

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	NA

Repatha (evolocumab)

Override(s)	Approval Duration
Prior Authorization	Initial requests – 6 months
Quantity Limit	Continuation requests – 12 months

Medications	Quantity Limit
Repatha (evolocumab) 140 mg/ml prefilled syringe or auto-injector*	2 prefilled syringes or auto-injectors per 28 days
Repatha (evolocumab) 420 mg/3.5 ml prefilled cartridge	1 prefilled cartridge per month

*May approve one additional prefilled syringe or auto-injector of Repatha every 28 days for individuals utilizing Repatha 420 mg per month.

APPROVAL CRITERIA

Initial requests for Repatha (evolocumab) may be approved if the following criteria are met:

- I. Individual is at high risk for atherosclerotic cardiovascular disease (ASCVD) events as identified by one of the following:
 - A. Individual has Homozygous Familial Hypercholesterolemia (HoFH) confirmed by (Cuchel 2014, Singh 2015):
 1. Presence of two mutant alleles at the LDLR, apolipoprotein B (apoB), PCSK9 or ARH adaptor protein (LDLRAP1) gene locus; **OR**
 2. Presence of the following:
 - a. An untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L); **OR**
 - b. Treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) **AND** one of the following:
 - i. Cutaneous or tendonous xanthoma before age of 10 years; **OR**
 - ii. Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than 190 mg/dL);
 - OR**
 - B. Individual Heterozygous Familial Hypercholesterolemia (HeFH) confirmed by (Singh 2015, WHO 1999):
 1. Presence of a mutation in LDLR, apolipoprotein B (apoB), or PCSK9, ARH adaptor protein (LDLRAP1) gene; **OR**

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2. World Health Organization (WHO)/Dutch Lipid Network Criteria with score of greater than eight points;

OR

- C. Individual has a history of clinical atherosclerotic cardiovascular disease (ASCVD), including **one or more** of the following (AHA/ACC 2018):
 1. Acute coronary syndromes;
 2. Coronary artery disease (CAD);
 3. History of myocardial infarction (MI);
 4. Stable or unstable angina;
 5. Coronary or other arterial revascularization;
 6. Stroke;
 7. Transient ischemic attack (TIA);
 8. Peripheral arterial disease (PAD) ;

AND

- II. Individual meets one of the following:
 - A. Individual is on a high intensity statin therapy, or statin therapy at the maximum tolerated dose (high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher) (AHA/ACC 2018, AACE 2017); **OR**
 - B. Individual is statin intolerant based on one of the following:
 1. Inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, demonstrated by intolerable symptoms or clinically significant biomarker changes (NLA 2014); **OR**
 2. Statin associated rhabdomyolysis after a trial of one statin;

OR

- C. Individual has a contraindication for statin therapy including active liver disease, unexplained persistent elevation of hepatic transaminases, or pregnancy;

AND

- III. Individual is on ezetimibe in addition to statin therapy (only applies to individuals on statin therapy) (ACC 2016);

AND

- IV. Individual, excluding HoFH, has achieved suboptimal lipid lowering response, despite at least 90 days of compliant lipid lowering therapy and lifestyle modifications as defined (AHA/ACC 2018):
 - A. For individuals where initial LDL-C is known:
 1. Less than 50% reduction LDL-C; **OR**
 - B. For individuals where initial LDL-C is unknown:
 1. ASCVD and LDL-C remains greater than or equal to 70mg/dL; **OR**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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2. No history of ASCVD and LDL-C remains greater than or equal to 100mg/dL.

Continuation requests for Repatha (evolocumab) may be approved when the following criteria are met:

- I. Individual continues to receive concomitant maximally tolerated statin therapy (unless contraindication or individual is statin intolerant); **AND**
- II. Confirmation of LDL reduction has been provided.

Repatha (evolocumab) may not be approved for the following:

- I. All other indications not included above; **OR**
- II. Concurrent use with Juxtapid (lomitapide).

Key References:

1. Cuchel M, Bruckert E, Ginsberg HN, et. al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. *European Heart Journal*. 2014; 35: 2146–2157.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 18, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Grundy SM, Stone NJ, Bailey AL, et. al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol. *J Am Coll Cardiol*. 2018. <https://doi.org/10.1016/j.jacc.2018.11.003>.
5. Guyton JR, Bays HE, Grundy SM, Jacobson TA. The National Lipid Association Statin Intolerance Panel. An assessment by the Statin Intolerance Panel: 2014 update. *J Clin Lipidol*. 2014;8(3 Suppl):S72–81.
6. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology (AAACE/ACE) guidelines for management of dyslipidemia and prevention of cardiovascular disease. *Endocr Pract*. 2017;23(Suppl 2):1-87.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
8. Rosenson RS, Durrington P. Familial hypercholesterolemia in adults: Overview. Last updated: July 1, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 18, 2020.
9. Singh S, Bittner V. Familial hypercholesterolemia--epidemiology, diagnosis, and screening. *Curr Atheroscler Rep*. 2015; 17(2):482.
10. World Health Organization. Familial hypercholesterolemia—report of a second WHO Consultation. Geneva, Switzerland: World Health Organization, 1999. Available at: http://whqlibdoc.who.int/hq/1999/WHO_HGN_FH_CONS_99.2.pdf?ua=1. Accessed: July 19, 2020.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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