Pharmacy Drug Policy

SUBJECT: Clinical Review Prior Authorization (CRPA) Medical
POLICY NUMBER: PHARMACY-63
EFFECTIVE DATE: 12/2004
LAST REVIEW DATE: 10/30/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☐ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

POLICY:

The drug Clinical Review Prior-Authorization (CRPA) process is designed to ensure that newly approved (FDA) prescription drugs are used appropriately in cases where a drug poses potential efficacy, quality, toxicity, or utilization concerns for the members and the Health Plan. In addition, this policy may be used for medications that have significant concerns about safety or inappropriate use, but do not warrant a stand-alone policy. The Pharmacy Management clinical team reviews the drugs found in this policy. A Letter of Medical Necessity (LOMN), Exception Form, or Prior Authorization Form completion is required for consideration of drug coverage under this policy.

Drug Name – generic name (Medical benefit)

Authorization Criteria

Briumvi - ublituximab-xiiy (Medical)

****Prior Authorization only applies to Managed Medicaid (MMC/HARP)/Child Health Plus (CHP)/ Dual Eligible Special Needs Plans (D-SNP); no prior authorization is required for lines of business other than MMC/HARP/CHP/D-SNP****

1. Must be at least 18 years of age **AND**
2. Must be prescribed by or in consultation with a neurologist **AND**
3. Must have a diagnosis of a relapsing form of multiple sclerosis which includes clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND**
4. Step Therapy Applies - The patient must have had serious side effects or drug failure of at least two medications (oral or self-injectable) indicated for the treatment of multiple sclerosis (minimum 12-week trials) **AND**
    a. The use of Briumvi as a first line therapy for the treatment of multiple sclerosis will be assessed on a case-by-case basis through a letter of medical necessity based on severity of the disease. Coverage will be considered if any of the following are met: >2 attacks within the last 18 months, brain stem/cerebellar/or spinal cord disease, greater than 3 gadolinium enhancing lesions with significant clinical exacerbations and/or motor involvement, bilateral optic neuritis, and/or rapid cognitive decline.
5. The patient must not currently be on combination therapy with any other multiple sclerosis disease modifying agent such as Avonex, Rebif, Ocrevus, Betaseron, Copaxone (or glatiramer), teriflunomide, dimethyl fumarate, fingolimod, Tysabri, or Lemtrada
6. See the Briumvi Prescribing Information for approved dosage and administration

HCPCS: J2329

Cablivi – caplacizumab-yhdp (Medical & Rx)

1. The medication must be prescribed by, or in consultation with, a hematologist **AND**
2. The patient must be at least 12 years of age or older **AND**
3. Must have a diagnosis or suspected diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) **AND**
4. Must be used in combination with plasma exchange and immunosuppressive therapy (such as systemic corticosteroids or a rituximab-containing product)
5. If the above criteria are met, Cablivi will be approved for 1 month under the medical benefit for administration while the patient is receiving plasma exchange.
6. Continued coverage post-plasma exchange, under the pharmacy benefit, will require the following:
   a. Documentation confirming a diagnosis of aTTP (i.e., suppressed ADAMTS13 activity levels, etc.) **AND**
   b. Documentation confirming the patient has not had more than 2 recurrences of aTTP while on therapy with Cablivi (a recurrence is defined as thrombocytopenia occurring after initial recovery of platelet count that requires re-initiation of daily plasma exchange) **AND**
   c. The date of last plasma exchange treatment **AND**
   d. The number of remaining doses (dosed once daily) needed to complete the post-plasma exchange treatment phase (maximum 30 days of treatment post-plasma exchange is allowed for the initial treatment course)
      i. Cablivi will be approved under the pharmacy benefit in accordance with the number of remaining doses required to complete the initial treatment course (up to 30 days post-plasma exchange). For example, a patient needing 24 doses to complete the initial treatment course will be approved for 24 days of treatment
7. Requests for additional therapy (after 30 days of treatment post-plasma exchange) will be approved for a maximum of 28 additional days if the provider submits the following:
   a. Documentation of remaining signs of persistent underlying disease (such as suppressed ADAMTS13 activity levels) **AND**
   b. Documentation confirming the patient has not had more than 2 recurrences of aTTP while on therapy with Cablivi (a recurrence is defined as thrombocytopenia occurring after initial recovery of platelet count that requires re-initiation of daily plasma exchange)

Ceprotin - Protein C Concentrate, Human (Medical)

1. Must be followed by a hematologist
2. Have a diagnosis of severe congenital protein C deficiency confirmed by antigenic and functional plasma coagulation assays

HCPCS: J2724

Gonadotropin-releasing hormone (GnRH) Analogs
Fensolvi (leuprolide acetate), Triptodur (triptorelin), Supprelin LA (histrelin acetate) (Medical)

1. The patient must meet ONE of the following (a, b, c):
   a. The patient must have a diagnosis of Central Precocious Puberty (CPP) **AND**
      i. Treatment must be prescribed by an Endocrinologist or Pediatrician **AND**
      ii. Step Therapy Applies – The patient must use Lupron Depot-Ped (J1950) unless there is adequate medical justification as to why Lupron Depot-Ped cannot be used
   b. The patient must have a diagnosis of Gender Dysphoria (GD) that meets the Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) criteria for Gender Dysphoria **AND**
      i. The diagnosis must be confirmed by an experienced mental health professional **AND**
      ii. The patient must be an adolescent that has reached tanner stage 2 of puberty **AND**
      iii. May be used with or without gender affirming hormones
   c. Any other off-label, compendia supported diagnosis (other than Gender Dysphoria [see criterion 1.b.]) will be reviewed using in the Off-Label Use of FDA Approved Drugs policy (Pharmacy-32)
2. Prior Authorization applies to all lines of business except Medicare
3. See prescribing information for determination of approved dose and dosing frequency

