This sample is provided for your guidance only. Use of the information in this letter does not guarantee that the insurance company will provide coverage for PRALUENT® (alirocumab) and is not intended to be a substitute for, or an influence on, the independent medical judgment of the physician. The physician/physician's office must compose any letter of medical necessity to be submitted on behalf of a patient.

Suggested Enclosures:
PRALUENT Prescribing Information: https://www.praluent.com/
Excerpts of medical records

This letter shows the types of information that may be provided when responding to a request from a patient's insurance company for a letter of medical necessity for treatment with PRALUENT injection. Please see full Prescribing Information available at www.PRALUENT.com. Please see full Important Safety Information that follows.

[Date]
ATTN: Medical Review
[Contact name]
[Insurance company]
[Insurance street address]
[Insurance city, state, ZIP]

Re:
[Patient name]
[Date of birth]
[Policy #]
[Group #]

I am writing on behalf of [patient name] to formally document the medical necessity for administering PRALUENT® (alirocumab). PRALUENT is indicated to reduce the risk of myocardial infarction (MI), stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease; and as 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.

Reason for PRALUENT use and/or medical exception:
_____
_____

This letter provides the clinical history, treatment rationale, and other documents that support the use of PRALUENT for this patient.

History of established CV disease:
_____
_____
_____

Treatments
Current Therapy (Treatment/Dosage)
1. _____
2. _____
3. _____
4. _____

Prior Therapy (Treatment/Dosage):
1._____
2._____
3._____
4._____

Reasons for Discontinuation:
_____
_____
_____
_____

Previous LDL-C Lab Results (LDL-C Value/Date)
1. _____
2. _____

Current LDL-C Lab Results (LDL-C Value/Date)
_____

Additional Relevant Information:
_____
_____

In summary, based on my clinical judgment, PRALUENT is medically necessary for [Patient name].

Please contact my office at [office's telephone number] if additional information is required for approval of this request. Thank you for your immediate attention to this very important matter.

Sincerely,

[Physician name, MD]

INDICATIONS AND USAGE

PRALUENT® (alirocumab) 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

1. PRALUENT® (alirocumab) Prescribing Information. Regeneron Pharmaceuticals.