Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Lipid Lowering Agents**

Effective: March 10, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

PCSK9 Inhibitors

- **Repatha (evolocumab):**
  - 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.
  - As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH).
  - As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH).
- **Praluent (alirocumab):**
  - To reduce the risk of major adverse cardiovascular (CV) events (coronary heart disease death, myocardial infarction, stroke, or unstable angina requiring hospitalization) 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.
  - As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH).
  - As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with homozygous familial hypercholesterolemia (HoFH).

Bempedoic Acid Products

- **Nexletol (bempedoic acid)** and **Nexlizet (bempedoic acid/ezetimibe):**
  - To reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin).
  - As an adjunct to diet and exercise, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

Clinical Guideline Coverage Criteria

1. Repatha (evolocumab):

The plan may authorize coverage of Repatha (evolocumab) for patients when the following criteria are met:

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:

1. Patient is at increased risk for major adverse cardiovascular (CV) events

AND

2. Current LDL-C level that is greater than or equal to 70 mg/dL while on maximally tolerated statin therapy (if not contraindicated or intolerant)

AND

3. One of the following:

a. Patient has a contraindication to statin therapy (e.g., rhabdomyolysis or significant allergic reaction)
b. Patient is statin intolerant to at least two statin medications
c. Patient is currently on a maximally tolerated dose of a statin
d. Patient has completed a 12-week trial of statin therapy at the maximum tolerated dose

OR

For management of primary or familial hyperlipidemia:

1. Documented diagnosis of primary or familial hyperlipidemia

AND

2. Current LDL-C level that is greater than or equal to 70 mg/dL while on maximally tolerated statin therapy (if not contraindicated or intolerant)

AND

3. One of the following:
    a. Patient has a contraindication to statin therapy (e.g., rhabdomyolysis or significant allergic reaction)
    b. Patient is statin intolerant to at least two statin medications
    c. Patient is currently on a maximally tolerated dose of a statin
    d. Patient has completed a 12-week trial of statin therapy at the maximum tolerated dose

2. Praluent (alirocumab):

The plan may authorize coverage of Praluent (alirocumab) for patients when the following criteria are met:

For management of clinical atherosclerotic cardiovascular disease (ASCVD):

1. Patient has a history of clinical atherosclerotic cardiovascular disease (ASCVD) or has experienced a cardiovascular event

AND

2. One of the following:
    a. Current LDL-C level that is greater than or equal to 70 mg/dL while on maximally tolerated statin therapy (if not contraindicated or intolerant)
    b. Current LDL-C level that is greater than or equal to 55 mg/dL while on maximally tolerated statin therapy (if not contraindicated or intolerant), 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. One of the following:
    a. Patient has a contraindication to statin therapy (e.g., rhabdomyolysis or significant allergic reaction)
    b. Patient is statin intolerant to at least two statin medications
    c. Patient is currently on a maximally tolerated dose of a statin

AND

4. For Praluent requests only for patients 10 years of age or older, patient has tried and failed or has an intolerance to evolocumab (Repatha)

OR

For management of primary or familial hyperlipidemia:

1. Documented diagnosis of primary or familial hyperlipidemia

AND

2. Current LDL-C level that is greater than or equal to 100 mg/dL while on maximally tolerated statin therapy (if not contraindicated or intolerant)

AND

3. One of the following:
    a. Patient has a contraindication to statin therapy (e.g., rhabdomyolysis or significant allergic reaction)
    b. Patient is statin intolerant to at least two statin medications
    c. Patient is currently on a maximally tolerated dose of a statin

AND

4. For Praluent requests only for patients 10 years of age or older, patient has tried and failed or has an intolerance to evolocumab (Repatha)

Renewal Authorization for Praluent (alirocumab):

1. Patient is adherent to the requested PCKS9 inhibitor as defined by having consistently filled it over the past 4 months

AND

2. Positive response to therapy confirmed by a reduction in LDL-C from baseline

3. Nexletol (bempedoic acid), Nexlizet (bempedoic acid/ezetimibe):

The plan may authorize coverage of Nexletol (bempedoic acid) or Nexlizet (bempedoic acid/ezetimibe) for patients when **ALL** of the following criteria are met:

For management of clinical atherosclerotic cardiovascular disease (ASCVD) or high risk for CVD event:

1. One of the following:
    a. Patient has a history of clinical atherosclerotic cardiovascular disease (ASCVD) or has experienced a cardiovascular event
    b. Patient is at high risk for CVD event, as defined by one of the following:
        i. Reynolds Risk score > 30%
        ii. Coronary artery calcium score > 400 Agatston units (AU)
        iii. Type 1 or Type 2 diabetes