HCPCS: Fensolvi – J1951, Triptodur – J3316, Supprelin LA – J9226

Hydroxyprogesterone Caproate Injection (Medical)

1. The patient must have a diagnosis of advanced adenocarcinoma of the uterine corpus (Stage III or IV) **OR**
2. The patient must have a diagnosis of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer **OR**
3. The medication must be used as a test for endogenous estrogen production and for the production of secretory endometrium and desquamation.
4. Hydroxyprogesterone Caproate Injection USP (J1729) is only indicated for use in non-pregnant women and **will not** be approved to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

HCPCS: J1729

Krystexxa - pegloticase (Medical)

1. The patient must be 18 years of age or older **AND**
2. The patient must have a diagnosis of chronic gout refractory to conventional therapy
   a. Note: Krystexxa is NOT recommended for the treatment of asymptomatic hyperuricemia **AND**
3. The patient must have been evaluated by a rheumatologist, nephrologist, or appropriate specialist experienced in the treatment of chronic refractory gout **AND**
4. The patient must have had failure of the highest therapeutic dose of either allopurinol or febuxostat in combination with either probenecid or losartan for a minimum 3-month trial unless contraindicated or serious side effects were experienced
5. Serum uric acid level must be > 6mg/dL at the time of request
6. The patient must have symptomatic gout defined by one of the following:
   a. 3 or more flares in the past 18 months
   b. 1 or more tophus
   c. chronic gouty arthritis
7. Individuals with a known glucose-6-phosphate dehydrogenase (G6PD) deficiency will be excluded from coverage
8. The recommended dosage is Krystexxa 8 mg given as an intravenous (IV) infusion every two weeks, co-administered with weekly oral methotrexate 15 mg and folic acid or folinic acid supplementation.
   a. Consideration for the use of Krystexxa without concurrent methotrexate may be given to patients for whom methotrexate is contraindicated or not clinically appropriate (includes those with a previous intolerance)
9. Initial approval will be for 1 year
10. Recertification will require documentation of a clinical response to therapy (such as a serum uric acid level <6 mg/dL, a decrease in tophus size, a decrease in the number of affected joints)

HCPCS: J2507

Lemtrada - alemtuzumab (Medical)

1. The patient must be 18 years of age or older **AND**
2. The medication must be prescribed by or in consultation with a neurologist **AND**
3. The patient must have a diagnosis of a relapsing form of multiple sclerosis (MS), including relapsing-remitting disease or active secondary progressive disease **AND**
4. The patient must have had serious side effects or drug failure of two or more medications (oral or self-injectable) indicated for the treatment of multiple sclerosis (minimum 12-week trials) **AND**
5. The patient must not have concurrent infection with Human Immunodeficiency Virus or any other uncontrolled active infection
6. The approved dosage of Lemtrada is for intravenous infusion over 4 hours for 2 or more treatment courses: 12mg/day on 5 consecutive days for the first course and 12mg/day on 3 consecutive days for a second course 12 months after the first treatment course
7. Following the second treatment course, subsequent treatment courses of 12 mg/day on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment courses

8. Lemtrada must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Patients should be monitored for 2 hours after each infusion
9. Coverage will be limited to 5 injections for the first year. Recertification for future courses with 3 injections will require documentation supporting disease response to Lemtrada without adverse effect. If recertification request is approved, the additional course of therapy will be approved to start 366 days after the date that the first dose of the most recent course of Lemtrada was administered.

HCPCS: J0202

Leqvio - inclisiran (Medical)

1. The medication must be prescribed by or in consultation with a cardiologist, endocrinologist, lipidologist, nephrologist **AND**
2. The patient must have one of the following diagnoses (a, b, c **OR** d):
    a. Clinical atherosclerotic cardiovascular disease (ASCVD)
        i. Patient must be 18 years of age or older **AND**
        ii. Must have a history of acute coronary syndrome, myocardial infarction (MI), stable or unstable angina, coronary/other arterial revascularization, stroke, TIA, peripheral arterial disease, or other documented atherosclerotic disease (such as coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, or Carotid plaque with ≥ 50% stenosis)
    b. Heterozygous Familial Hypercholesterolemia (HeFH)
        i. Patient must be 12 years of age or older **AND**
        ii. Molecular genetic testing must demonstrate evidence of an LDL-R mutation, LDLRAP1 mutation, familial defective apo B100, or a PCSK9 mutation **OR**
        iii. Diagnosis must be confirmed as "definite" according to the World Health Organization Criteria (Dutch Lipid Network) **OR** Simon-Broome Register Diagnostic Criteria [Refer to table 1 and table 2 in the appendix]. Documentation of the following must be provided to calculate an accurate score:
            A. Patient's first-degree relatives with ANY of the following:
                a) Tendon xanthoma
                b) Corneal arcus
                c) Known LDL-C >95th percentile by age and gender for country
                d) Known premature (<55 years, men <60 years, women) coronary heart disease (CHD)
            B. Patient's child(ren) <18 years with LDL-C >95th percentile by age and gender for country
            C. Patient's baseline LDL-C level prior to use of ALL-cholesterol lowering medications
            D. Patient's history of CHD
            E. Patient's history of cerebral or peripheral vascular disease
            F. Physical exam finding of tendon xanthoma
            G. Physical exam finding of corneal arcus
    c. Primary hypercholesterolemia without ASCVD or HeFH
        i. Patient must be 18 years of age or older **AND**
        ii. Patient is at high risk for ASCVD as evidenced by one of the following (documentation must be submitted):
            A. Severe hypercholesterolemia with an untreated LDL-C ≥ 190 mg/dL and poorly controlled risk factors (i.e., age > 35, male sex, obesity, smoking, hypertension, low HDL-C < 35 mg/DL) **OR**
            B. American Heart Association Predicting Risk of cardiovascular Disease EVENTs (PREVENT-ASCVD) 10-year risk equation ≥ 5% **OR**
            C. American College of Cardiology/American Heart Association (ACC/AHA) pooled cohort risk assessment score ≥ 7.5% **OR**
            D. Framingham Risk Score ≥ 20% **OR**
            E. Coronary artery calcium (CAC) score ≥ 300 **OR**

