

Common Repatha® Documentation Requirements for Patients With Primary Hyperlipidemia and Established CVD^{1,2}

Primary and Secondary Diagnosis Codes

Clinical Details	Documentation Examples
Primary Diagnosis: <input type="checkbox"/> Primary hyperlipidemia	ICD-10 code*: <ul style="list-style-type: none"> E78.00 Pure hypercholesterolemia, unspecified E78.2 Mixed hyperlipidemia E78.4 Other hyperlipidemia E78.5 Hyperlipidemia, unspecified
Secondary Diagnosis: <input type="checkbox"/> Established CVD, including but not limited to: <ul style="list-style-type: none"> Acute coronary syndrome History of myocardial infarction Stable or unstable angina Coronary or other arterial revascularization Stroke Peripheral arterial disease 	Select the appropriate secondary ICD-10 code* (examples of ICD-10 codes can be found on the RepathaReady® or Specialty Pharmacy Intake Form). <ul style="list-style-type: none"> I20.0__ Unstable angina I20.9__ Angina pectoris, unspecified I21.___ Acute myocardial infarction I22.___ Subsequent myocardial infarction I25.___ Chronic ischemic heart disease I63.___ Cerebral infarction I65.___ Occlusion and stenosis of cerebral arteries, extracranial I66.___ Occlusion and stenosis of cerebral arteries, intracranial I67.___ Other cerebrovascular disease I70.___ Atherosclerosis I73.9__ Peripheral vascular disease, unspecified G45.9__ Transient cerebral ischemic attack, unspecified G46.___ Vascular syndromes

* 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.

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®. Serious hypersensitivity reactions including angioedema have occurred in patients treated with Repatha®.

Please see additional Important Safety Information on the last page.



Common Repatha® Documentation Requirements for Patients With Primary Hyperlipidemia and Established CVD^{1,2}

Diagnostic Findings

Clinical Details	Documentation Examples
<input type="checkbox"/> Baseline and current lipid levels <input type="checkbox"/> Diagnostic tests	<ul style="list-style-type: none"> Lipid level values and lab dates (at baseline and most recent) <ul style="list-style-type: none"> - LDL-C - Triglyceride - Total cholesterol Diagnostic test results and dates (angiogram, stress test, echocardiogram, nuclear imaging, etc) CVD risk score

History of Other Lipid-lowering Treatment *(may include multiple therapies)*

Clinical Details	Documentation Examples
<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)	<ul style="list-style-type: none"> Duration/dates of therapy LDL-C level pre- and post-treatment

Intolerance or Contraindication to Other Lipid-lowering Treatment

Clinical Details	Documentation Examples
<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 to treatment	<input type="checkbox"/> Intolerance <ul style="list-style-type: none"> Maximum tolerated statin dose Documented lab results Duration of symptoms Response to statin re-challenge <input type="checkbox"/> Documented contraindication

Important Safety Information

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.

Please see additional Important Safety Information on the last page.



Common Repatha® Documentation Requirements for Patients With Primary Hyperlipidemia and Established CVD^{1,2}

Experience With Repatha®

Clinical Details	Documentation Examples
<input type="checkbox"/> Repatha® treatment history	<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

Lifestyle Modification

Clinical Details	Documentation Examples
<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

Important Safety Information

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.

Please see additional Important Safety Information on the last page.



Common Repatha® Documentation Requirements for Patients With FH^{1,2}

Primary and Secondary Diagnosis

Clinical Details	Documentation Examples
Primary Diagnosis: <input type="checkbox"/> HeFH <input type="checkbox"/> HoFH	ICD-10 code*: <input type="checkbox"/> 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* (examples of ICD-10 codes can be found on the RepathaReady® or Specialty Pharmacy Intake Form). <input type="checkbox"/> E75.5 Other lipid storage disorders (approximate synonyms include tendon xanthoma) <input type="checkbox"/> Z83.42 Family history of familial hypercholesterolemia

Diagnostic Findings

Clinical Details	Documentation Examples
<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 	<input type="checkbox"/> Genetic mutation diagnosis and date <input type="checkbox"/> Other <i>definitive</i> diagnostic evidence for HeFH: <ul style="list-style-type: none"> • Simon Broom Diagnostic Criteria for definitive familial hypercholesterolemia • Dutch Lipid Clinic Network Criteria total score > 8 points <input type="checkbox"/> Other <i>definitive</i> 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

* 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.

Important Safety Information

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.

Please see additional Important Safety Information on the last page.



Common Repatha® Documentation Requirements for Patients With FH^{1,2}

History of Other Lipid-lowering Treatment *(may include multiple therapies)*

Clinical Details	Documentation Examples
<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	<input type="checkbox"/> Duration/dates of therapy <input type="checkbox"/> LDL-C level pre- and post-treatment

Intolerance or Contraindication to Other Lipid-lowering Treatment

Clinical Details	Documentation Examples
<input type="checkbox"/> Intolerance, including but not limited to: <ul style="list-style-type: none"> • Rhabdomyolysis • Muscle pain or weakness • Elevated creatine kinase • Elevated liver function tests <input type="checkbox"/> Contraindication to treatment	<input type="checkbox"/> Intolerance <ul style="list-style-type: none"> • Maximum tolerated statin dose • Documented lab results • Duration of symptoms • Response to statin re-challenge <input type="checkbox"/> Documented contraindication

Important Safety Information

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%).

Please see additional Important Safety Information on the last page.



Common Repatha[®] Documentation Requirements for Patients With FH^{1,2}

Experience With Repatha[®]

Clinical Details	Documentation Examples
<input type="checkbox"/> Repatha [®] treatment history	<input type="checkbox"/> Percentage reduction in LDL-C level (goal, achieved, etc) <input type="checkbox"/> Duration/dates of therapy <input type="checkbox"/> LDL-C level pre- and post-treatment

Lifestyle Modification

Clinical Details	Documentation Examples
<input type="checkbox"/> Diet <input type="checkbox"/> Exercise	<input type="checkbox"/> Low-fat diet (documented dietitian visits, group support, etc) <input type="checkbox"/> Exercise (gym attendance, documented physical activity, etc) <input type="checkbox"/> Enrollment in weight management programs

Important Safety Information

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).

Please see additional Important Safety Information on the last page.



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 see full Prescribing Information.

Reference: 1. Data on file, Amgen; 2016. 2. Repatha® (evolocumab) Prescribing Information, Amgen.

AMGEN®

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 **Repatha®**
(evolocumab) injection
140 mg/mL