8.5" x 11"

# Repatha® (evolocumab) Appeals Letter

***Physician Letterhead***

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

[Date]

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

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

Dear [Medical/Pharmacy Director]:

I am writing this letter to appeal the denial of coverage for Repatha® on behalf of my patient, [Patient Name] . Repatha® is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adult patients with established cardiovascular disease.

On [date of denial] , your organization cited [indicate reason for denial] as the reason for denial. However, 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 I can provide you with any additional information to approve my request.

Sincerely,
[Physician's name]

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

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**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-145-84282

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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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