F. Lp(a) ≥ 125 nmol/L (≥ 50 mg/dL)

d. Homozygous familial hypercholesterolemia (HoFH)
   i. Patient is 12 to < 18 years of age **AND**
   ii. Patient must meet one of the following (A or B):
      A. Molecular genetic testing must demonstrate two mutant allelles on different chromosomes at the LDLR, LDLRAP1, APOB, or PSCK9 genes or show at least 2 such pathogenic variants at different loci
         a) Coverage will not be provided for patients with evidence of two LDLR negative alleles (null homozygous) as these genotypes have little to no response to medications that inhibit proprotein convertase subtilisin kexin type 9 (PCSK9)
      B. Patient has a history of untreated LDL-C > 400 mg/dL with either (a or b)
         a) Xanthoma before the age of 10 years **OR**
         b) Evidence of heterozygous familial hypercholesterolemia in at least one parent

3. The provider must attest that a discussion with the patient has taken place regarding lifestyle modifications (i.e., a heart healthy diet, the importance of exercise, and smoking cessation [if applicable])
4. Documentation of baseline LDL-C level must be provided- measurement must occur within 60 days prior to treatment.
5. The patient must have failed to reach target LDL-C while receiving treatment with high-intensity statin therapy (i.e., atorvastatin 80 mg/day or rosuvastatin 40 mg/day), or maximally tolerated statin therapy, for at least 8 weeks
   a. Target LDL-C for:
      i. ASCVD: < 55 mg/dL
      ii. HeFH for adults 18 and older: < 70 mg/dL
      iii. HeFH or HoFH for adolescents 12 to < 18: <100 mg/dL
      iv. Primary Hyperlipidemia:
         A. Severe hypercholesterolemia: < 100 mg/dL
         B. PREVENT-ASCVD 10-year risk equation 5% to <10%: < 100 mg/dL
         C. PREVENT-ASCVD 10-year risk equation ≥ 10%: < 70 mg/dL
         D. ACC/AHA pooled cohort risk assessment score ≥ 7.5% to < 20%: < 100 mg/dL
         E. ACC/AHA pooled cohort risk assessment score ≥ 20%: < 70 mg/dL
         F. Framingham Risk Score ≥ 20% : < 70 mg/dL
         G. CAC ≥ 300: < 70 mg/dL
         H. Lp(a) ≥ 125 nmol/L (≥50 mg/dL): < 70 mg/dL
   b. If patient is unable to tolerate statin therapy, documentation in progress notes must include:
      i. A contraindication to statin therapy according to FDA labeling **OR**
      ii. History of statin-related rhabdomyolysis:
         A. Must have symptoms consistent with rhabdomyolysis (i.e., muscle pain, swelling, and weakness, dark urine) **AND**
         B. Must have creatine kinase (CK) level > 10 times upper limit of normal, myoglobinuria, or acute renal failure (increase in serum creatinine >0.5 mg/dL) **AND**
         C. Patient was receiving a statin at the time of the event and symptoms resolved upon discontinuation of the statin **OR**
      iii. History of statin intolerance. Documentation must include the following:
         A. Inability to tolerate at least 2 different statins
            a) At least 1 statin must be hydrophilic (such as pravastatin, fluvastatin, or rosuvastatin) starting at the lowest starting average daily dose **AND**
            b) Intolerance associated with confirmed, intolerable statin-related adverse effects (i.e., muscle related symptoms) or significant biomarker abnormalities (i.e., ALT/AST > 3 times the upper limit of normal accompanied by increase in total bilirubin > 2 times the upper limit of normal) **AND**

c) Non-statin causes of muscle symptoms or biomarker abnormalities have been ruled out (for example, hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders such as polymyalgia rheumatic, steroid myopathy, vitamin D deficiency, or primary muscle disease)

