

## Pharmacy Medical Necessity Guidelines: PCSK9 Inhibitor Therapy

Effective: November 10, 2020

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
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p><b>Commercial Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans</li> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans</li> <li>• CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</li> </ul> <p><b>Tufts Health Public Plans Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)</li> <li><input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans</li> <li><input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan</li> </ul>		<p><b>Fax Numbers:</b></p> <p>RXUM: 617.673.0988</p>	

**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:

- **Prevention of cardiovascular events**  
To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease
- **Primary hyperlipidemia (including heterozygous familial hypercholesterolemia)**  
As an adjunct to diet, alone or in combination with other lipid-lowering therapies, for the treatment of adults with primary hyperlipidemia to reduce low-density lipoprotein cholesterol
- **Homozygous familial hypercholesterolemia**  
As an adjunct to diet and other low density lipoprotein (LDL)-lowering therapies for the treatment of patients with homozygous familial hypercholesterolemia who require additional lowering of LDL cholesterol

Praluent (alirocumab) is another PCSK9 inhibitor indicated reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with cardiovascular disease and as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) who require additional lowering of LDL cholesterol. Praluent (alirocumab) is currently non-covered.

### COVERAGE GUIDELINES

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

#### **Clinical atherosclerotic cardiovascular disease**

1. Documentation the Member has a history of clinical atherosclerotic cardiovascular disease or has experienced a cardiovascular event
- AND**
2. Documentation the Member has a current LDL-C level  $\geq 70$  mg/dL
- AND**
3. Documentation of at least one of the following:
    - a. Member is receiving maximally tolerated statin therapy
    - b. Member is statin intolerant

### Primary or familial hyperlipidemia

1. Documentation the Member had an untreated (i.e., before any lipid lowering therapy was initiated) LDL-C level  $\geq 190$  mg/dL
- AND**
2. Documentation the Member has a current LDL-C level  $\geq 100$  mg/dL
- AND**
3. Documentation of at least one of the following:
    - a. Member is receiving maximally tolerated statin therapy
    - b. Member is statin intolerant

### 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. The plan does not cover the following medications on all Commercial and Medicaid formularies: Praluent. Refer to the Pharmacy Medical Necessity Guidelines for Noncovered Drugs with Suggested Alternatives (Commercial products) or Noncovered Medications (Tufts Health Together)
3. Coverage of Repatha (evolocumab) will be limited to 28-day supplies as follows:
  - 140 mg dose every 14 days
  - 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**

January 12, 2016: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- February 14, 2016: No changes.
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- October 17, 2017: Based on the results of the FOURIER trial and current treatment guidelines, the criteria was updated to remove the requirement of ezetimibe monotherapy for patients with a statin intolerance, allow coverage of PCSK9 inhibitor therapy for patients with ASCVD on moderate intensity statins who are not meeting LDL goal and who are unable to receive high intensity statins, and to remove requirement for triglyceride levels to be less than 400 mg/dL.
- November 14, 2017: Removed the requirement of provider attestation the patient is not experiencing any significant adverse events related to therapy from reauthorization criteria.
- October 16, 2018: Effective January 1, 2019, updated coverage criteria to require documentation the Member is receiving maximally tolerated statin therapy or is statin intolerant, a current LDL-C level  $\geq 70$  mg/dL (for clinical atherosclerotic cardiovascular disease) or  $\geq 100$  mg/dL (for primary or familial hyperlipidemia), and documentation the Member has a history of clinical atherosclerotic cardiovascular disease or has experienced a cardiovascular event or an untreated LDL-C level  $\geq 190$  mg/dL. Updated the duration of approval to 12 month interval and updated continuation of therapy requirements. Added the following Limitation: The plan does not cover the following medications on all Commercial and Medicaid formularies: Praluent. Refer to the Pharmacy Medical Necessity Guidelines for Noncovered Drugs with Suggested Alternatives or Drugs Without Drug- or Drug Class-Specific Criteria. Removed the following limitations: a) The plan will not cover other PCSK9 inhibitors (including Praluent [alirocumab]) unless the Member has either failed an adequate trial of or has a contraindication to Repatha (evolocumab). Coverage Guidelines for PCSK9 inhibitors as outlined for Repatha (evolocumab) above apply; b) Members new to the Plan and currently taking a PCSK9 inhibitor must meet initial authorization criteria if on PCSK9 inhibitor therapy for less than 6 months and must meet reauthorization criteria if on PCSK9 inhibitor therapy for at least 6 months; c) For Praluent (alirocumab), the Plan requires documentation of a therapeutic failure on Praluent 75 mg every 2 weeks before the 150 mg dose may be approved. Therapeutic failure to Praluent 75 mg every 2 weeks is defined as an inability to reach target LDL goals despite an adherent  $\geq 4$  to 8 week trial (adherence calculation must be supported by claims data or, if not available, by physician attestation); and d) Coverage of Praluent (alirocumab) will be limited to 28-day supplies as follows: Praluent 75 mg/mL or 150 mg/mL – two single-dose prefilled pens or syringes every 28 days.
- June 11, 2019: Added supplemental indication to Praluent. No changes to criteria itself.
- November 10, 2020: No changes

#### **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.