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Evolocumab

Table of Contents

Overview 1
Medical Necessity Criteria 1
Reauthorization Criteria 4
Authorization Duration 4
Conditions Not Covered..... 4
Background..... 4
References 7
Supplemental References 8

Related Coverage Resources

[Genetic Testing of Heritable Disorders](#)

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Overview

This policy supports medical necessity review for evolocumab (**Repatha**[®]).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Evolocumab (Repatha) is considered medically necessary when ONE of the following is met (1, 2, 3, or 4):

1. **Atherosclerotic Cardiovascular Disease.** Individual meets **ALL** of the following criteria (A, B, C, D, and E):
 - A. Individual is 18 years of age or older
 - B. Documentation of **ONE** of the following conditions or diagnoses (i, ii, iii, iv or v):
 - i. A previous myocardial infarction or a history of an acute coronary syndrome

- ii. Angina (stable or unstable)
 - iii. A past history of stroke or transient ischemic attack
 - iv. Peripheral arterial disease (PAD) of atherosclerotic origin
 - v. Individual has undergone a coronary or other arterial revascularization procedure in the past (for example, coronary artery bypass graft surgery, percutaneous coronary intervention, angioplasty, and coronary stent procedures)
- C. Individual meets **ONE** of the following criteria (i or ii):
- i. Documented contraindication or intolerance to statin therapy
 - ii. Individual meets **BOTH** of the following (a and b):
 - a. Documented trial of **ONE** high-intensity statin therapy (for example, atorvastatin 40 mg daily or higher; rosuvastatin 20 mg daily or higher [as a single-entity or as a combination product]) for at least 8 continuous weeks
 - b. Low-density lipoprotein cholesterol level after this treatment remains at 70 mg/dL or higher
- D. Use is adjunctive to diet and maximally tolerated statin therapy (unless contraindicated or intolerant [\[Appendix A\]](#))
- E. Medication is prescribed by, or in consultation with, a cardiologist; an endocrinologist; or a physician who focuses on the treatment of cardiovascular (CV) risk management and/or lipid disorders
2. **Heterozygous Familial Hypercholesterolemia.** Individual meets **ALL** of the following criteria (A, B, C, D, and E):
- A. Individual is 10 years of age or older
 - B. Individual meets **ONE** of the following criteria (i, ii, or iii):
 - i. Individual has an untreated low-density lipoprotein cholesterol (LDL-C) of at least 190 mg/dL (prior to treatment with any antihyperlipidemic agents)
 - ii. Individual has genetic confirmation of HeFH by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene
 - iii. Individual has been diagnosed with HeFH meeting **ONE** of the following diagnostic criteria thresholds (a or b):
 - a. Individual meets **BOTH** of the following [1] and 2]:
 - 1) Prescriber used the Dutch Lipid Network criteria [\[Appendix C\]](#) to diagnose HeFH
 - 2) Individual had a score greater than 5
 - b. Individual meets **BOTH** of the following [1] and 2]:
 - 1) Prescriber used the Simon Broome criteria [\[Appendix B\]](#) to diagnose heterozygous familial hypercholesterolemia
 - 2) Individual met the threshold for “definite” or “possible (or probable)” familial hypercholesterolemia
 - C. Individual meets **ONE** of the following criteria (i or ii):
 - i. Documented contraindication or intolerance to statin therapy
 - ii. Individual meets **BOTH** of the following (a and b):
 - a. Documented trial of **ONE** high-intensity statin therapy (for example, atorvastatin 40 mg daily or higher; rosuvastatin 20 mg daily or higher [as a single-entity or as a combination product]) for at least 8 continuous weeks
 - b. Low-density lipoprotein cholesterol level after this treatment remains at 70 mg/dL or higher
 - D. Use is adjunctive to diet and maximally tolerated statin therapy (unless contraindicated or intolerant [\[Appendix A\]](#))
 - E. Medication is prescribed by, or in consultation with, a cardiologist; an endocrinologist; or a physician who focuses on the treatment of cardiovascular (CV) risk management and/or lipid disorders
3. **Homozygous Familial Hypercholesterolemia (HoFH).** Individual meets **ALL** of the following criteria (A, B, C, D, and E):

- A. Individual is 10 years of age or older
 - B. Individual meets **ONE** of the following (i, ii, or iii):
 - i. Individual has genetic confirmation of two mutant alleles at the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 gene locus
 - ii. Individual has an untreated low-density lipoprotein (LDL-C) level of at least 500 mg/dL (prior to treatment with any antihyperlipidemic agent) AND meets **ONE** of the following (a or b):
 - a. Individual had clinical manifestations of HoFH before 10 years of age (for example, cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma)
 - b. Both parents of the individual had untreated LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (HeFH) (for example, both parents had an untreated LDL-C level of at least 190 mg/dL and/or an untreated total cholesterol level greater than 250 mg/dL)
 - iii. Individual has a treated LDL-C level of at least 300 mg/dL AND meets **ONE** of the following (a or b):

Treated refers to after therapy with at least one antihyperlipidemic agent. Some examples of antihyperlipidemic agents include statins (e.g., atorvastatin, rosuvastatin, lovastatin, simvastatin, pravastatin), ezetimibe, a PCSK9 inhibitor (e.g., Repatha [evolocumab injection], Praluent [alirocumab injection]), Evkeeza (evinacumab-dgnb injection), or Juxtapid (lomitapide capsules).