6. The patient must have serious side effects or drug failure to Repatha
7. If patient can tolerate statins, Leqvio must be prescribed in combination with the maximum tolerated dose of a statin
8. Leqvio will not be approved in combination with Praluent, Repatha, Lerochol, Nexletol, or Nexlizet as current medical literature does not support this
9. Approval timeframes: 6 months for initial, 12 months for all recertifications
    a. Initial recertification requires:
        i. Documentation of adequate reduction in LDL cholesterol defined as:
            A. ≥40% reduction in LDL as compared to baseline LDL level or reduction to LDL goal for patients with a diagnosis of ASCVD **OR**
            B. Reduction in LDL level as compared to baseline LDL level for patients with a diagnosis of HeFH, HoFH, or primary hypercholesterolemia without ASCVD or HeFH **AND**
        ii. Continued adherence to a high intensity statin at maximum tolerated dose (if patient is able to tolerate) **AND**
        iii. Continued adherence to lifestyle modifications (non-smoker, diet, and exercise)
    b. Subsequent recertification requires:
        i. Documentation that confirms the patient has maintained an adequate reduction in LDL cholesterol compared to baseline
        ii. Continued adherence to a high intensity statin at maximum tolerated dose (if patient is able to tolerate) **AND**
        iii. Continued adherence to lifestyle modifications (non-smoker, diet, and exercise)
10. Approved dosing: 284 mg administered as a single subcutaneous injection initially, again at 3 months, and then every 6 months thereafter

HCPCS: J1306

Ocrevus (ocrelizumab) and Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) – (Medical)

****Prior authorization does NOT apply to Medicare Advantage or D-SNP****

1. Must be prescribed by or in consultation with a neurologist **AND**
2. Must meet one of the following (a or b):
    a. Must be 18 years of age or older **AND**
        i. Must have a diagnosis of primary progressive multiple sclerosis **OR**
        ii. Must have a diagnosis of a relapsing form of multiple sclerosis which includes clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease
            (1) The patient must have had serious side effects or drug failure of at least two medications (oral or self-injectable) indicated for the treatment of multiple sclerosis (minimum 12-week trials)
            (2) For those requesting Ocrevus or Ocrevus Zunovo as initial treatment for severe disease with no prior therapy, as defined below, an adequate trial (minimum 12 weeks) of Kesimpta or clinical justification of why it cannot be used, will be required
                (a) Clinical symptoms defining severe disease: >2 attacks within the last 18 months, brain stem/cerebellar/or spinal cord disease, greater than 3 gadolinium enhancing lesions with significant clinical exacerbations and/or motor involvement, bilateral optic neuritis, and/or rapid cognitive decline **OR**
    b. Must be 10 to less than 18 years of age and weigh 25 kg or more **AND**
        i. Must be requesting treatment with Ocrevus (Ocrevus Zunovo is not FDA-approved in the pediatric population) **AND**
        ii. Must have a diagnosis of relapsing-remitting multiple sclerosis

(1) The patient must have had serious side effects or drug failure to fingolimod
(2) For those requesting Ocrevus as initial treatment for severe disease with no prior therapy, coverage will be considered if any of the following are met:
(a) Clinical symptoms defining severe disease: >2 attacks within the last 18 months, brain stem/cerebellar/or spinal cord disease, greater than 3 gadolinium enhancing lesions with significant clinical exacerbations and/or motor involvement, bilateral optic neuritis, and/or rapid cognitive decline

3. The patient must not currently be on combination therapy with any other multiple sclerosis disease modifying agent such as Avonex, Rebif, Briumvi, Betaseron, Copaxone (or glatiramer), teriflunomide, dimethyl fumarate, fingolimod, Tysabri, or Lemtrada
4. The approved dosage for Ocrevus is as follows:
   a. For adults and pediatric patients 10 years and older weighting 35 kg or more: 300mg via intravenous infusion, followed 2 weeks later by a second 300mg IV infusion and then 600mg via IV infusion every 6 months.
   b. For pediatric patients 10 years and older who weigh 25 kg to less than 35 kg: 150 mg via intravenous infusion, followed 2 weeks later by a second 150 mg infusion and then 300 mg via IV infusion every 6 months.
5. The approved dosage for Ocrevus Zunovo is 920 mg/23,000 units administered as a single subcutaneous injection every 6 months.

HCPCS: Ocrevus - J2350
Ocrevus Zunovo – J2351

Otarmeni (lunsotogene parvec) (Medical)

1. Otarmeni is provided at no cost by the manufacturer, Regeneron, to treat clinically eligible U.S. residents at Regeneron Authorized Treatment Centers in the U.S. The authorized treatment centers are not allowed to bill/charge for Otarmeni.
   - For additional information, please refer to Regeneron's access program https://www.otarmenihcp.com/gtx/patient-support-and-access.
   - Clinically eligible U.S. residents include all eligible commercial, Medicare Advantage and Managed Medicaid (MMC/HARP) members with severe to profound and profound hearing loss due to variants of the otoferlin gene.
   - There may be other out-of-pocket costs associated with Otarmeni therapy. For more information on access, contact Regeneron's OnPath with OTARMENI™ patient support program at 1-866-500-GENE (1-866-500-4363).
2. Services related to the administration of this medication may require prior authorization and must be requested separately via the medical ***UM Service*** team.
   - Providers may bill for the appropriate facility, professional, and procedure services per the applicable payer policy. Coding and coverage for those services are payer specific. Consult Regeneron Billing and Coding Guide. OTARMENI_Billing_and_Coding_Guide.pdf

HCPCS: refer to OTARMENI_Billing_and_Coding_Guide.pdf

Pemgarda - pemivibart (Medical)

For Essential Plan, Child Health Plus, Commercial and Exchange Plans:

1. Based upon our criteria and assessment of the peer-reviewed evidence, the use of Pemgarda (pemivibart) has not been medically proven to be effective and, therefore, is considered not medically necessary for the pre-exposure prophylaxis of COVID-19. The justification for Pemgarda (pemivibart) to be considered not medically necessary is as follows:
   a. Pemgarda has not received final approval from the appropriate government regulatory bodies, such as the United States Food and Drug Administration (FDA).
   b. Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence that the drug has a definite positive effect on health outcomes.

c. Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence that the drug, over time, leads to improvement in health outcomes (e.g., the beneficial effects of the service outweigh any harmful effects).
d. Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence that the drug is at least as effective in improving health outcomes as established services or technologies.
e. Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence that the drug provides improvement in health outcomes in standard conditions of medical practice, outside the clinical investigatory setting.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

For Medicaid Managed Care (MMC/HARP), Medicare Advantage, and D-SNP Plans:

1. Patient must be 12 years of age or older weighing at least 40 mg
2. Must be prescribed for **pre-exposure** prophylaxis of COVID-19
3. Must not be currently infected with SARS-CoV-2 and have not had a known recent exposure to an individual infected with SARS-CoV-2
4. Must have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications and are unlikely to mount an adequate immune response to COVID-19 vaccination as documented by **ONE** of the following:
   a. Active treatment for solid tumor and hematologic malignancies
   b. Hematologic malignancies associated with poor response to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
   c. Receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy
   d. Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppressive drugs)
   e. Moderate or severe primary immunodeficiency (e.g., common variable immunodeficiency
   f. Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
   g. Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, and biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)
5. Must not be administered within 2 weeks of receiving the COVID-19 vaccine
6. The recommended dosage is Pemgarda 4500 mg as a single IV infusion every 3 months
7. Initial approval will be for 1 year
8. Recertification for 1 year at a time will require documentation patient continues to meet initial criteria for approval

HCPCS: Q0224

Rebyota - fecal microbiota,live-jslm (Medical)

1. The patient must be at least 18 years of age **AND**
2. Must be prescribed by, or in consultation with, an Infectious Disease or GI specialist **AND**
3. Rebyota must be used to *prevent* the recurrence of Clostridioides difficile infection (CDI) **AND**
4. The patient must have a recurrent episode of Clostridioides difficile infection (CDI) **AND**
5. The patient must have had a positive stool test for the presence of Clostridioides difficile toxin within the past 30 days **AND**
6. Current CDI must be controlled following completion of at least 10 days of standard of care antibiotic therapy (e.g., vancomycin, fidaxomicin) **AND**

7. Administration must take place within 24-72 hours following the completion of an antibiotic course used for CDI treatment **AND**
8. Patient must not be immune compromised
9. Retreatment with Rebyota for the same CDI will not be covered
10. Rebyota will not be covered for the treatment of Clostridioides difficile infection (CDI) or any other non-FDA approved indications
11. Approval will be granted for 1 month to allow for administration of a single dose
    a. All approvals are valid only when it is confirmed that Rebyota will be administered within the required timeframe relative to the CDI antibiotic course (i.e., therapeutic window of administration). As such, providers must confirm, prior to approval (on initial or appeal), that the member will receive the therapy within the therapeutic window of administration. If the therapeutic window of administration has expired, the request will not be approved.
12. Approved dosing: 150 mL single dose

HCPCS: J1440

Tysabri (natalizumab) and Tyruko (natalizumab-sztn) - (Medical)

****Prior Authorization only applies to Managed Medicaid (MMC/HARP)/Child Health Plus (CHP)/ Dual Eligible Special Needs Plans (D-SNP); no prior authorization is required for lines of business other than MMC/HARP/CHP/ D-SNP****

1. Must have a diagnosis of **Multiple Sclerosis**:
    a. The patient must have a diagnosis of relapsing-remitting or active secondary progressive multiple sclerosis **AND**
    b. The patient must have had serious side effects or drug failure of at least two medications (oral or self-injectable) indicated for the treatment of multiple sclerosis (minimum 12-week trials)
    c. Patients must not be on concurrent immunosuppressive therapy, including mycophenolate, azathioprine, steroids, and/or IVIG due to increased risk of side effects
    d. Approved Dose: 300 mg IV every 4 weeks
    e. Approval will be for 3 years **OR**
2. Must have a diagnosis of **Crohn's Disease**:
    a. Must have a diagnosis of moderately to severely active Crohn's disease made by a gastroenterologist
        i. Moderate to severe disease Crohn's Disease is defined as having a Crohn's Disease Activity Index (CDAI) score of 220-450 and is typically described as having more prominent symptoms of fever, significant weight loss, abdominal pain or tenderness, intermittent nausea or vomiting or significant anemia **AND**
    b. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is ineffective, contraindicated or not tolerated **AND**
    c. The patient must have had serious side effects or drug failure of Entyvio **AND** Inflectra or Avsola
    d. Approved Dose: 300 mg IV every 4 weeks
    e. Approval will be for 1 year
3. Patients who are approved for coverage of Tysabri or Tyruko under the medical benefit will be excluded from the concomitant use of biologics (such as Humira, Cimzia, infliximab) under the pharmacy or medical benefit
4. Tysabri and Tyruko are not to be used in immunocompromised patients due to the possible risk of serious infection
5. Tysabri and Tyruko are contraindicated in patients with current PML or a history of PML
6. The use of Tysabri or Tyruko as a first line therapy for the treatment of multiple sclerosis will be assessed on a case-by-case basis through a letter of medical necessity based on severity of the disease. Coverage will be considered if any of the following are met: >2 attacks within the last 18 months, brain stem/cerebellar/or spinal cord disease, greater than 3 gadolinium enhancing lesions with significant clinical exacerbations and/or motor involvement, bilateral optic neuritis, and/or rapid cognitive decline

