Repatha® (evolocumab) Sample Letter of Medical Necessity

Physician Letterhead

[Insurance Company]
[Address Line 1]
[Address Line 2]

RE: Patient Name: _____
Policy ID: _____
Policy Group: _____
Date of Birth: _____

[Date]

Attn: [Medical/Pharmacy Director], [Department]:

Dear [Medical/Pharmacy Director]:

I am writing this letter on behalf of my patient, [Patient's Name]. Repatha® is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization in patients with established cardiovascular disease.
[If prior authorization has been submitted previously, indicate date of submission and the outcome.]

Based on the FDA-approved indication, I strongly believe that treatment with Repatha® is medically necessary.

Repatha® is medically necessary for [Patient's Name] as documented by:

- **History of established cardiovascular disease:** [Indicate if the patient has suffered from a prior event, including MI, stroke, symptomatic PAD and/or coronary revascularization; in addition, list any comorbidities that may impact the patient's risk for a cardiovascular event, including family history, hypertension, smoking, and diabetes, if applicable. Additional information on coronary anatomy to document the disease could be helpful]
- **Inadequate LDL-C lowering despite prior treatment:** [Provide the patient's recent LDL-C level and a brief history of lipid-lowering treatment, including maximally tolerated statin dose, treatment duration, and any tolerability issues, reactions or contraindications. Further documentation of events while on current lipid-lowering therapy could also be useful]

Furthermore, the need for Repatha® is also supported by the latest treatment guidelines and pathways issued by [eg, the American College of Cardiology (ACC), the National Lipid Association (NLA), and/or the American Association of Clinical Endocrinologists (AACE)], on the use of PCSK9 inhibitors (such as Repatha®) in patients with clinical cardiovascular disease who are unable to reach LDL-C goals with maximally tolerated statin therapy.

In summary, based on my clinical opinion, Repatha® is medically necessary for [Patient's Name]. This is fully consistent with both the FDA-approved indication and the current standards of care.

Please call my office at [Office Phone Number] if any additional information is required to ensure prompt approval for this course of treatment.

Sincerely,
[Physician's name]

[List enclosures as appropriate: Examples of enclosures include excerpt(s) from patient's medical record, clinical studies, relevant treatment guidelines, and product Prescribing Information.]

This page is for your reference only. Content on this page does not need to be sent to the insurance company.

INDICATIONS

Repatha® is indicated:

- In adults with established cardiovascular disease to reduce the risk of myocardial infarction, stroke, and coronary revascularization
- 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 patients with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C

The safety and effectiveness of Repatha® have not been established in pediatric patients with HoFH who are younger than 13 years old or in pediatric patients with primary hyperlipidemia.

IMPORTANT SAFETY INFORMATION

- **Contraindication:** Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to evolocumab or any of the excipients in Repatha®. Serious hypersensitivity reactions including angioedema have occurred in patients treated with Repatha®.
- **Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema, have been reported in patients treated with Repatha®. If signs or symptoms of serious hypersensitivity reactions occur, discontinue treatment with Repatha®, treat according to the standard of care, and monitor until signs and symptoms resolve.
- **Adverse Reactions in Primary Hyperlipidemia:** The most common adverse reactions (>5% of patients treated with Repatha® and more frequently than placebo) were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

  From a pool of the 52-week trial and seven 12-week trials: Local injection site reactions occurred in 3.2% and 3.0% of Repatha®-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. Hypersensitivity reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common hypersensitivity reactions were rash (1.0% versus 0.5% for Repatha® and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).
- **Adverse Reactions in the Cardiovascular Outcomes Trial:** The most common adverse reactions (>5% of patients treated with Repatha® and more frequently than placebo) were: diabetes mellitus (8.8% Repatha®, 8.2% placebo), nasopharyngitis (7.8% Repatha®, 7.4% placebo), and upper respiratory tract infection (5.1% Repatha®, 4.8% placebo).

  Among the 16,676 patients without diabetes mellitus at baseline, the incidence of new-onset diabetes mellitus during the trial was 8.1% in patients treated with Repatha® compared with 7.7% in patients that received placebo.
- **Adverse Reactions in HoFH:** In a 12-week study in 49 patients, the adverse reactions that occurred in at least two patients treated with Repatha® and more frequently than placebo were: upper respiratory tract infection, influenza, gastroenteritis, and nasopharyngitis. In an open-label extension study in 106 patients, including 14 pediatric patients, no new adverse reactions were observed.
- **Immunogenicity:** Repatha® is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity with Repatha®.

Please see full Prescribing Information.

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