERIK

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

EPITHELIOID SARCOMA: Age 16 years or older.

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TECENTRIQ

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TECFIDERA

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a neurologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TEGSEDI

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a neurologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TENEX

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

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

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TETRABENAZINE

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a neurologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TIBSOVO

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Presence of an isocitrate dehydrogenase-1 (IDH1) mutation. For newly diagnosed acute myeloid leukemia (AML), member is age 60 years or older OR medical justification supports inability to use intensive induction therapy.

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist or hematologist.

Coverage Duration:

12 months.

Other Criteria:

For age less than 60 years where medical justification does not support inability to use intensive induction therapy, disease has relapsed or is refractory following treatment with standard antineoplastic induction agents (e.g., cytarabine, idarubicin, daunorubicin, cladribine, midostaurin).

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TOLSURA

Prior Authorization Indication:

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

Off Label Uses:

Hematologic malignancy for prophylaxis of aspergillosis or candidiasis.

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

HISTOPLASMOSIS: 6 weeks. ASPERGILLOSIS: 3 months. BLASTOMYCOSIS, HEMATOLOGIC MALIGNANCY: 6 months.

Other Criteria:

ALL INDICATIONS: Failure of generic itraconazole capsule, unless contraindicated or clinically significant adverse effects are experienced. ASPERGILLOSIS: Failure of voriconazole, unless contraindicated or clinically significant adverse effects are experienced. HEMATOLOGIC MALIGNANCY: For candidiasis prophylaxis, failure of fluconazole, unless contraindicated or clinically significant adverse effects are experienced.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TREMFYA

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a rheumatologist or dermatologist.

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TRIHEXYPHENIDYL

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

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

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Parkinsons disease/Parkinsonism: Failure of two of the following, unless contraindicated or clinically significant adverse effects are experienced: amantadine, levodopa/carbidopa, entacapone, pramipexole, ropinirole, selegiline.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TRIKAFTA

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

CYSTIC FIBROSIS: Diagnosis of cystic fibrosis (CF) confirmed by both of the following (a and b): a) Clinical symptoms consistent with CF in at least one organ system, or positive newborn screen or genetic testing for siblings of patients with CF, AND b) Evidence of cystic fibrosis transmembrane conductance regulator (CFTR) dysfunction confirmed by one of the following (i or ii): i) Evidence of clinical severity as defined by an average sweat chloride greater than 60 mmol/L, OR ii) Genetic testing confirming the presence of two disease-causing mutations in CFTR gene, one from each parent allele, and one of which is a F508del mutation. Confirmation that pulmonary function tests, performed within the last 90 days, show a percent predicted forced expiratory volume in 1 second (ppFEV1) that is between 40-90%. Trikafta is not prescribed concurrently with other CFTR modulators (e.g., Orkambi, Kalydeco, Symdeko). CONTINUATION OF THERAPY, CYSTIC FIBROSIS: For members that received at least 12 weeks of therapy, member is responding positively to therapy as evidenced by stabilization in ppFEV1 if baseline was 70% or greater or increase in ppFEV1 if baseline was less than 70%.

Age Restrictions:

CYSTIC FIBROSIS: Age greater than or equal to 12 years.

Prescriber Restrictions:

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

Coverage Duration:

Initial: 4 months. Reauthorization: 12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TUKYSA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TURALIO

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TYMLOS

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Total duration of therapy on parathyroid hormone (PTH) analogs (e.g., Tymlos, Forteo) has not exceeded 2 years.

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Member meets one of the following (a, b, or c): a) Failure of a bisphosphonate (e.g., alendronate) unless contraindicated or clinically significant adverse effects are experienced. OR b) Bone mineral density T-score at hip or spine is -3.5 or less. OR c) Bone mineral density T-score at hip or spine is -2.5 or less with a history of major osteoporotic fracture of the hip, spine, forearm, wrist, or humerus.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

TYSABRI

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

MULTIPLE SCLEROSIS: Prescribed by or in consultation with a neurologist. CROHN'S DISEASE: Prescribed by or in consultation with a gastroenterologist.

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

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:

12 months.

Other Criteria:

Failure of generic halobetasol propionate and generic clobetasol propionate, unless contraindicated or clinically significant adverse effects are experienced.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

UPTRAVI

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VALCHLOR

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Failure of one of the following skin-directed therapies unless contraindicated or clinically significant adverse effects are experienced: topical corticosteroid (e.g., betamethasone, clobetasol), topical retinoid (e.g., Targretin, Avage, Fabior, Tazorac), topical imiquimod (Aldara).

