CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Repatha (evolocumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior authorization required (Non-preferred product) QUANTITY LIMIT – 420 mg (1 injection per 28 days) 140 mg (2 injections per 28 days)
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Repatha (evolocumab) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HoFH)

For **initial** authorization:

1. Member must be 13 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 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**: 420 mg once monthly.

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 member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HeFH))

For **initial** authorization:

1. Member must be 18 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**: 140mg every 2 weeks OR 420mg every month.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, 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. Medication must be prescribed by or in consultation with a lipid specialist or a cardiologist; AND
3. 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
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 < 70 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**: 140mg every 2 weeks OR 420mg every month.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Repatha (evolocumab) not medically necessary for the treatment of the diseases that are not listed in this document.

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.

References:

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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
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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.
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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.

Effective date: 10/1/2021
Revised date: 04/27/2021

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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)