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

Specialist Consultation Referral Form

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 lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C).

Important Safety Information

PRALUENT is contraindicated in patients with a history of a serious hypersensitivity reaction to PRALUENT, including hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization.

Hypersensitivity reactions (e.g., pruritus, rash, urticaria), including some serious events (e.g., hypersensitivity vasculitis, angioedema, and 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.

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) in a trial in which all patients received an injection of drug or placebo every 2 weeks to maintain the blind. 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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Referring physician's name _____ Referring physician's phone _____ Referring physician's fax _____

Consulting physician's name _____ Consulting physician's phone _____ Consulting physician's fax _____

I am referring my patient to you for consultation on the initiation of PRALUENT therapy. The patient's insurance plan requires PRALUENT to be written in consultation with or by a specialist. Please see the *payer requirements* and *consulting physician* sections for required actions.

Referring physician

Patient information

Patient name _____ Patient phone _____ Date of birth _____

Patient medical information

Select at least one primary and one secondary ICD-10-CM code[a]

Primary diagnosis (if E78.2, E78.4, or E78.5 is selected as a primary diagnosis, select a secondary diagnosis code as applicable)

- ◯ E78.0 (Pure hypercholesterolemia, including HeFH)
- ◯ E78.2 (Mixed hyperlipidemia)
- ◯ E78.4 (Other hyperlipidemia)
- ◯ E78.5 (Unspecified hyperlipidemia)
- ◯ __.___ ◯ __.___ Other

Include as many appropriate clinical ASCVD codes as necessary to support your patient's diagnosis

- ◯ G45.__ Transient cerebral ischemic attack
- ◯ I21.__ ◯ I22.__ ◯ I23.__ Ischemic heart disease
- ◯ I25.__ Chronic ischemic heart disease
- ◯ I63.__ ◯ I65.__ ◯ I66.__ ◯ I67.__ Cerebrovascular diseases
- ◯ I70.__ Atherosclerosis
- ◯ I73.__ Other peripheral vascular diseases
- ◯ __.___ ◯ __.___ Other

Treatment history

◯ Patient treatment history attached **or** ◯ Patient treatment history below Current LDL-C _____mg/dL Date (mm/yyyy)_____

Previous and/or current lipid-lowering treatments

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

Has the patient achieved maximally tolerated statin dose? ◯ Yes ◯ No

Has the patient failed on or had contraindications to any of the therapies in the left-hand column? ◯ Yes ◯ No

If yes, please explain _____

Has the patient had any myocardial infarction(s) in the past 6 months? ◯ Yes ◯ No If yes, date(s) _____

Family history of ASCVD _____ Allergies _____

Payer requirements—choose one

◯ **Payer requires prescription be written by specialist—appointment requested**
Please complete and submit the attached MyPRALUENT® Enrollment Form and the past medical history documentation/chart notes to your preferred specialty pharmacy

◯ **Payer requires prescription to be written in consultation with specialist** (please complete section below)

Consulting physician

To authorize coverage, the patient's payer requires that PRALUENT be prescribed in consultation with or by a cardiologist, endocrinologist, or lipidologist. Upon review of the treatment rationale, please complete the following section and fax back this form to the referring physician.

Consulting physician's notes _____

Consulting physician's name _____ Consulting physician's specialty _____

Consulting physician's signature _____ Date _____

Additional follow-up is needed (check all that apply):

- ◯ Contact my office to schedule a phone consultation
- ◯ Schedule patient appointment for in-office evaluation
- ◯ Medical staff name _____ Medical staff phone number _____
- ◯ Provide other supporting information (please specify) _____

ASCVD=atherosclerotic cardiovascular disease; HeFH=heterozygous familial hypercholesterolemia; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*; LDL-C=low-density lipoprotein cholesterol.

[a]The sample diagnostic codes are for your information only and are not intended to be directive or a guarantee of reimbursement; they include potential codes that might be related to indications for PRALUENT as approved by the US Food and Drug Administration. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

Please see full Important Safety Information on the previous page and click here for full Prescribing Information.