

## PHARMACY POLICY STATEMENT Georgia 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 <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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; OR
  - b. LDL-C >500 mg/dL before any treatment or LDL-C >300 mg/dL<sup>8</sup> if treated with a lipid-lowering drug (not including PCSK9 or Juxtapid)<sup>8</sup> AND **one** of the following:
    - i. Xanthoma before 10 years of age<sup>8</sup>;
    - ii. Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents<sup>8</sup>; 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) 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<sup>3</sup> after a 90-day trial of a high-intensity statin (i.e., rosuvastatin ≥ 20mg, atorvastatin ≥ 40mg) 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<sup>3</sup> after a 90-day trial of a high-intensity statin (i.e., rosuvastatin ≥ 20mg, atorvastatin ≥ 40mg) 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.

References:

1. Repatha [Package Insert]. Thousand Oaks, CA: Amgen Inc.; February 2019.
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.

Effective date: 12/01/2020

Revised date: 07/09/2020

Table 1

<b>Simon Broom Criteria</b>
<ul style="list-style-type: none"> <li>• Total cholesterol level &gt; 290 mg/dL OR LDL-C &gt; 190 mg/dL at baseline AND</li> <li>• <u>One</u> of the following:               <ul style="list-style-type: none"> <li>○ Physical finding of tendon xanthomas in 1<sup>st</sup> or 2<sup>nd</sup> degree relative;</li> <li>○ Confirmation by gene or receptor testing (presence of LDL-R, ApoB, or PCSK9 mutation)</li> </ul> </li> </ul>