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VALTOCO

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Diagnosis of partial or generalized epilepsy.

Age Restrictions:

6 years of age or older.

Prescriber Restrictions:

Prescribed by or in consultation with a neurologist.

Coverage Duration:

12 months.

Other Criteria:

Medical justification supports inability to use diazepam rectal gel (e.g., contraindications to excipients).

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VANCOGIN

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

C. Diff diarrhea: 14 days. Staph enterocolitis: 10 days. Recurrent C. Diff: 12 weeks.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VENCLEXTA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

AML: Age 60 years or greater, OR medical justification supports inability to use intensive induction chemotherapy. Prescribed in combination with azacitidine, decitabine, or low-dose cytarabine.

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist or hematologist.

Coverage Duration:

12 months.

Other Criteria:

MANTLE CELL LYMPHOMA: Failure of at least one previous therapy (e.g., a Rituxan based regimen), unless contraindicated or clinically significant adverse effects are experienced. CLL/SLL: Request meets one of the following (a or b): a) Prescribed in combination with Gazyva as first-line therapy OR b) Failure of at least one previous therapy (e.g., Imbruvica, Campath, or high-dose methylprednisolone with Rituxan), unless contraindicated or clinically significant adverse effects are experienced.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VERSACLOZ

Prior Authorization Indication:

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

Off Label Uses:

Psychotic disorder associated with Parkinson's disease.

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Failure of clozapine (Clozaril) or FazaClo, unless contraindicated or clinically significant adverse effects are experienced.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VERZENIO

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prescribed as a single agent or in combination with an aromatase inhibitor (e.g., letrozole, anastrozole or exemestane) or fulvestrant. For men receiving an aromatase inhibitor: Prescribed in combination with an agent that suppresses testicular steroidogenesis (e.g., gonadotropin-releasing hormone agonists).

Prior Authorization Protocol

Medicare Part D – 2020

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:

12 months.

Other Criteria:

Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: pantoprazole, lansoprazole or omeprazole AND For osteoarthritis or rheumatoid arthritis: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: ibuprofen, diclofenac sodium or potassium, etodolac, fenoprofen, ketoprofen, meloxicam, naproxen, oxaprozin, piroxicam, salsalate, sulindac, tolmetin OR For ankylosing spondylitis: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: diclofenac sodium, naproxen or sulindac OR For juvenile idiopathic arthritis: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: etodolac, ibuprofen, meloxicam, naproxen, oxaprozin, tolmetin.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VINBLASTINE

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Confirmation that vinblastine is being used as palliative therapy.

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist or hematologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VINCRIStINE

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Patients with the demyelinating form of Charcot-Marie-Tooth syndrome.

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist or hematologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VITRAKVI

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Known acquired tropomyosin receptor kinase resistance mutation.

Required Medical Information:

Confirmation of positive neurotrophic receptor tyrosine kinase gene fusion mutation.

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VIZIMPRO

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Disease is positive for a sensitizing EGFR mutation (e.g., exon 19 deletion or insertion, exon 21 point mutation (L858R, L861Q), exon 18 point mutation (G719X), exon 20 point mutation (S768I)).

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VOSEVI

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 weeks.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VOTRIENT

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VRAYLAR

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VUMERITY

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

VYONDYS 53

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

DUCHENNE MUSCULAR DYSTROPHY (DMD): DMD with mutation amenable to exon 53 skipping confirmed by genetic testing.

Age Restrictions:

Prescriber Restrictions:

DMD: Prescribed by or in consultation with a neurologist.

Coverage Duration:

6 months.

Other Criteria:

DMD: Currently stable on an oral corticosteroid regimen (e.g., prednisone), unless contraindicated or clinically significant adverse effects are experienced.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

WAKIX

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

NARCOLEPSY: Prescribed by or in consultation with a neurologist.

Coverage Duration:

12 months.

Other Criteria:

NARCOLEPSY: Failure of Sunosi, unless contraindicated or clinically significant adverse effects are experienced.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

XALKORI

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

NON-SMALL CELL LUNG CANCER: Disease is ALK, ROS1, or MET positive. INFLAMMATORY MYOFIBROBLASTIC TUMOR, ANAPLASTIC LARGE CELL LYMPHOMA: Disease is ALK-positive.