 - a. Individual had clinical manifestations of HoFH before 10 years of age
Note: Examples of clinical manifestations of HoFH are cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma.
 - b. Both parents of the patient had untreated LDL-C levels or total cholesterol levels consistent with HeFH (for example, both parents had an untreated LDL-C of at least 190 mg/dL and/or an untreated total cholesterol level greater than 250 mg/dL)
 - C. Individual meets **ONE** of the following criteria (i or ii):
 - i. Documented contraindication or intolerance to statin therapy
 - ii. Individual meets **BOTH** of the following (a and b):
 - a. Documented trial of **ONE** high-intensity statin therapy (for example, atorvastatin 40 mg daily or higher; rosuvastatin 20 mg daily or higher [as a single-entity or as a combination product]) for at least 8 continuous weeks
 - b. Low-density lipoprotein cholesterol level after this treatment remains at 70 mg/dL or higher
 - D. Use is adjunctive to diet and maximally tolerated statin therapy (unless contraindicated or intolerant [\[Appendix A\]](#))
 - E. Medication is prescribed by, or in consultation with, a cardiologist; an endocrinologist; or a physician who focuses on the treatment of cardiovascular (CV) risk management and/or lipid disorders
4. **Primary Hyperlipidemia.** Individual meets **ALL** of the following criteria (A, B, C, D, and E):
This is not associated with atherosclerotic cardiovascular disease (ASCVD), heterozygous familial hypercholesterolemia (HeFH), or homozygous familial hypercholesterolemia (HoFH) and may be referred to as combined hyperlipidemia, hypercholesterolemia (pure, primary), dyslipidemia, or increased/elevated low-density lipoprotein cholesterol (LDL-C) levels.
- A. Individual is 18 years of age or older
 - B. Individual meets **ONE** of the following (i or ii):
 - i. Individual has a coronary artery calcium (CAC) or calcification score of 100 or greater Agatston units or 75th percentile or greater for the individual's age, gender, and ethnicity [coronary calcium scan may require prior authorization].
 - ii. Calculated 10-year ASCVD risk score of 7.5% or higher

- C. Individual meets **ONE** of the following criteria (i or ii):
- i. Documented contraindication or intolerance to statin therapy
 - ii. Individual meets **BOTH** of the following (a and b):
 - a. Documented trial of **ONE** high-intensity statin therapy (for example, atorvastatin 40 mg daily or higher; rosuvastatin 20 mg daily or higher [as a single-entity or as a combination product]) for at least 8 continuous weeks
 - b. LDL-C level after this treatment regimen remains at 100 mg/dL or higher (for diabetic individuals at 70mg/dL or higher)
- D. Use is adjunctive to diet and maximally tolerated statin therapy (unless contraindicated or intolerant [Appendix A](#))
- E. Medication is prescribed by, or in consultation with, a cardiologist; an endocrinologist; or a physician who focuses on the treatment of cardiovascular (CV) risk management and/or lipid disorders

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Repatha (evolocumab) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response (for example, demonstrated reduction of LDL-C).

Authorization Duration

Initial and reauthorization approval duration: up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

1. **Concurrent use of Repatha with Praluent (alirocumab injection for subcutaneous use) or Leqvio (inclisiran subcutaneous injection).** Praluent is another PCSK9 inhibitor and should not be used with Repatha.² Leqvio, a small interfering ribonucleic acid (RNA) directed to PCSK9 messenger RNA, is a similar product and should not be given with Repatha.¹

Background

OVERVIEW

Repatha, a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor antibody, is indicated for the following uses:¹

- **Established cardiovascular (CV) disease**, in adults to reduce the risk of myocardial infarction (MI), stroke, and coronary revascularization.
- **Primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH])**, in adults as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies to reduce LDL-C.
- **HeFH, in pediatric patients ≥ 10 years of age**, as an adjunct to diet and other LDL-C lowering therapies.
- **Homozygous familial hypercholesterolemia (HoFH)**, as an adjunct to diet and other low-density lipoprotein (LDL)-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients ≥ 10 years of age and older, 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 of age.¹ Another PCSK9 inhibitor that is available is Praluent® (alirocumab subcutaneous injection).² Leqvio® (inclisiran subcutaneous injection), a small interfering ribonucleic acid (RNA) directed to PCSK9 messenger RNA, is a similar product.³

