Repatha® (evolocumab) Letter of Medical Necessity

Sample Letter: You may want to consider printing this letter on your Physician's Letterhead

Repatha® (evolocumab) 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

[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] .

[If prior authorization has been submitted previously, indicate date of submission and the outcome. If patient is continuing Repatha, consider stating the patient is stable on current medication. Also include any pre-Repatha LDL-C labs and current LDL-C labs.]

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 known atherosclerotic cardiovascular disease (ASCVD) as evidenced by: MI, stroke/TIA, PAD (list any artery involved including history of revascularization procedures – aorta, subclavian femoral, carotid, renal, celiac, retinal, etc.). 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]

  - **History of Heterozygous *OR* Homozygous Familial Hypercholesterolemia (HeFH / HoFH):**

    [Indicate what evidence (Dutch Lipid Score, Simon Broome Score, Genetic testing, presence of tendon xanthomas etc.) shows patient has HeFH / HoFH. 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 (patients with history of established cardiovascular disease and/or HeFH / HoFH):**

    [State what the patient's LDL-C goal is, and what their current LDL-C is, despite other lipid-lowering treatments used. If patient's LDL-C goal is less than 70, consider referencing the 2018 ACC/AHA guideline below. If patient's LDL-C goal is less than 55, consider referencing the 2022 ACC Expert Consensus Decision Pathway. The ACC Consensus Pathway recommends a lower threshold of LDL-C ≤ 55 mg/dl for adult patients with ASCVD at very high risk.
    Very high risk is defined as: multiple major ASCVD events (recent ACS, history of MI, history of ischemic stroke, symptomatic PAD)
    OR
    One major ASCVD event and multiple high-risk conditions (Age ≥ 65 years, prior CABG or PCI outside of major ASCVD event(s), diabetes mellitus, HeFH, CKD, hypertension, current smoking, history of CHF, persistently elevated LDL-C).

    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]

- **Primary hyperlipidemia in other patient types (Those who do not meet criteria for established cardiovascular disease *OR* HeFH / HoFH):**

  [State what the patient's LDL-C goal is, and what their current LDL-C is, despite other lipid-lowering treatments used. In the cases where the 2022 ACC Expert Consensus Decision Pathway does not specify the LDL-C goal for your patient type, the goal can be suggested by the prescribing provider based on available evidence, including guidelines and recommendations published by other organizations.

  Primary hyperlipidemia patients of this type may also have high ASCVD risk score, evidence of subclinical disease on catheterization, LHC, elevated calcium score (CAC), abnormal CT angiogram. Additional information on coronary anatomy to document the disease could be helpful. 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. Consider listing any biomarkers which are listed as risk enhancing factors by the 2018 ACC/AHA Multisociety guidelines e.g. elevated triglycerides, low HDL-C or high Lp(a)]

Furthermore, the need for Repatha® is also supported by the latest treatment recommendations issued by:

[eg, 2018 The American College of Cardiology (ACC) / American Heart Association (AHA), 2022 ACC Expert Consensus Decision Pathway, 2017 American Association of Clinical Endocrinologists (AACE), 2023 American Diabetes Association (ADA) and/or 2019 European Society of Cardiology (ESC) / European Atherosclerosis Society (EAS)]

On the use of PCSK9i mAbs (such as Repatha®) in patients with [clinical cardiovascular disease and/or primary hyperlipidemia] who are unable to reach LDL-C goals with maximally tolerated statin therapy.

[Patient's Name] LDL-C mg/dl remains at [Enter Value] on [Enter Date]

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 standard of care.

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

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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 full Prescribing Information.

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