CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Repatha (evolocumab)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Repatha, originally approved by the FDA in 2015, is an inhibitor of PCSK9 (proprotein convertase subtilisin/kexin type 9) for the treatment of familial hypercholesterolemia and to reduce the risk of cardiovascular events (heart attack, stroke) in cardiovascular disease patients. It is a subcutaneous injection self-administered every 2 weeks or once a month.
PCSK9 bind to LDL receptors in the liver to promote their degradation. Inhibiting PCSK9 from binding the LDL receptors increases the number of them available to clear LDL from the blood, which reduces LDL cholesterol levels.

Repatha (evolocumab) will be considered for coverage when the following criteria are met:

Homozygous Familial Hypercholesterolemia (HoFH)

For **initial** authorization:

1. Member is at least 10 years of age; AND
2. Medication must be prescribed by or in consultation with a lipid specialist or cardiologist; AND
3. Member has a diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by one of the following:
   a) Genetic testing confirmation of two mutant alleles in the LDLR, Apo-B, PCSK9, or LDLRAP1 gene locus; OR
   b) LDL-C > 500 mg/dL before any treatment or LDL-C > 300 mg/dL if treated with a lipid-lowering drug AND one of the following:
      i) Xanthoma before 10 years of age; OR
      ii) Evidence of heterozygous familial hypercholesterolemia (HeFH) (i.e., total cholesterol > 250 mg/dL) in both parents; AND
4. Chart notes must include documentation of baseline LDL-C level, taken within the past 90 days; AND
5. Member is unable to achieve LDL-C goal (see Note below) after a 90-day trial of a high-intensity statin (i.e., rosuvastatin ≥ 20mg, atorvastatin ≥ 40mg for 18 years or older, ≥ 20mg for under 18 years old) together with ezetimibe. If intolerance occurs, a second attempt must be initiated with a moderate or low-intensity statin + ezetimibe; AND
6. Repatha will be used as an adjunct to other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis), unless contraindicated or intolerant; AND
7. Prescriber attests that the member will adhere to a diet regimen or a diet modification.
8. **Dosage allowed/Quantity limit:** 420 mg subQ once monthly.
   May increase to 420 mg every 2 weeks if clinically meaningful response not reached after 12 weeks, or if also on lipid apheresis.
   (Limit: 2 injections per 28 days)

NOTE: The LDL-C goals are <100 mg/dL for adults 18 years or older, < 135 mg/dL for children, and < 70 mg/dL for adults with clinical ASCVD.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes along with recent labs have been provided showing a meaningful reduction of LDL-C level from baseline OR LDL-C is at goal.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Heterozygous Familial Hypercholesterolemia (HeFH)

For **initial** authorization:
1. Member must be 10 years of age or older; AND
2. Medication must be prescribed by or in consultation with a lipid specialist or a cardiologist; AND
3. Member has a diagnosis of heterozygous familial hypercholesterolemia (FeFH) confirmed by one of the following:
   a) Dutch Lipid Network Criteria score of 9 or higher;
   b) Genetic testing confirmation;
   c) "Definite" Simon Broome Criteria (see Table 1 to determine eligibility, if not submitted with chart notes); AND
4. Chart notes must include documentation of baseline LDL-C level, taken within the past 90 days; AND
5. Member is unable to achieve LDL < 100 mg/dL[3] after a 90-day trial of a high-intensity statin (i.e., rosuvastatin ≥ 20mg, atorvastatin ≥ 40mg for 18 years or older, ≥ 20mg for under 18 years old) together with ezetimibe. If intolerance occurs, a second attempt must be initiated with a moderate or low-intensity statin + ezetimibe; AND
6. Repatha will be used in combination with a statin and/or ezetimibe, unless contraindicated or intolerant; AND
7. Prescriber attests that the member will adhere to a diet regimen or a diet modification.
8. **Dosage allowed/Quantity limit:** 140mg every 2 weeks OR 420mg every month. (Limit: 2 injections per 28 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes along with recent labs have been provided showing a meaningful reduction of LDL-C level from baseline OR LDL-C is at goal.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Prevention of Cardiovascular Events

