8.5" x 11"

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 issued by [eg, the American College of Cardiology (ACC), the National Lipid Association (NLA), and/or the American Association of Clinical Endocrinologists (AACE)],
and recommendations issued by the 2022 ACC Expert Consensus Decision Pathway, 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.]

Please see Indications and Important Safety Information on next page.

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 diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C
- As an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C

The safety and effectiveness of Repatha® have not been established in pediatric patients with HeFH or HoFH who are younger than 10 years old or in pediatric patients with other types of 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 Adults with 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 Pediatric Patients with HeFH:** The most common adverse reactions (>5% of patients treated with Repatha® and more frequently than placebo) were: nasopharyngitis, headache, oropharyngeal pain, influenza, and upper respiratory tract infection.
- **Adverse Reactions in Adults and Pediatric Patients with 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 accompanying full Prescribing Information.

USA-145-84283

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  [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]

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