Sample appeal letters for PRALUENT® (alirocumab)

These sample letters are for your guidance only.

The sample letters attached to this document show the type of information that may be provided when responding to a request from a patient's health plan to provide an appeal letter for PRALUENT. Use of the information in this document or the attached sample letters does not guarantee that the health plan will provide reimbursement for PRALUENT and is not intended to be a substitute for or to influence the independent medical judgment of you, the physician.

How to use this document

Attached to this document are editable sample appeal letters for some common reasons for denial of PRALUENT. Click below on the denial reason pertinent to your patient to view the corresponding sample appeal letter. For your consideration, a list of potential enclosures are provided at the bottom of each letter. If applicable, you may include these enclosures as supporting documentation alongside your letter.

Reasons for denial

- Diet/exercise
- Lack of documentation/diagnosis of HeFH
- Inadequate trial of statin
- Prescribed starting dose
- Step therapy required
- Reauthorization denial

Key Reminders

- Appeal letters should reflect your independent clinical judgment as to what is best for your patient
- Appeal letters are typically signed by both the patient and the physician
- Consider asking the health plan to have the appeal letter reviewed by a like specialist (e.g., a peer cardiologist)
- Consider requesting a peer-to-peer dialogue with the health plan
- Be sure to populate an appropriate ICD-10 code matching your patient's diagnosis. A guide can be accessed online at: praluenthcp.com/ICD10codes

INDICATIONS AND USAGE

- PRALUENT 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

Please see additional Important Safety Information on the next page.

Please click here for full Prescribing Information.

Important Safety Information (cont'd)

- 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) 300 mg dosing regimen had a higher rate of local injection site reactions as compared to PRALUENT 75 mg 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 click here for full Prescribing Information.