AND

2. One of the following:
    a. For patients with ASCVD, current LDL-C level that is greater than or equal to 55 mg/dL while on maximally tolerated statin therapy in combination with ezetimibe (unless member has a contraindication or history of intolerance to each such therapy)
    b. For patients at high risk for CVD event, current LDL-C that is greater than or equal to 70 mg/dL while on maximally tolerated statin therapy in combination with ezetimibe (unless member has a contraindication or history of intolerance to each such therapy)

AND

3. One of the following:
    a. Patient has a contraindication to statin therapy (e.g., rhabdomyolysis or significant allergic reaction)
    b. Patient is statin intolerant to at least two statin medications
    c. Patient is currently on a maximally tolerated dose of a statin

AND

4. One of the following:
    a. Patient is currently on ezetimibe
    b. Patient has history of contraindication or intolerance to ezetimibe

OR

For management of primary or familial hyperlipidemia:

1. Documented diagnosis of primary or familial hyperlipidemia

AND

2. Current LDL-C level that is greater than or equal to 70 mg/dL while on maximally tolerated statin therapy in combination with ezetimibe (unless member has a contraindication or history of intolerance to each such therapy)

AND

3. One of the following:
    a. Patient has a contraindication to statin therapy (e.g., rhabdomyolysis or significant allergic reaction)
    b. Patient is statin intolerant to at least two statin medications
    c. Patient is currently on a maximally tolerated dose of a statin

AND

4. One of the following:
    a. Patient is currently on ezetimibe
    b. Patient has history of contraindication or intolerance to ezetimibe

Renewal Authorization of Nexletol (bempedoic acid) or Nexlizet (bempedoic acid/ezetimibe):

1. Positive response to therapy confirmed by a reduction in LDL-C from baseline

Limitations

1. Initial authorization of Praluent, Nexletol, and Nexlizet will be limited to 12 months. Subsequent authorization requests may be given in 12-month intervals for patients who are continuing therapy.
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

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

References

1. Repatha (evolocumab) [prescribing information]. Thousand Oaks, CA. Amgen Inc. January 2026.
2. Praluent (alirocumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc; October 2025.
3. Nexletol (bempedoic acid) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics Inc; January 2026.
4. Nexlizet (bempedoic acid and ezetimibe) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics Inc; January 2026.
5. Rosenson RS, Durrington P. Familial Hypercholesterolemia in Adults: Treatment. In: UpToDate, Parikh N (ed). Waltham, MA. Accessed September 18, 2023.

6. Gidding SS, Champagne MA, DeFerranti SD, et al. The Agenda for Familial Hypercholesterolemia: A Scientific Statement from the American Heart Association. Circulation. 2015; 132: 1-27.
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-e350.
8. Cheeley MK, Saseen JJ, Agarwala A, Ravilla S, Ciffone N, Jacobson TA, Dixon DL, Maki KC. 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 Jul-Aug;16(4):361-375. doi: 10.1016/j.jacl.2022.05.068. Epub 2022 Jun 9. PMID: 35718660.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 13, 2023: Administrative update to remove the statement within the overview that cardiovascular morbidity and mortality has not been determined with bempedoic acid, following results from the CLEAR Outcomes trial.
- November 14, 2023: Effective December 1, 2023, renewal authorization for Repatha, Praluent, Nexletol, and Nexlizet updated to remove requirement that LDL-C is taken within the last 12 months, and clarified that positive response to therapy is confirmed by a reduction in LDL-C from baseline.
- December 10, 2024: Effective March 1, 2025:
  - Defined statin intolerance as intolerance to at least two statin medications.
  - Administrative update in overview to Repatha's indication, and added Praluent's supplemental indication as an adjunct to diet and other LDL-lowering therapies in pediatric patients aged 8 years and older with HeFH.
  - For Praluent requests, clarified that Repatha is the preferred PCSK9 inhibitor in patients 10 years of age or older.
  - For primary or familial hyperlipidemia, removed criterion for untreated LDL-C level greater than or equal to 190 mg/dL (prior to treatment with antihyperlipidemic agents).
  - Updated overview and criteria for Nexletol and Nexlizet based on expanded indications.
  - Added criterion for Nexletol and Nexlizet for member to be on maximally tolerated statin therapy in combination with ezetimibe (unless member has a contraindication or history of intolerance to each such therapy).
  - Updated LDL thresholds for Nexletol and Nexlizet.
- 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.
- March 10, 2026: Effective 3/10/26, updated indications for Repatha, Praluent, Nexletol, and Nexlizet within the overview section. Updated criteria for Repatha to indicate members no longer require a diagnosis of established cardiovascular disease based on updated package labeling. Removed renewal criteria for Repatha. Administrative update to remove CareLink from Medical Necessity Guideline template.

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.