Praluent® (alirocumab) Injection 75mg/mL 150mg/mL

Prior authorization tips for PRALUENT

Your patient's health plan is likely to require prior authorization (PA) before it approves PRALUENT. Although coverage criteria for PRALUENT may vary, the PA process is generally predictable across plans. To simplify the process, we have identified some helpful practices for healthcare providers to use when completing PA requests. It is important to review the insurer's guidelines for obtaining a PA because they can differ depending on the insurer, the medication prescribed, and other factors.

What to include when requesting PA

Appropriate documentation, including:

- Patient's diagnosis with appropriate ICD-10-CM codes
- LLTs (including dosage, frequency, and dates of use)
- Results of patient's most recent cholesterol test
- Rationale for dose adjustments or changes in therapy
- Patient's family history and comorbidities
- Lifestyle modifications (eg, diet and exercise)

Completed and signed plan-specific PA form

See the next page for specific documentation that may be required when submitting a PA request for PRALUENT

Common causes for coverage denials

Be sure to double check your documentation to avoid these common causes for denial.

Diagnosis

- Clerical error resulting in incorrect ICD-10-CM code(s)
- Lack of secondary code
- Lack of documentation supporting appropriate diagnosis

Lab values

- Outdated lab panels (per payer time requirement)
- Submission of lipid profiles without LDL-C calculations

Previous LLTs

- Not treated with a high-intensity statin
- Did not try and fail on ezetimibe
- Missing data (eg, dates of trial, dosage)
- No reason provided for discontinuation of previous therapy/therapies

As a provider, you are solely responsible for billing third-party payers correctly, and you should determine if any payer-specific guidelines apply. The information provided here is general in nature and is not intended to be conclusive or exhaustive, nor is it intended to replace the guidance of a qualified professional advisor

ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*; LDL-C=low-density lipoprotein cholesterol; LLTs=lipid-lowering therapies.

Indications and Usage

PRALUENT is indicated:

- to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies in adults with primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH) to reduce LDL-C.
- as an adjunct to other LDL-C-lowering therapies in adults with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

Important Safety Information

PRALUENT is contraindicated in patients with a history of a serious hypersensitivity reaction to alirocumab or any of the excipients in PRALUENT. Hypersensitivity reactions, including hypersensitivity vasculitis, angioedema, and other hypersensitivity reactions requiring hospitalization, have been reported with PRALUENT treatment. If signs or symptoms of serious allergic reactions occur, discontinue treatment with PRALUENT, treat according to the standard of care, and monitor until signs and symptoms resolve.

The most commonly occurring adverse reactions in clinical trials in primary hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH)) (≥5% of patients treated with PRALUENT and occurring more frequently than with placebo) are nasopharyngitis, injection site reactions, and influenza.

Please see additional Important Safety Information on the next page.
Please click here for full Prescribing Information.

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Common documentation required by health plans

Current LDL-C values (within last 30 days)

_____ mg/dL Date measured: _____ ◯ On LLT ◯ Off LLT

Diagnosis:
- ◯ Primary hypercholesterolemia, including HeFH
- ◯ HoFH

Determined by:
- ◯ Clinical criteria (eg, DLCN, SB, LDL-C levels, family history, xanthomas)
- ◯ Genetic testing (if applicable)

and/or

◯ ASCVD criteria:
- ◯ Angina, stable or unstable
- ◯ Coronary syndromes, acute
- ◯ Myocardial infarction, history of
- ◯ Revascularization, coronary or other arterial (eg, PTCA, CABG)
- ◯ Peripheral arterial disease
- ◯ Positive findings in CT angiogram/catheterization
- ◯ Stroke
- ◯ TIA
- ◯ Other: _____

Previous and/or current LLTs

	Dose(s)	Start date	Stop date	Current
◯ atorvastatin				◯
◯ pravastatin				◯
◯ rosuvastatin				◯
◯ simvastatin				◯
◯ ezetimibe				◯
◯ _____				◯
◯ _____				◯

Medical history with statin therapy _____

Last date on LLTs: mm/dd/yyyy _____ ◯ Prescribed by or in consultation with specialist (eg, cardiologist, lipidologist)

Rationale for dose adjustments or changes in therapy _____

◯ Lifestyle modifications (eg, exercise, diet) _____

◯ LDL apheresis _____

ASCVD=atherosclerotic cardiovascular disease; CABG=coronary artery bypass grafting; CT=computed tomography; DLCN=Dutch Lipid Clinical Network; HeFH=heterozygous familial hypercholesterolemia; HoFH=homozygous familial hypercholesterolemia; PTCA=percutaneous transluminal coronary angioplasty; SB=Simon Broome; TIA=transient ischemic attack.

Important Safety Information (cont'd)

The most commonly occurring adverse reactions in the cardiovascular outcomes trial (>5% of patients treated with PRALUENT and occurring more frequently than placebo) were non-cardiac chest pain, nasopharyngitis, and myalgia.

In the primary hyperlipidemia (including HeFH) clinical trials, local injection site reactions including erythema/redness, itching, swelling, and pain/tenderness were reported more frequently in patients treated with PRALUENT 75 mg and/or 150 mg every 2 weeks (7.2% versus 5.1% for PRALUENT and placebo, respectively). Few patients discontinued treatment because of these reactions (0.2% versus 0.4% for PRALUENT and placebo, respectively), but patients receiving PRALUENT had a greater number of injection site reactions, had more reports of associated symptoms, and had reactions of longer average duration than patients receiving placebo.

The once-monthly (Q4W) 300mg dosing regimen had a higher rate of local injection site reactions as compared to PRALUENT 75mg Q2W or placebo (16.6%, 9.6%, and 7.9%, respectively). The discontinuation rate due to injection site reactions was 0.7% in the 300 mg Q4W arm and 0% in the other 2 arms.

In a cardiovascular outcomes trial, local injection site reactions were reported in 3.8% of patients treated with PRALUENT versus 2.1% patients treated with placebo, and led to permanent discontinuation in 0.3% of patients versus <0.1% of patients, respectively.

In the primary hyperlipidemia trials, liver-related disorders (primarily related to abnormalities in liver enzymes) were reported in 2.5% of patients treated with PRALUENT and 1.8% of patients treated with placebo, leading to treatment discontinuation in 0.4% and 0.2% of patients, respectively. Increases in serum transaminases to greater than 3 times the upper limit of normal occurred in 1.7% of patients treated with PRALUENT and 1.4% of patients treated with placebo.

In the primary hyperlipidemia trials, the most common adverse reactions leading to treatment discontinuation in patients treated with PRALUENT were allergic reactions (0.6% versus 0.2% for PRALUENT and placebo, respectively) and elevated liver enzymes (0.3% versus <0.1%).

PRALUENT is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with PRALUENT.

Please click here for full Prescribing Information.

REGENERON

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