Guidelines

Many guidelines are available regarding the treatment of patients with dyslipidemia.⁴⁻¹⁰ For patients with elevated LDL-C, statins are the cornerstone of therapy and recommended first-line to be used at maximally tolerated doses due to the established benefits regarding the reduction of CV risks. Atorvastatin 40 mg to 80 mg once daily (QD) and rosuvastatin 20 mg to 40 mg QD are considered high-intensity statins as they achieve LDL-C lowering of $\geq 50\%$. Ezetimibe is usually the next therapy added.

- The **American College of Cardiology Expert Consensus Decision Pathway on the Role of Non-Statin Therapies** for LDL-Cholesterol Lowering in the Management of Atherosclerotic cardiovascular disease (ASCVD) Risk (2022) make several recommendations regarding PCSK9 inhibitors.⁴ For adults with clinical ASCVD at very high risk (e.g., patients with major ASCVD events, HeFH, diabetes) who are on statin therapy for secondary prevention, the general goal is $\geq 50\%$ LDL-C reduction and an LDL-C < 55 mg/dL with maximally tolerated statin therapy. If the above goals are not achieved, the initial non-statin agents recommended include ezetimibe and/or a PCSK9 monoclonal antibody (i.e., Repatha or Praluent). For adults without clinical ASCVD or diabetes or LDL-C ≥ 190 mg/dL who have undergone subclinical atherosclerosis imaging, if the coronary artery calcium score is $\geq 1,000$ Agatston units, PCSK9 monoclonal antibodies (i.e., Repatha or Praluent) may be non-statin agents to consider following high-intensity statin therapy and ezetimibe to achieve the goal of a $\geq 50\%$ LDL-C reduction (and LDL-C threshold < 70 mg/dL).
- The **American Heart Association/American College of Cardiology guidelines on the management of blood cholesterol** (updated 2018) defines ASCVD as an acute coronary syndrome, those with a history of MI, stable or unstable angina or coronary or other revascularizations, stroke, transient ischemic attack, or peripheral arterial disease.^{5,6} Although LDL-C thresholds are not always recognized, in general, an LDL-C < 70 mg/dL is recommended for most patients with ASCVD to reduce CV risk. Use of a PCSK9 as an adjunct is justified if this goal is not met with maximally tolerated statins.^{5,6} Additionally, guidelines and reviews have recognized that patients with an elevated coronary artery calcium or calcification score (e.g., ≥ 300 Agatston units) are at an increased risk of CV events.^{8,11-14}
- The **National Lipid Association** published guidelines for the screening, diagnosis, and management of pediatric and adult patients with familial hypercholesterolemia (2011).⁹ Genetic testing can identify HoFH and HeFH in some cases. Also, HeFH can be diagnosed utilizing Simon Broome criteria or Dutch Lipid Clinical Network criteria. Patients with an untreated LDL-C ≥ 190 mg/dL suggest familial hypercholesterolemia. Statins are the initial treatment for all adults with familial hypercholesterolemia, usually at high-potency doses. Ezetimibe can also be added. In general, for patients with HeFH who have not yet manifested ASCVD, LDL-C levels ≤ 100 mg/dL are recommended.
- The **2014 HoFH position paper from the Consensus Panel on familial hypercholesterolemia of the European Atherosclerosis Society** states the diagnosis of HoFH is made based on genetic or clinical criteria.¹⁵ A definitive diagnosis can be made by genetic confirmation of two mutant alleles at the LDL receptor, apolipoprotein B, PCSK9, or LDL receptor adaptor protein 1 gene locus. However, in some patients, genetic confirmation remains elusive. Historically, HoFH has been commonly diagnosed based on LDL-C levels such as an untreated LDL-C > 500 mg/dL, or a treated LDL-C ≥ 300 mg/dL. Also confirming the diagnosis is the presence of xanthomas (cutaneous or tendinous) before the age of 10 years or a family history of elevated LDL-C levels consistent with HeFH in both parents. Other clinical manifestations of HoFH include arcus cornea or xanthelasma. Initial therapy for HoFH is high-intensity statins.¹⁵ Other guidelines note that ezetimibe and PCSK9 inhibitors can be added for patients with HoFH if further reductions are needed; Juxtapid® (lomitapide capsules) and Evkeeza® (evinacumab-dgnb intravenous infusion) can be considered.⁴

Appendix A Statin Intolerance

Statin intolerance occurs when an individual is unable to continue to use a statin, either because of the development of a side effect or because of evidence on a blood test that certain markers of liver function or

muscle function (creatine kinase) are sufficiently abnormal to cause concern. The intolerance can be either partial (for example, only some statins at some doses) or complete (for example, all statins at any dose). The most common presentation of statin intolerance is myalgia (for example, muscle aches, pains, weakness, or cramps), which can occur in up to 15% of individuals treated with statins. In most cases, the symptoms are mild and are rarely associated with myositis (muscle inflammation) and markers of muscle injury (creatine kinase). Of note, the symptoms are completely reversible shortly after the statin is stopped.

