

Repatha® (evolocumab) Sample Letter of Medical Necessity

Physician Letterhead

(mm/dd/yyyy)

RE: Patient Name: _____
Policy ID: _____
Policy Group: _____
Date of Birth: _____
(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 any additional information is required to ensure prompt approval for this course of treatment. (xxx) xxx-xxxx

Sincerely,

Please see Indication and Important Safety Information on next page.

USA-145-82879

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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