

Common Repatha® Documentation Requirements for Patients With FH^{1,*}

Information Category	Clinical Details	Documentation Examples
Primary Diagnosis	<input type="checkbox"/> HeFH <input type="checkbox"/> HoFH	ICD-10 code [†] : <ul style="list-style-type: none"> E78.01 Familial hypercholesterolemia
Secondary Diagnosis	<input type="checkbox"/> Tendon or cutaneous xanthomas <input type="checkbox"/> Relevant family history	Select the appropriate secondary ICD-10 code [†] : <ul style="list-style-type: none"> E75.5 Other lipid storage disorders (approximate synonyms include tendon xanthoma) Z83.42 Family history of familial hypercholesterolemia
Diagnostic Findings	<input type="checkbox"/> Baseline and current lipid levels: <ul style="list-style-type: none"> Genetic tests Established diagnostic criteria and/or related score Clinical findings Family history 	<ul style="list-style-type: none"> Genetic mutation diagnosis and date Other definitive diagnostic evidence for HeFH <ul style="list-style-type: none"> Simon-Broome Diagnostic Criteria for definitive familial hypercholesterolemia Dutch Lipid Clinic Network Criteria total score > 8 points Other definitive diagnostic evidence for HoFH <ul style="list-style-type: none"> LDL-C > 500 mg/dL AND Tendon or cutaneous xanthomas at ≤ 10 years of age OR definitive diagnosis or evidence of familial hypercholesterolemia in both parents
Experience With Repatha®	<input type="checkbox"/> Repatha®	<ul style="list-style-type: none"> Percentage reduction in LDL-C level (goal, achieved, etc) Duration/dates of therapy LDL-C level pre- and post-treatment
History of Other Lipid-lowering Treatment <i>(may include multiple therapies)</i>	<input type="checkbox"/> High-intensity statin: <ul style="list-style-type: none"> Atorvastatin 40 mg or 80 mg Rosuvastatin 20 mg or 40 mg <input type="checkbox"/> Other therapies (eg, ezetimibe) <input type="checkbox"/> Lipid apheresis	<ul style="list-style-type: none"> Duration/dates of therapy LDL-C level pre- and post-treatment

OR Intolerance/Contraindication to Other Lipid-lowering Treatments

Intolerance or Contraindication to Other Lipid-lowering Treatment	<input type="checkbox"/> Intolerance, including but not limited to: <ul style="list-style-type: none"> Rhabdomyolysis Muscle pain or weakness Elevated creatine kinase (CK) Elevated liver function tests <input type="checkbox"/> Contraindication <ul style="list-style-type: none"> Contraindication to treatment 	<ul style="list-style-type: none"> Intolerance <ul style="list-style-type: none"> Maximum tolerated statin dose Documented lab results Duration of symptoms Response to statin re-challenge Contraindication <ul style="list-style-type: none"> Documented contraindication
Lifestyle Modification	<input type="checkbox"/> Diet <input type="checkbox"/> Exercise	<ul style="list-style-type: none"> Low-fat diet (documented dietitian visits, group support, etc) Exercise (gym attendance, documented physical activity, etc) Enrollment in weight management programs



A Letter of Medical Necessity may be helpful to use with your PA request.

For access to coverage information, PA requirements, and Health Plan Forms for Repatha®, visit RepathaCoverage.com.

FH = familial hypercholesterolemia; HeFH = heterozygous familial hypercholesterolemia; HoFH = homozygous familial hypercholesterolemia; LDL = low-density lipoprotein.

* Lives covered across the United States. May 2016.

[†] The sample diagnosis codes are informational and not intended to be directive or a guarantee of reimbursement, and include potential codes that would include FDA-approved indications for Repatha®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

Reference: 1. Data on file, Amgen; 2016.

Please see Indications and Important Safety Information on the next page.


Repatha®
 (evolocumab) injection
 140 mg/mL

Indications and Important Safety Information

Indications

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®.

Allergic Reactions: Hypersensitivity reactions (e.g., 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 Repatha®-treated patients and occurring more frequently than placebo) in clinical trials in primary hyperlipidemia (including HeFH) were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

In a 52-week trial, adverse reactions led to discontinuation of treatment in 2.2% of Repatha®-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to Repatha® treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for Repatha® and placebo, respectively).

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. The proportions of patients who discontinued treatment due to local injection site reactions in Repatha®-treated patients and placebo-treated patients were 0.1% and 0%, respectively.

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 safety profile of Repatha® in this trial was generally consistent with the safety profile described above in the 12- and 52-week controlled trials involving patients with primary hyperlipidemia (including HeFH). Serious adverse events occurred in 24.8% and 24.7% of Repatha®-treated and placebo-treated patients, respectively. Adverse events led to discontinuation of study treatment in 4.4% of patients assigned to Repatha® and 4.2% assigned to placebo. Common adverse reactions (> 5% of patients treated with Repatha® and occurring more frequently than placebo) included 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): In 49 patients with HoFH studied in a 12-week, double-blind, randomized, placebo-controlled trial, 33 patients received 420 mg of Repatha® subcutaneously once monthly. The adverse reactions that occurred in at least two (6.1%) Repatha®-treated patients, and more frequently than in placebo-treated patients, included upper respiratory tract infection (9.1% versus 6.3%), influenza (9.1% versus 0%), gastroenteritis (6.1% versus 0%), and nasopharyngitis (6.1% versus 0%).

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

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



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