Pharmacy Medical Necessity Guidelines:
Nexletol (bempedoic acid) and Nexlizet (bempedoic acid/ezetimibe)

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

Nexletol (bempedoic acid) and **Nexlizet (bempedoic acid/ezetimibe)**: Bempedoic acid is indicated as an adjunct to diet, in combination with other LDL-C lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia. Nexlizet™ (bempedoic acid/ezetimibe) also carries this indication and is formulated with a lipid absorption inhibitor.

Bempedoic acid is indicated 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).

COVERAGE GUIDELINES

The plan may authorize coverage of **Nexletol** and **Nexlizet** for Members when the following criteria are met and limitations do not apply:

1. The Member is 18 years of age or older

AND

2. The Member has one of the following diagnoses:
    a. Primary or familial hypercholesterolemia
    b. Established atherosclerotic cardiovascular disease (ASCVD), including one or more of the following:
        i. Acute coronary syndrome (ACS)
        ii. History of myocardial infarction (MI)
        iii. Stable or unstable angina
        iv. Coronary or other arterial revascularization
        v. Stroke
        vi. Transient ischemic attack (TIA)
        vii. Peripheral arterial disease (PAD)
        viii. Coronary artery disease (CAD)
    c. High risk for a CVD event but without established CVD including 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

3. One of the following:
    a. For patients with ASCVD, current LDL-C level that is greater than or equal to 55 mg/dL
    b. For patients at high risk for CVD event, but without established CVD, current LDL-C that is greater than or equal to 70 mg/dL

AND

4. The Member is on a maximally tolerated statin or a clinical rationale why the member cannot take a statin is provided

AND

5. The Member has had an inadequate response, adverse reaction, or contraindication to ezetimibe

LIMITATIONS

None

CODES

None

REFERENCES

1. Grundy SM, Stone NJ, Bailey AL, et al. 2018 ADA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASP Guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines. *Circulation*. 2019;139(25):e1082-1143.
2. Lloyd-Jones D, Morris PB, Ballantyne CM, et al. 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;80(14):1366-1418.
3. Nexletol (bempedoic acid) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; January 2026.
4. Nexlizet (bempedoic acid/ezetimibe) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; January 2026.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 8, 2023: No changes.
- August 13, 2024: Updated overview and criteria for Nexletol and Nexlizet based on expanded indication as an adjunct to diet, alone or in combination with other LDL-C lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), and for bempedoic acid to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD. Administrative fax number update.
- August 12, 2025: Effective September 1, 2025: Defined High risk for a CVD event but without established CVD including to include one of the following (Reynolds Risk score > 30% or Coronary artery calcium score > 400 Agatston units (AU) or Type 1 or Type 2 diabetes). Updated LDL thresholds for Nexletol
- September 15, 2026: Effective October 1, 2026, updated overview based on expanded indication to reduce the risk of major adverse cardiovascular events in adults at increased risk for these events who are unable to take recommended statin therapy. Updated coverage criteria to require trial with ezetimibe instead of two generic statins.

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