Patient Documentation Consideration Checklist

Patient Name: _____ Date of Service: _____

Potential Diagnosis Details:*

Established CVD	Familial Hypercholesterolemia (FH)
☐ Acute coronary syndrome	☐ Simon Broome diagnostic criteria met
☐ History of myocardial infarction	☐ Dutch Lipid Clinic Network score: _____
☐ Stable or unstable angina	☐ Other: _____
☐ Coronary or other arterial revascularization	
☐ Stroke	
☐ Peripheral artery disease (PAD)	
☐ Other: _____	

Please use the QR code to access further information with the Repatha® Coding Guide, including a list illustrative ICD-10 codes.

Treatment History Considerations:*

Recent Lipid Panel, Including LDL-C	Date Measured
Recent LDL-C level: _____ mg/dL	_____

Current and Previous Lipid-lowering Therapy								Dates/Duration
☐ Atorvastatin		☐ 10mg	☐ 20mg	☐ 40mg	☐ 80mg	☐ Current	☐ Previous	_____
☐ Pravastatin		☐ 10mg	☐ 20mg	☐ 40mg	☐ 80mg	☐ Current	☐ Previous	_____
☐ Rosuvastatin	☐ 5mg	☐ 10mg	☐ 20mg	☐ 40mg		☐ Current	☐ Previous	_____
☐ Simvastatin	☐ 5mg	☐ 10mg	☐ 20mg	☐ 40mg	☐ 80mg	☐ Current	☐ Previous	_____
☐ Ezetimibe (10 mg)						☐ Current	☐ Previous	_____
☐ Other: _____						☐ Current	☐ Previous	_____

History of Statin Intolerance or Contraindication	Date
☐ Intolerance symptoms: _____	_____
☐ Rhabdomyolysis ☐ Muscle pain or weakness	_____
☐ Elevated creatine kinase (CK) ☐ Elevated liver function tests	_____
☐ Symptoms reappeared after statin re-challenge with a lower dose	_____
☐ Contraindication: _____	

CVD = cardiovascular disease; LDL-C = low-density lipoprotein cholesterol.

Consult payer coverage policy for prior authorization criteria and documentation requirements.

INDICATION

Repatha® is indicated:

- To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults with established cardiovascular disease

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®.

Please see additional Important Safety Information on the next 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 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 Adults with 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 Pediatric Patients with HeFH:** The most common adverse reactions (>5% of patients treated with Repatha® and more frequently than placebo) were: nasopharyngitis, headache, oropharyngeal pain, influenza, and upper respiratory tract infection.
- **Adverse Reactions in Adults and Pediatric Patients with 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®.

INDICATIONS

Repatha® is indicated:

- To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults with established cardiovascular disease
- 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 diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C
- as an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C

  The safety and effectiveness of Repatha® have not been established in pediatric patients with HeFH or HoFH who are younger than 10 years old or in pediatric patients with other types of hyperlipidemia.

Please see full Prescribing Information.

*These examples are informational and provided as a courtesy only. They should not be a substitute for an independent clinical decision. It is the duty of the healthcare provider to understand individual patient considerations and use their own judgment and clinical decision-making when determining a particular patient's diagnosis and treatment.

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Repatha® (evolocumab) injection 140 mg/mL