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

XATMEP

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Less than 18 years of age.

Prescriber Restrictions:

ACUTE LYMPHOCYTIC LEUKEMIA: Prescribed by or in consultation with an oncologist or hematologist.
POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist.

Coverage Duration:

12 months.

Other Criteria:

Medical justification as to why member cannot use methotrexate tablets.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

XCOPRI

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a neurologist.

Coverage Duration:

12 months.

Other Criteria:

Failure of two of the following generic antiepileptic drugs, unless contraindicated or clinically significant adverse effects are experienced: lamotrigine, topiramate, oxcarbazepine, carbamazepine, phenytoin, valproic acid, divalproex sodium, felbamate, gabapentin, levetiracetam, pregabalin, tiagabine, zonisamide.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

XELJANZ

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

RHEUMATOID ARTHRITIS: Prescribed by or in consultation with a rheumatologist. PSORIATIC ARTHRITIS: Prescribed by or in consultation with a rheumatologist or dermatologist. ULCERATIVE COLITIS (IMMEDIATE-RELEASE ONLY): Prescribed by or in consultation with a gastroenterologist.

Coverage Duration:

12 months.

Other Criteria:

RHEUMATOID ARTHRITIS: Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, sulfasalazine, hydroxychloroquine, d-penicillamine, azathioprine or auranofin. PSORIATIC ARTHRITIS: Failure of one TNF inhibitor (e.g., Humira, Enbrel, Cimzia, Simponi, Simponi Aria, Remicade, Inflectra), unless predominantly axial disease, contraindicated, or clinically significant adverse effects are experienced.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

XENLETA

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

7 days.

Other Criteria:

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

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

XEOMIN

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

XERMELO

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Prescribed in combination with a somatostatin analog (e.g., octreotide, lanreotide) unless contraindicated or clinically significant adverse effects are experienced.

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Failure of a somatostatin analog (e.g., octreotide, lanreotide) unless contraindicated or clinically significant adverse effects are experienced.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

XOLAIR

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

ASTHMA: Positive skin test or in vitro reactivity to a perennial aeroallergen AND immunoglobulin E (IgE) level greater than or equal to 30 IU/mL.

Age Restrictions:

ASTHMA: 6 years of age or older. CHRONIC IDIOPATHIC URTICARIA: 12 years of age or older.

Prescriber Restrictions:

ASTHMA: Prescribed by or in consultation with a pulmonologist, immunologist, or allergist. CHRONIC IDIOPATHIC URTICARIA: Prescribed by or in consultation with an allergist, dermatologist, or immunologist.

Coverage Duration:

12 months.

Other Criteria:

ASTHMA: Failure of one inhaled corticosteroid (e.g., beclomethasone, budesonide, flunisolide, fluticasone, mometasone, ciclesonide), unless contraindicated or clinically significant adverse effects are experienced.
CHRONIC IDIOPATHIC URTICARIA: Failure of one H1 Antihistamine (e.g., levocetirizine or desloratadine), unless contraindicated or clinically significant adverse effects are experienced.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

XOSPATA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Confirmation of the presence of a FLT3 mutation.

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist or hematologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

XPOVIO

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

MULTIPLE MYELOMA: Member has received at least 4 prior lines of therapy that include all of the following (a, b, and c): a) Two proteasome inhibitors (e.g., bortezomib, Kyprolis, Ninlaro), b) Two immunomodulatory agents (e.g., Revlimid, pomalidomide, Thalomid), c) One anti-CD38 monoclonal antibody (e.g., Darzalex).

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist or hematologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

XTANDI

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

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

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist or urologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

YERVOY

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

HEPATOCELLULAR CARCINOMA (new starts only): Member has not had previous treatment with a checkpoint inhibitor (e.g., Opdivo, Keytruda, Tecentriq, Imfinzi). NON-SMALL CELL LUNG CANCER (new starts only): Member has not previously progressed on a PD-1/PD-L1 inhibitor (e.g., Opdivo, Keytruda, Tecentriq, Imfinzi).

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

SMALL CELL LUNG CANCER, MALIGNANT PLEURAL MESOTHELIOMA: Failure of a platinum-containing regimen (e.g., cisplatin, carboplatin), unless contraindicated or clinically significant adverse effects are experienced.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

YONSA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist or urologist.

