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: ☐ Primary hyperlipidemia	**ICD-10 code*:** • E78.00 Pure hypercholesterolemia, unspecified • E78.2 Mixed hyperlipidemia • E78.4 Other hyperlipidemia • E78.5 Hyperlipidemia, unspecified
Secondary Diagnosis: ☐ Established CVD, including but not limited to: • 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 Repatha*Ready*® or Specialty Pharmacy Intake Form).** • 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®.

Please see additional Important Safety Information on the last page.

Repatha® (evolocumab) injection 140 mg/mL

Common Repatha® Documentation Requirements for Patients With Primary Hyperlipidemia and Established CVD[1,2]

Diagnostic Findings

Clinical Details	Documentation Examples
☐ Baseline and current lipid levels ☐ Diagnostic tests	• Lipid level values and lab dates (at baseline and most recent) - 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
☐ High-intensity statin: • Atorvastatin 40 mg or 80 mg • Rosuvastatin 20 mg or 40 mg ☐ Other therapies (eg, ezetimibe)	• Duration/dates of therapy • LDL-C level pre- and post-treatment

Intolerance or Contraindication to Other Lipid-lowering Treatment

Clinical Details	Documentation Examples
☐ Intolerance, including but not limited to: • Rhabdomyolysis • Muscle pain or weakness • Elevated creatine kinase (CK) • Elevated liver function tests ☐ Contraindication to treatment	☐ Intolerance • Maximum tolerated statin dose • Documented lab results • Duration of symptoms • Response to statin re-challenge ☐ Documented contraindication

Important Safety Information

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.

Please see additional Important Safety Information on the last page.

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Experience With Repatha®

Clinical Details	Documentation Examples
☐ Repatha® treatment history	• 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
☐ Diet ☐ Exercise	• 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 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.

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Repatha® (evolocumab) injection 140 mg/mL

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

Primary and Secondary Diagnosis

Clinical Details	Documentation Examples
Primary Diagnosis: ☐ HeFH ☐ HoFH	**ICD-10 code*:** ☐ E78.01 Familial hypercholesterolemia
Secondary Diagnosis: ☐ Tendon or cutaneous xanthomas ☐ Relevant family history	**Select the appropriate secondary ICD-10 code* (examples of ICD-10 codes can be found on the Repatha*Ready*® or Specialty Pharmacy Intake Form).** ☐ E75.5 Other lipid storage disorders (approximate synonyms include tendon xanthoma) ☐ Z83.42 Family history of familial hypercholesterolemia

Diagnostic Findings

Clinical Details	Documentation Examples
☐ Baseline and current lipid levels • Genetic tests • Established diagnostic criteria and/or related score • Clinical findings • Family history	☐ Genetic mutation diagnosis and date ☐ Other *definitive* diagnostic evidence for HeFH: • Simon Broom Diagnostic Criteria for definitive familial hypercholesterolemia • Dutch Lipid Clinic Network Criteria total score > 8 points ☐ Other *definitive* diagnostic evidence for HoFH • 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

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).

Please see additional Important Safety Information on the last page.

Repatha® (evolocumab) injection 140 mg/mL

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

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

Clinical Details	Documentation Examples
☐ High-intensity statin: • Atorvastatin 40 mg or 80 mg • Rosuvastatin 20 mg or 40 mg ☐ Other therapies (eg, ezetimibe) ☐ Lipid apheresis	☐ Duration/dates of therapy ☐ LDL-C level pre- and post-treatment

Intolerance or Contraindication to Other Lipid-lowering Treatment

Clinical Details	Documentation Examples
☐ Intolerance, including but not limited to: • Rhabdomyolysis • Muscle pain or weakness • Elevated creatine kinase • Elevated liver function tests ☐ Contraindication to treatment	☐ Intolerance • Maximum tolerated statin dose • Documented lab results • Duration of symptoms • Response to statin re-challenge ☐ Documented contraindication

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. 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.

Please see additional Important Safety Information on the last page.

Repatha® (evolocumab) injection 140 mg/mL

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

Experience With Repatha®

Clinical Details	Documentation Examples
☐ Repatha® treatment history	☐ 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
☐ Diet ☐ Exercise	☐ Low-fat diet (documented dietitian visits, group support, etc) ☐ Exercise (gym attendance, documented physical activity, etc) ☐ Enrollment in weight management programs

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.

Repatha® (evolocumab) injection 140 mg/mL

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 see the full Prescribing Information.

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

AMGEN®

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