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

Specialist Consultation Referral Form

INDICATION

PRALUENT® (alirocumab) is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C.

The effect of PRALUENT on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION

PRALUENT is contraindicated in patients with a history of a serious hypersensitivity reaction to PRALUENT. Reactions have included hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization.

Hypersensitivity reactions(e.g., pruritus, rash, urticaria), including some serious events (e.g., hypersensitivity vasculitis 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 (≥5% of patients treated with PRALUENT and occurring more frequently than with placebo) are nasopharyngitis, injection site reactions, and influenza.

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.

Neurocognitive events were reported in 0.8% of patients treated with PRALUENT and 0.7% of patients treated with placebo. Confusion or memory impairment were reported more frequently by those treated with PRALUENT (0.2% for each) than in those treated with placebo (<0.1% for each).

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.

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 see accompanying PRALUENT® full Prescribing Information.

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Referring Physician's Name	Consulting Physician's Name
Referring Physician's Phone	Consulting Physician's Phone
Referring Physician's Fax	Consulting Physician's Fax

I am referring my patient to you for consultation in the initiation of PRALUENT® therapy. The patient's insurance plan requires PRALUENT® 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

Please provide appropriate **primary** and **secondary** ICD-10-CM code(s)*

Primary Codes:

- ☐ E78.00 Pure Hypercholesterolemia, unspecified
- ☐ E78.01 Familial Hypercholesterolemia
- ☐ E78.2 Mixed Hyperlipidemia
- ☐ E78.4 Other Hyperlipidemia
- ☐ E78.5 Hyperlipidemia, Unspecified

Secondary Codes:

- ☐ I20.0 ___ Unstable Angina
- ☐ I20.9 ___ Angina Pectoris, Unspecified
- ☐ I21. ___ Acute Myocardial Infarction
- ☐ I22. ___ Subsequent Myocardial Infarction
- ☐ I25. ___ Chronic Ischemic Heart Disease
- ☐ I63. ___ Cerebral Infarction
- ☐ I65. ___ Occlusion and Stenosis of Cerebral Arteries, Extracranial
- ☐ I66. ___ Occlusion and Stenosis of Cerebral Arteries, Intracranial
- ☐ I67. ___ Other Cerebrovascular Diseases
- ☐ I I70. ___ Atherosclerosis
- ☐ I73.9 ___ Peripheral Vascular Disease, Unspecified
- ☐ G45.9 ___ Transient Cerebral Ischemic Attack, Unspecified
- ☐ G46. ___ Vascular Syndromes
- ☐ Z83.42 ___ Family history of familial hypercholesterolemia
- ☐ Other (specify ICD-10-CM): _____

TREATMENT HISTORY

☐ Patient Treatent History attached **OR** ☐ Patient Treatment History below

LDL-C on Treatment: _____ **Date:** _____

- ☐ Atorvastatin (Lipitor®) ☐ 10mg ☐ 20mg ☐ 40mg ☐ 80mg
- ☐ Rosuvastatin (Crestor®) ☐ 5mg ☐ 10mg ☐ 20mg ☐ 40mg
- ☐ Simvastatin (Zocor®) ☐ 5mg ☐ 10mg ☐ 20mg ☐ 40mg
- ☐ Ezetimibe (Zetia®) ☐ 10mg
- ☐ Other statin/lipid-lowering medication(s): _____
- ☐ Achieved maximum tolerated statin dose? _____

Has the patient failed on or do they have contraindications to any of the above therapies?

_____

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

_____

Family history of atherosclerotic cardiovascular disease (ASCVD):

_____

Allergies: _____

PAYER REQUIREMENTS – CHOOSE ONE

☐ **Payer requires prescription be written by specialist – Appointment Requested**

Please complete and submit the attached PRALUENT enrollment form and the past medical history documentation/chart notes to your preferred specialty pharmacy.

☐ **Payer requires prescription be written in consultation with specialist. (PLEASE COMPLETE SECTION BELOW)**

TO BE COMPLETED BY THE CONSULTING PHYSICIAN

In order to authorize coverage, the patient's payer requires that PRALUENT® is 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: _____ Date: _____

Consulting Physician's Signature: _____

Consulting Physician's Specialty: _____

☐ **ADDITIONAL FOLLOW-UP IS NEEDED:**

- ☐ 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): _____

* The sample diagnosis codes are informational and not intended to be directive or a guarantee of reimbursement, and include potential codes that would include FDA-approved indications for PRALUENT®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

Please see Indication and Important Safety Information on the first page.
Please see accompanying PRALUENT® full Prescribing Information.

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