7. Patient must be enrolled in the TOUCH program (Tysabri Outreach: Unified Commitment to Health) or the Tyruko REMS program
8. Physician office must meet the following (a or b):
   a. For Tysabri, must be approved by the manufacturer (Biogen Idec) to have met the risk management criteria
   b. For Tyruko, must be enrolled in the Tyruko REMS program

HCPCS: Tysabri - J2323, Tyruko – Q5134

Ycanth – cantharidin (Medical)

1. Must be 2 years of age or older **AND**
2. Must be prescribed by or in consultation with a dermatologist **AND**
3. Must have a diagnosis of molluscum contagiosum (MC) **AND**
4. Must have documentation of at least **ONE** of the following:
   a. Member is experiencing itching or pain
   b. Concomitant bacterial infection
   c. Concomitant atopic dermatitis (AD)
   d. Concern for contagion (e.g., other siblings, daycare) and lesions cannot be reasonably covered using a bandage
   e. Member is immunocompromised (e.g., patients with HIV/AIDS, patients taking immunosuppressive drugs for cancer, transplantation, etc., and children who have underdeveloped immunocompetency)
5. Must have treatment failure of at least one other treatment modality (including but not limited to cryotherapy, curettage, or podofilox) or clinical justification why other treatments cannot be used
6. One of the following must be true (a or b):
   a. Patient has molluscum contagiosum lesions that were not previously treated with Ycanth; **OR**
   b. Patient has molluscum contagiosum lesions that were previously treated with Ycanth and has not exceeded a total of 4 treatments.
7. Approved dosing: Apply a single application to each lesion every 3 weeks as needed for a maximum of four applications. Do not use more than 2 Ycanth applicators during a single treatment session.
8. Approval will be provided for 4 months to allow for a maximum of four treatments per course of therapy.
9. Re-authorization is not permitted. Members must meet the initial approval criteria.

HCPCS: J7354

Zilretta – triamcinolone acetonide extended-release (Medical)

1. The patient must have a diagnosis of osteoarthritis of the knee confirmed by **ONE** of the following (a or b)
   a. Radiologic evidence of osteoarthritis of the knee such as joint space narrowing, subchondral sclerosis, osteophytes, and sub-chondral cysts **OR**
   b. Documentation of at least 5 of the following American College of Rheumatology (ACR) clinical and laboratory criteria to confirm symptomatic osteoarthritis of the knee:
      i. Bony enlargement
      ii. Bony tenderness
      iii. Crepitus (noisy, grating sound) on active motion
      iv. Erythrocyte sedimentation rate (ESR) <40 mm/hour
      v. Less than 30 minutes of morning stiffness (>45 minutes may indicate rheumatoid arthritis)
      vi. No palpable warmth of the synovium
      vii. Over 50 years of age
      viii. Rheumatoid factor (RF) <1:40 titer (agglutination method)
      ix. Synovial fluid signs (clear fluid of normal viscosity and white blood cell [WBC] count <2000/mm^3 **AND**
2. The patient must have attempted all the following:
   a. Nonpharmacologic therapy (i.e., weight loss, exercise) **AND**

   b. Must have had serious side effects or drug failure of a 3-month trial of a prescription strength oral nonsteroidal anti-inflammatory drug (NSAID)
      i. For individuals with a medical reason why oral NSAID therapy cannot be used, a 3-month trial of a topical NSAID is appropriate **AND**
   c. Step Therapy Applies - Must have had serious side effects or drug failure to **BOTH** of the following corticosteroid injections: triamcinolone acetonide [Kenalog] **AND** methylprednisolone acetate [Depo-Medrol]
3. Zilretta has not been evaluated for the treatment of osteoarthritis-related shoulder or hip pain and will not be covered for any non-Food and Drug Administration (FDA) approved indications
4. Approval timeframe: 3-months to allow for a one-time administration of Zilretta

HCPCS: J3304

Zoladex – goserelin implant (Medical)

****Prior Authorization only applies to Managed Medicaid (MMC/HARP); no prior authorization is required for lines of business other than MMC/HARP****

Pursuant to Social Security Law Sec. 1927. [42 U.S.C. 1396r–8] (a), Centers for Medicare & Medicaid Services (CMS) requires drug manufacturers to participate in the (MDRP) for their drugs to be eligible for coverage under Medicaid, except in certain circumstances. See Table 3 in the appendix section for additional information.