Coverage Duration:

12 months.

Other Criteria:

Medical justification supports inability to use Zytiga. Prescribed in combination with methylprednisolone. Member has previously had bilateral orchiectomy, failed androgen deprivation therapy (ADT) or will use ADT concurrently with Yonsa.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

ZALTRAP

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prescribed in combination with irinotecan or FOLFIRI (5-fluorouracil, leucovorin, and irinotecan). Previous treatment with one of the following: oxaliplatin-containing regimen (e.g., FOLFIRI, FOLFOX [leucovorin, 5-fluorouracil, oxaliplatin], CapeOX [capecitabine, oxaliplatin]) OR 5-fluorouracil and leucovorin containing regimen OR capecitabine containing regimen.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

ZARXIO

Prior Authorization Indication:

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

Off Label Uses:

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

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

ZEJULA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

OVARIAN, FALLOPIAN, OR PRIMARY PERITONEAL CANCER: Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

ZELBORAF

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

MELANOMA, ERDHEIM-CHESTER DISEASE: Positive for the BRAF V600 mutation. NON-SMALL CELL LUNG CANCER, COLORECTAL CANCER: Positive for the BRAF V600E mutation. DIFFERENTIATED THYROID CARCINOMA: Positive for the BRAF mutation.

Age Restrictions:

Prescriber Restrictions:

ERDHEIM-CHESTER DISEASE, HAIRY CELL LEUKEMIA: Prescribed by or in consultation with an oncologist or hematologist. ALL OTHER ONCOLOGY INDICATION: Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

NON-SMALL CELL LUNG CANCER: Failure of Tafenlar or Mekinist, unless contraindicated or clinically significant adverse effects are experienced. COLORECTAL CANCER: Failure of irinotecan or platinum-based therapy (e.g., oxaliplatin), unless contraindicated or clinically significant adverse effects are experienced.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

ZEPATIER

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

If cirrhosis is present, confirmation of Child-Pugh A status. For genotype 1a, confirmation of presence or absence of NS5A resistance-associated polymorphisms. Refer to the document, "Recommendations for Testing, Managing, and Treating Hepatitis C," by AASLD-IDSA available at <http://www.hcvguidelines.org> for drug regimen and duration of treatment based on genotype, treatment status, previous drug regimens used, past medical history and comorbidities.

Age Restrictions:

Prescriber Restrictions:

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

Coverage Duration:

12 to 16 wks based on genotype,presence of NS5A resistance-associated polymorphisms,prior treatment.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

ZINPLAVA

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Confirmation of positive Clostridium difficile test.

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

4 weeks.

Other Criteria:

Will receive or is currently receiving antibacterial drug treatment for Clostridium difficile infection (e.g., metronidazole, vancomycin, fidaxomicin) concomitantly with Zinplava. Has received appropriate treatment for past CDI recurrences, including a pulsed vancomycin regimen.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

ZULRESSO

Prior Authorization Indication:

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

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

No more than 6 months have passed since member has given birth.

Age Restrictions:

Prescriber Restrictions:

Coverage Duration:

4 weeks.

Other Criteria:

Failure of one of the following oral antidepressants, unless contraindicated or clinically significant adverse effects are experienced: selective serotonin reuptake inhibitor (SSRI), serotonin-norepinephrine reuptake inhibitor (SNRI), tricyclic antidepressant (TCA), bupropion, mirtazapine.

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

ZYDELIG

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with a hematologist or oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

ZYKADIA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

NON-SMALL CELL LUNG CANCER: Disease is ALK or ROS1 positive. If disease is ROS1 positive, Zykadia is prescribed as first-line therapy. INFLAMMATORY MYOFIBROBLASTIC TUMOR: Disease is ALK-positive.

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist.

Coverage Duration:

12 months.

Other Criteria:

Prior Authorization Protocol

Medicare Part D – 2020

Prior Authorization Group Description:

ZYTIGA

Prior Authorization Indication:

All medically accepted indications not otherwise excluded from Part D.

Off Label Uses:

Exclusion Criteria:

Required Medical Information:

Age Restrictions:

Prescriber Restrictions:

Prescribed by or in consultation with an oncologist or urologist.

Coverage Duration:

12 months.

Other Criteria:

Prescribed in combination with prednisone. Member has previously had bilateral orchiectomy, failed androgen deprivation therapy (ADT) or will use ADT concurrently with abiraterone.

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