Repatha (evolocumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial Approval: 1 year Continuation Approval: 1 year

Medications	Quantity Limit
Repatha (evolocumab) 140 mg/mL prefilled syringe or auto-injector Repatha (evolocumab) 420 mg/3.5 mL prefilled cartridge	3 prefilled syringes or auto-injectors per 28 days 1 prefilled cartridge per 28 days

For individuals with homozygous familial hypercholesterolemia (HoFH), may approve 2 Repatha 420 mg/3.5 mL prefilled cartridges or 6 prefilled syringes/auto-injectors per 28 days for the following:

1. Individual has tried Repatha 420 mg per 28 days for 12 weeks and not achieved adequate LDL-C reduction; **OR**
2. Individual is on lipid apheresis.

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) verified by (Cuchel 2023):
      1. Biallelic pathogenic/likely pathogenic variants on different chromosomes at the LDLR, APOB, PCSK9 or LDLRAP1 genes or ≥2 such variants at different loci; **OR**
      2. An untreated LDL-C concentration greater than 400 mg/dL (10 mmol/L) **AND** one of the following:
         a. Cutaneous or tendonous xanthoma before age of 10 years; **OR**
         b. Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than 190 mg/dL);

   OR

   B. Individual has Heterozygous Familial Hypercholesterolemia (HeFH) verified by (Singh 2015, WHO 1999):
      1. Presence of a mutation in LDLR, apolipoprotein B (apoB), or PCSK9, ARH adaptor protein (LDLRAP1) gene; **OR**
      2. World Health Organization (WHO)/Dutch Lipid Clinic 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);

OR

D. Individual has primary hyperlipidemia;

AND

II. Individual meets one of the following:
    A. Individual is on 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); **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 adverse effects associated with statin therapy that resolve or improve with dose reduction or discontinuation (NLA 2022); **OR**
        2. Statin associated rhabdomyolysis or immune-mediated necrotizing myopathy (IMNM) after a trial of one statin;

    OR

    C. Individual has a contraindication for statin therapy including but not limited to active liver disease, unexplained persistent elevation of hepatic transaminases, or pregnancy;

AND

III. 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, ACC 2022):
    A. For individuals where initial LDL-C is known:
        1. Less than 50% reduction in LDL-C; **OR**
    B. For individuals where initial LDL-C is unknown:
        1. ASCVD and LDL-C remains greater than or equal to 55 mg/dL; **OR**
        2. No history of ASCVD and LDL-C remains greater than or equal to 100 mg/dL.

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

I. Individual continues to use in combination with maximally tolerated statin therapy (unless contraindication or individual is statin intolerant); **AND**
II. Individual has achieved LDL-C reduction.

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

I. Use in combination with Leqvio or Praluent; **OR**
II. May not be approved when the above criteria are not met and for all other indications.

Key References:

1. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol* 2022;Aug 24:[Epub ahead of print].
2. Cheeley MK, Saseen JJ, Agarwala A, et. al. NLA scientific statement on statin intolerance: a new definition and key considerations for ASCVD risk reduction in the statin intolerant patient. *J Clin Lipidol*. 2022. https://doi.org/10.1016/j.jacl.2022.05.068.
3. Cuchel M, Raal FJ, Hegele RA, et. al. 2023 Update on European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolaemia: new treatments and clinical guidance. *European Heart Journal.* 2023; 44: 2277-2291.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: December 7, 2025.
5. de Ferranti SD, Steinberger J, Ameduri R, et al. Cardiovascular Risk Reduction in High-Risk Pediatric Patients: A Scientific Statement From the American Heart Association. *Circulation*. 2019; 139: e603-e634.
6. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
7. 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: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019;73:e285–350.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
9. Rosenson RS, Durrington P. Familial hypercholesterolemia in adults: Overview. Last updated: December 10, 2023. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 24, 2024.
10. Rosenson RS, Durrington P. Familial hypercholesterolemia in adults: Treatment. Last updated: December 7, 2023. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 24, 2024.
11. Singh S, Bittner V. Familial hypercholesterolemia--epidemiology, diagnosis, and screening. *Curr Atheroscler Rep*. 2015; 17(2):482.
12. World Health Organization. Familial hypercholesterolemia—report of a second WHO Consultation. Geneva, Switzerland: World Health Organization, 1999.

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.