Coverage of Zoladex for Medicaid/HARP members will require the following criteria:

New Starts

1. The patient must be unable to obtain Zoladex through the Zoladex Patient Assistance Program
   a. The Zoladex Patient Assistance Program is managed by the drug company (TerSera Therapeutics) and offers coverage of the drug Zoladex free of charge for patients who qualify. To apply for patient assistance please visit https://www.zoladexhcp.com/access-support/ or contact TerSera Support Source at 855-686-8725 **AND**
2. The patient must be using for palliation of advanced breast cancer in pre- and peri-menopausal women **OR**
3. The patient must be using for a diagnosis of abnormal uterine bleeding

Existing Users

1. The patient must be unable to obtain Zoladex through the Zoladex Patient Assistance Program **AND**
2. The patient must have one of the following FDA approved or compendia supported diagnoses
   a. Palliation of advanced breast cancer in pre- and peri-menopausal women or men **OR**
   b. Hormone receptor-positive breast cancer in pre-menopausal women or men **OR**
   c. Endometriosis **OR**
   d. Uterine hypoplasia **OR**
   e. Abnormal uterine bleeding **OR**
   f. Gender dysphoria **OR**
   g. Central precocious puberty **OR**
   h. Prostate Cancer **AND**
3. The patient must have had serious side effects or drug failure of a gonadotropin-releasing hormone (GnRH)
   a. This require does not apply to existing users with a diagnosis of abnormal uterine bleeding or for those using as palliative therapy for advanced breast cancer in pre- and peri-menopausal women or men

HCPCS: J9202

POLICY GUIDELINES:

1. Unless otherwise stated above within the individual drug criteria, approval time-period will be as follows:

Line of Business	Medical Initial approval	Medical Recert
Commercial/Exchange and SafetyNet (Medicaid, HARP, CHP, Essential Plan)	2 years	2 years
Medicare	2 years	2 years

2. Utilization Management is contract dependent. Refer to specific contract/benefit language for exclusions.
    a. Coverage criteria may be dependent on the contract renewal date.
    b. Coverage of drugs listed in this policy are contract dependent.
    c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit.
    d. Not all contracts/benefits cover all medical infusible drugs.
    e. Not all policy criteria may apply if treatment of specific disease states or conditions is not a covered benefit.
3. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging and other objective or subjective measures of clinical benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in the disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue to align with the current policy's preferred formulary. Recertification reviews may result in a requirement to trial more cost-effective treatment alternatives as they become available (e.g., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations. \This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
4. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS permits a Medicare Advantage Organization (MAO) to establish its own coverage determinations in accordance with 42 CFR § 422.101(b)(6). Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
5. Unless otherwise indicated within drug specific criteria, the drugs listed in this policy are administered by a healthcare professional and therefore are covered under the medical benefit.
6. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
7. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.

8. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
9. Clinical review criteria related to gender dysphoria has been reviewed and approved by the New York State Office of mental Health.
10. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
11. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
12. The requested site of care may impact approval timeframe and subject to review.
13. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
14. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
15. Approval timeframes may be extended to align authorization periods for drugs administered as part of a multidrug regimen, including when regimen components are administered across different benefits. This provision does not apply when the approval timeframe reflects a drug-specific limitation on duration of therapy

UPDATES:

Date	Revision
10/30/2026	Revised
09/14/2026	Revised
08/28/2026	Revised
08/13/2026	Reviewed / P&T Committee Approval
07/01/2026	Revised
06/01/2026	Revised
05/22/2026	Revised
05/14/2026	Reviewed / P&T Committee Approval
04/15/2026	Revised
04/01/2026	Revised
02/26/2026	Revised
02/12/2026	Reviewed / P&T Committee Approval
01/14/2026	Revised
01/06/2026	Revised
01/01/2026	Revised
12/01/2025	Revised
11/13/2025	Reviewed / P&T Committee Approval
10/31/2025	Revised
10/09/2025	Revised
10/06/2025	Revised

10/01/2025	Revised
08/14/2025	Reviewed / P&T Committee Approval
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04/28/2025	Revised
03/14/2025	Revised
03/06/2025	Revised
03/04/2025	Revised
02/21/2025	Revised
02/06/2025	Reviewed / Approved by P&T Committee
02/01/2025	Revised
01/23/2025	Revised
01/01/2025	Revised
11/21/2024	Reviewed / Approved P&T Committee
11/19/2024	Revised
10/31/2024	Revised
10/04/2024	Revised
10/01/2024	Revised
09/04/2024	Revised
09/01/2024	Revised
07/01/2024	Revised
06/20/2024	Revised
06/17/2024	Revised
04/17/2024	Revised
04/11/2024	Revised
03/06/2024	Revised
02/08/2024	Reviewed / P&T Committee Approval
01/09/2024	Revised
12/21/2023	Revised
12/07/2023	Revised
12/01/2023	Revised
11/02/2023	Revised
09/12/2023	Revised
08/24/2023	Revised
07/07/2023	Revised
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03/15/2023	Revised
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02/2022	Revised / P&T Committee Approval

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04/2021	Revised
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08/2018	Revised
03/2018	Revised
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08/2017	Revised
06/2017	Revised
05/2017	Revised
04/2017	Revised
03/2017	Revised
02/2017	Revised

APPENDIX:

Table 1: Diagnostic Criteria for the Clinical Diagnosis of HeFH (WHO)

	Criteria	Score
Family history	First-degree relative known with premature CAD[a] and/or first-degree relative with LDL-C >95th percentile	1
	First-degree relative with tendon xanthomata and/or children <18 y with LDL-C >95th percentile	2
Clinical history	Patient has premature CAD[a]	2
	Patient has premature cerebral/peripheral vascular disease	1
Physical examination	Tendon xanthomata	6
	Arcus cornealis age <45 y	4
LDL-C	>8.5 mmol/L (> ≈330 mg/dL)	8
	6.5-8.4 mmol/L (≈250-329 mg/dL)	5
	5.0-6.4 mmol/L (≈190-249 mg/dL)	3
	4.0-4.9 mmol/L (≈155-189 mg/dL)	1
Definite FH		Score >8
Probable FH		Score 6-8
Possible FH		Score 3-5
No diagnosis		Score <3

CAD: coronary artery disease; FH: familial hypercholesterolemia; HeFH: heterozygous familial hypercholesterolemia; LDL-C: low-density lipoprotein cholesterol; WHO: World Health Organization.
[a] Premature CAD: male before age 55, women before age 60.

