TUFTS Health Plan

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

Effective: October 19, 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

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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

OVERVIEW

Nexletol® (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. Nexlizet™ (bempedoic acid/ezetimibe) also carries this indication and is formulated with a lipid absorption inhibitor.

The recommended dosage of Nexletol, in combination with maximally tolerated statin therapy, is 180 mg once daily.

The effect of Nexletol and Nexlizet on cardiovascular morbidity and mortality has not been determined.

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. Heterozygous 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)

AND

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

AND

4. The Member has had an inadequate response or adverse reaction to at least two generic statins or has a contraindication to all statins

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. Nexletol (bempedoic acid) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; February 2020.
3. Nexlizet (bempedoic acid/ezetimibe) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; February 2020

APPROVAL HISTORY

October 13, 2020: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1.

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.