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Member has a history of clinical atherosclerotic cardiovascular disease (ASCVD) (e.g. angina, acute coronary syndrome, coronary or other arterial revascularization, myocardial infarction (MI), stroke, transient ischemic attack, or peripheral arterial disease); AND
3. Chart notes must include documentation of baseline LDL-C level, taken within the past 90 days; AND
4. Member is unable to achieve LDL-C < 70 mg/dL3 after a 90-day trial of a high-intensity statin (i.e., rosuvastatin ≥ 20mg, atorvastatin ≥ 40mg for 18 years or older, ≥ 20mg for under 18 years old) together with ezetimibe. If intolerance occurs, a second attempt must be initiated with a moderate or low-intensity statin + ezetimibe; AND
5. Repatha will be used in combination with a statin and/or ezetimibe, unless contraindicated or intolerant; AND
6. Prescriber attests that the member will adhere to a diet regimen or a diet modification

7. **Dosage allowed/Quantity limit:** 140mg every 2 weeks OR 420mg every month.
   (Limit: 2 injections per 28 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes along with recent labs have been provided showing a meaningful reduction of LDL-C level from baseline OR LDL-C is at goal.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Repatha (evolocumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/09/2020	New policy for Repatha created. Retired old Biologic Cholesterol Agents policy.
04/27/2021	Updated genetic testing requirement under HoFH to ask for specific alleles (previously not specified). Updated atorvastatin high-intensity requirement to reflect pediatric vs. adult dosing for all diagnoses.
11/15/2021	Transferred to new template. Updated age for HoFH and HeFH and dosing for HoFH.
02/22/2022	Removed specialist requirement from ASCVD indication.

References:

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2. Blom D, 2020. Homozygous Familial Hypercholesterolemia (HoFH). National Organization for Rare Disorder. NORD. April 2020.
3. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC Guideline on the Management of Blood Cholesterol. JACC. 2018;73(24)doi:10.1016/j.jacc.2018.11.002.
4. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk. JACC. 2017;70(14):1785-1822.
5. Sabatine MS, Giugliano RP, Keech AC, et al. Evolocumab and clinical outcomes in patients with cardiovascular disease. N Engl J Med 2017; 376:1713-1722
6. Harada M, Arai H, Ishigaki Y, et al. Guidelines for diagnosis and treatment of familial hypercholesterolemia 2017. J Atheroscler Thromb. 2018 Aug 1; 25(8): 751–770.
7. McGowen, Dehkordi S, Moriarty P, et al. Diagnosis and treatment of heterozygous familial hypercholesterolemia. J Am Heart Assoc. 2019 Dec 17;8(24):e013225.
8. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014;35(32):2146-2157.
9. American Diabetes Association. Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes-2020. Diabetes Care. 2020;43(Suppl 1):S111-S134.
10. Santos RD, Stein EA, Hovingh GK, et al. Long-term Evolocumab in patients with familial hypercholesterolemia. J Am Coll Cardiol. 2020;75(6):565-574.
11. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways. J Am Coll Cardiol. 2017;70(14):1785-1822.
12. Pignone M. Management of elevated low density lipoprotein-cholesterol (LDL-C) in primary prevention of cardiovascular disease. In: Freeman MW, ed. UpToDate. Waltham, MA.; UpToDate; 2020. www.uptodate.com. Accessed July 09, 2020.

Table 1

Simon Broom Criteria

• Total cholesterol level > 290 mg/dL OR LDL-C > 190 mg/dL at baseline AND
• One of the following:
  ○ Physical finding of tendon xanthomas in 1st or 2nd degree relative;
  ○ Confirmation by gene or receptor testing (presence of LDL-R, ApoB, or PCSK9 mutation)

Effective date: 07/01/2022
Revised date: 02/22/2022