Table 2: Simone-Broome Criteria for Diagnosis of FH

FH	Criteria
Definite	• TC >6.7 mmol/L or LDL-C >4.0 mmol/L in a child aged <16 y OR • TC >7.5 mmol/L or LDL-C >4.9 mmol/L in an adult (levels either pretreatment or highest on-treatment) PLUS Tendon xanthomas in patient, or in first-degree relative (parent, sibling or child), or in second-degree relative (grandparent, uncle, or aunt) OR • DNA-based evidence of an LDL-R mutation, familial defective apo B_{100}, or a PCSK9 mutation.
Possible	• TC >6.7 mmol/L or LDL-C >4.0 mmol/L in a child aged <16 y OR • TC >7.5 mmol/L or LDL-C >4.9 mmol/L in an adult (levels either pretreatment or highest on-treatment) AND AT LEAST ONE OF THE FOLLOWING • Family history of myocardial infarction: <50 y of age in second-degree relative or <60 y of age in first-degree relative • Family history of raised TC: >7.5 mmol/L in adult first- or second-degree relative or >6.7 mmol/L in child or sibling aged <16 y.

apo: apolipoprotein; FH: familial hypercholesterolemia; LDL-C: low-density lipoprotein cholesterol; LDL-R: low-density lipoprotein receptor; PCSK9: proprotein convertase subtilisin/kexin type 9; TC: total cholesterol.

Table 3: Medicaid Managed Care – TerSera Therapeutics Coverage

Discontinued Coverage for TerSera Therapeutics LLC Drugs

Effective October 1, 2021, TerSera Therapeutics LLC voluntarily withdrew from participation in the Medicaid Drug Rebate Program (MDRP). As a result, New York State (NYS) Medicaid fee-for-service (FFS) and Medicaid Managed Care (MMC) will no longer provide coverage for most drugs manufactured by TerSera Therapeutics LLC.

Pursuant to Social Security Law Sec. 1927 [42 U.S.C. 1396r–8] (a), Centers for Medicare and Medicaid Services (CMS) requires drug manufacturers to participate in the MDRP for their drugs to be eligible for coverage under Medicaid, except in certain circumstances. ZOLADEX® (goserelin implant) is a practitioner-administered drug manufactured by TerSera Therapeutics LLC which is available through a Patient Assistance Program (PAP) from the manufacturer free of charge for those who qualify. For program applications and additional information, providers must visit the ZOLADEX® "Access and support" web page, located at: https://www.zoladexhcp.com/access-support/, or contact TerSera Support Source at (855) 686-8725.

Coverage of ZOLADEX® will continue to be provided for Medicaid members who are unable to obtain the medication through the PAP and when used under the following conditions:

- for a Food and Drug Administration (FDA)-approved indication for which there are no alternative options ***and***
- as a continuation of established therapy if another gonadotropin-releasing hormone (GnRH) product has been tried and failed or if transition to another GnRH is medically contraindicated.

Effective April 14, 2022, providers are to follow the "By Report" billing process for ZOLADEX® and claims will be manually reviewed to validate the above criteria. Additional instructions can be found on the NYS Department of Health (DOH) "New York State Medicaid Fee-for-Service Practitioner Administered Drug Policies and Billing Guidance" web page, located at: https://www.health.ny.gov/health_care/medicaid/program/practitioner_administered/ffs_practitioner_administer.htm.

Questions and Additional Information:

- FFS claim questions should be directed to the eMedNY Call Center at (800) 343-9000.
- FFS coverage and policy questions should be directed to the Medicaid Pharmacy Policy Unit by telephone at (518) 486-3209 or by email at PPNO@health.ny.gov.
- MMC reimbursement, billing, and/or documentation requirement questions should be directed to enrollee's MMC Plan.
- MMC Plan contact information can be found in the eMedNY *New York State Medicaid Program Information for All Providers Managed Care Information* document, located at: https://www.emedny.org/ProviderManuals/AllProviders/PDFS/Information_for_All_Providers_Managed_Care_Information.pdf.

REFERENCES:

In addition to the full prescribing information for each individual drug, the following references have been utilized in creating drug specific criteria

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1. Robinson JG, Jayanna MB, Brown AS, et al. Enhancing the Value of PCSK9 Monoclonal Antibodies by Identifying Patients Most Likely to Benefit, J Clin Lipidol. 2019 Jul-Aug;13(4):525-537. doi: 10.1016/j.jacl.2019.05.005
2. ACC/AHA Pooled Cohort calculator: https://clincalc.com/cardiology/ascvd/pooledcohort.aspx
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4. Ahmad Z, Agarwala A, Cuchel M. et al. (2026) Update on familial hypercholesterolemia: An expert clinical consensus from the National Lipid Association. *Journal of Clinical Lipidology* https://doi.org/10.1016/j.jacl.2026.01.011
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Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. JACC. 2026. https://doi.org/10.1016/j.jacc.2025.11.016

Zilretta -

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