Serious muscle damage or rhabdomyolysis associated with statin treatment is extremely rare, for instance, occurring in 1 in 23 million individuals with prescriptions for atorvastatin. Rhabdomyolysis is statin-induced muscle breakdown that is associated with markedly elevated creatine kinase levels (at least 10 times the upper limit of normal), along with evidence of end organ damage which can include signs of acute renal injury (noted by substantial increases in serum creatinine [Scr] levels [a \geq 0.5 mg/dL increase in Scr or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine]).

Mild to moderate increases in creatine kinase may occasionally be seen in patients taking statins who have no muscle-related side effects, but this should not be grounds to stop statin therapy.¹⁸

Appendix B

Simon Broome Register Diagnostic Criteria.¹⁶

Definite Familial Hypercholesterolemia
Raised cholesterol
--Total cholesterol greater than 6.7 mmol/L (260 mg/dL) or LDL-C > 4.0 mmol/L (155 mg/dL) in a child < 16 years; OR
--Total cholesterol > 7.5 mmol/L (290 mg/dL) or LDL-C > 4.9 mmol/L (190 mg/dL) in an adult (aged > 16 years);
AND
--Tendon xanthomas in the patient or in a first (parent, sibling, or child) or second-degree relative (grandparent, aunt, or uncle);
OR
DNA-based evidence of LDL-receptor, familial defective APOB, or PCSK9 mutation.
Possible (or Probable) Familial Hypercholesterolemia
Raised cholesterol
--Total cholesterol greater than 6.7 mmol/L (260 mg/dL) or LDL-C > 4.0 mmol/L (155 mg/dL) in a child < 16 years; OR
--Total cholesterol > 7.5 mmol/L (290 mg/dL) or LDL-C > 4.9 mmol/L (190 mg/dL) in an adult (aged > 16 years);
AND
Family history of premature myocardial infarction younger than 50 years of age in second-degree relative or younger than 60 years of age in first-degree relative;
OR
Raised cholesterol
--Total cholesterol greater than 6.7 mmol/L (260 mg/dL) or LDL-C > 4.0 mmol/L (155 mg/dL) in a child < 16 years; OR
--Total cholesterol > 7.5 mmol/L (290 mg/dL) or LDL-C > 4.9 mmol/L (190 mg/dL) in an adult (aged > 16 years);
AND
Family history of raised cholesterol > 7.5 mmol (290 mg/dL) in adult first-degree or second-degree relative or > 6.7 mmol/L (260 mg/dL) in child or sibling aged < 16 years.

LDL-C – Low-density lipoprotein cholesterol; LDL – Low-density lipoprotein; APOB – Apolipoprotein B; PCSK9 – Proprotein convertase subtilisin kexin type 9.

Appendix C

Dutch Lipid Network Criteria.¹⁷

Criteria	Score
Family History	
First-degree relative with known premature coronary and/or vascular disease (men < 55 years, women < 60 years)	1
First degree relative with known LDL-C > 95 th percentile for age and sex	1
First-degree relative with tendon xanthomata and/or arcus cornealis, OR	2
Children aged < 18 years with LDL-C > 95 th percentile for age and sex	2
Clinical History	
Patient with premature CAD (age as above)	2
Patient with premature cerebral or peripheral vascular disease (age as above)	1
Physical Examination	

Criteria	Score
Tendon xanthomas	6
Arcus cornealis at age < 45 years	4
LDL-C	
LDL-C \geq 8.5 mmol/L (330 mg/dL)	8
LDL-C 6.5 to 8.4 mmol/L (250 to 329 mg/dL)	5
LDL-C 5.0 to 6.4 mmol/L (190 to 249 mg/dL)	3
LDL-C 4.0 to 4.9 mmol/L (155 to 189 mg/dL)	1
DNA analysis	
Functional mutation LDLR, APOB or PCSK9 gene	8
Stratification	
Definite familial hypercholesterolemia	> 8
Probable familial hypercholesterolemia	6 to 8
Possible familial hypercholesterolemia	3 to 5
Unlikely familial hypercholesterolemia	< 3

LDL-C – Low-density lipoprotein cholesterol; CAD – Coronary artery disease; LDLR – Low-density lipoprotein receptor; APOB – Apolipoprotein B; PCSK9 – Proprotein convertase subtilisin kexin type 9.

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