

Repatha® (evolocumab) Sample Letter of Medical Necessity

Physician Letterhead

RE: Patient Name: _____
Policy ID: _____
Policy Group: _____
Date of Birth: _____
(mm/dd/yyyy)

(mm/dd/yyyy)

Attn: _____, _____

Dear _____,

I am writing this letter on behalf of my patient, _____. Repatha® is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization in patients with established cardiovascular disease.

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

Repatha® is medically necessary for _____ as documented by:

- **History of established cardiovascular disease:**

- **Inadequate LDL-C lowering despite prior treatment:**

Furthermore, the need for Repatha® is also supported by the latest treatment guidelines and pathways issued by _____ 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 _____. This is fully consistent with both the FDA-approved indication and the current standards of care.

Please call my office at _____ if I can provide you with any additional information to approve my request.
(xxx) xxx-xxxx

Sincerely,

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

INDICATION

Prevention of Cardiovascular Events: In adults with established cardiovascular disease, Repatha® is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization.

Primary Hyperlipidemia (including Heterozygous Familial Hypercholesterolemia): Repatha® is indicated as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C).

Homozygous Familial Hypercholesterolemia: Repatha® is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of 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 or HeFH.

IMPORTANT SAFETY INFORMATION

Contraindication: Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to Repatha®. Serious hypersensitivity reactions including angioedema have occurred in patients treated with Repatha®.

Allergic Reactions: Hypersensitivity reactions (e.g. angioedema, rash, urticaria) have been reported in patients treated with Repatha®, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic 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 (including HeFH): The most common adverse reactions (>5% of patients treated with Repatha® and occurring 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.

Allergic reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common allergic 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 occurring 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 assigned to Repatha® compared with 7.7% in those assigned to placebo.

Adverse Reactions in Homozygous Familial

Hypercholesterolemia (HoFH): 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.

Immunogenicity: Repatha® is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity with Repatha®.

Please [click here](#) for full Prescribing Information.

USA-145-80801