Pharmacy Medical Necessity Guidelines:
PCSK9 Inhibitor Therapy

Effective: October 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Repatha (evolocumab) is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated:

- To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults at increased risk for these events
- As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in:
  - Adults with hypercholesterolemia
  - Adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH)
  - Adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH)
- Praluent (alirocumab) is another PCSK9 inhibitor indicated to reduce the risk of major adverse CV events (coronary heart disease death, myocardial infarction, stroke, or unstable angina requiring hospitalization) in adults at increased risk for these events. Praluent is also approved as an adjunct to diet and exercise to reduce LDL-C in adults with hypercholesterolemia or HoFH and adults and pediatric patients aged 8 years and older with HeFH. Praluent (alirocumab) is non-covered for Tufts Health RITogether.

COVERAGE GUIDELINES

Tufts Health Plan may authorize coverage of **Repatha (evolocumab)** for Members when **ALL** of the following criteria are met:

Initial

Risk Reduction of Major Adverse Cardiovascular Events

1. Documentation the Member has increased risk of major adverse cardiovascular events as evidenced by ONE of the following:
   a. History of clinical atherosclerotic cardiovascular disease or has experienced a cardiovascular event
   b. High-risk diabetes mellitus defined as diabetes that is long-standing (at least 10 years of diagnosis), complicated by microvascular disease, or daily insulin use

AND

2. One of the following:
   a. Documentation the Member has a current LDL-C level ≥70 mg/dL
   b. Documentation the Member has a current LDL-C level ≥55 mg/dL if member is at very high risk of ASCVD events if they have ASCVD and one or more of the following conditions:
      i. Myocardial infarction in the past 2 years
      ii. History of recurrent (at least two) myocardial infarctions
      iii. History of coronary artery bypass graft surgery
      iv. Symptomatic peripheral artery disease (i.e., intermittent claudication with ankle-brachial index < 0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease)
      v. Diabetes mellitus

AND

3. Documentation the Member has previously failed at least two lipid lowering therapies

AND

4. Documentation of at least one of the following:
    a. Member is receiving maximally tolerated statin therapy
    b. Member is statin intolerant
    c. Member has a contraindication to statin therapy

Primary or familial hyperlipidemia

1. The Member had an untreated (i.e., before any lipid lowering therapy was initiated) LDL-C level ≥190 mg/dL

OR

The Member is 10-17 years of age and had an untreated LDL-C level ≥ 160 mg/dL

AND

2. Documentation the Member has a current LDL-C level ≥100 mg/dL

AND

3. Documentation the Member has previously failed at least two generic lipid lowering therapies

AND

4. Documentation of at least one of the following:
    a. Member is receiving maximally tolerated statin therapy
    b. Member is statin intolerant
    c. Member has a contraindication to statin therapy

Reauthorization

1. Documentation of a positive response to therapy confirmed by consistent pharmacy claims and reduction in LDL-C since beginning therapy with the requested agent

LIMITATIONS

1. Initial authorization will be limited to 12 months. Subsequent authorization requests may be given in 12-month intervals for Members who are continuing PCSK9 inhibitor therapy.
2. Coverage of Repatha (evolocumab) will be limited to 28-day supplies as follows:
    - 140 mg dose every 14 days
    - 420 mg every 28 days
3. Adult and pediatric patients 10 years of age and older with HoFH may be approved for 420 mg every 2 weeks if a clinically meaningful response is not achieved after at least 12 weeks of therapy with 420 mg every 28 days.

CODES

Medical billing codes may not be used for these medications. These medications must be obtained via the member's pharmacy benefit.

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APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 14, 2023: Effective February 1, 2024, added reauthorization criteria to require consistent pharmacy claims and reduced LDL. Updated initial approval criteria to include contraindication to statin therapy in step therapy language. Updated fax number for Pharmacy UM.
2. November 12, 2024: Added additional indication for Praluent in overview section: As an adjunct to diet and other LDL-C lowering therapies in pediatric patients aged 8 years and older with HeFH to reduce LDL-C
3. August 12, 2025: Effective September 1, 2025, updated coverage criteria for Repatha and Praluent to include minimum LDL requirement to 55 mg/dL for members with ASCVD at very high risk.
4. September 15, 2026: Effective October 1, 2026, updated overview for Repatha and Praluent based on updated package insert for use in risk reduction of major adverse cardiovascular events in adults at increased risk for these events. Updated initial coverage criteria based on updated indication to require that member has increased risk of major adverse cardiovascular events as evidenced by ONE of the following: history of clinical atherosclerotic cardiovascular disease or has experienced a cardiovascular event or high risk diabetes mellitus.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services