Sample appeal letter for PRALUENT® (alirocumab)

This sample is provided for your guidance only. To download a copy of the appeal letter, visit **praluenthcp.com**. Use of information in this letter 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.

Recommended enclosures of additional documentation to submit with letter of appeal:

- PRALUENT Prescribing Information available at: https://www.praluenthcp.com/
- Medical record excerpts
- Health plan appeal form, if available
- History prior to your care, if applicable

Instructions for use:
Based on your clinical judgment, you may use this letter as an example of the types of information that could be necessary when appealing a denial of coverage for PRALUENT injection from a patient's health plan. This sample letter serves as an appeal stating that your patient's condition warrants treatment with PRALUENT. Example reasons include: a list of patient comorbidities, a continuation of patient history (including clinical support for medical necessity), a list of dates of diet/exercise counseling, types of counseling provided, and modification made and outcome—reference supporting documentation, etc.

Please click here for full Prescribing Information. Please see full Important Safety Information below.

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

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

Reasons for denial: [To be filled in by prescriber based on plan reason for denial]

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

Dear [contact name]:

This letter serves as the [first/second] appeal for approval of PRALUENT® (alirocumab), which was originally denied for [patient full name] on [date of service], because the patient did not meet the plan's requirement due to [reason for denial].

Since [date], [patient full name] has been under my care for [primary diagnosis, secondary diagnosis]:
- [Cardiovascular disease, type, date, outcome]
- Treatment with other LDL-C lowering therapies, including [discuss previous and/or current therapies (eg, statin intolerance) and patient response/tolerability to therapy]

Additional relevant information:

_____
_____

[Provide summary statement of your rationale for sending this letter on behalf of this patient].

_____
_____

Please call me at _____ if I can be of further assistance or you require additional information. Thank you in advance for your immediate attention and prompt review of this request.

Sincerely,

Treating physician signature _____
Treating physician name, MD/DO/NP/PA _____

Patient/Legal representative signature, if required _____
Patient/Legal representative name _____

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 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
- 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.