Pharmacy Medical Necessity Guidelines:
Xenleta® (lefamulin acetate) tablets

Effective: May 12, 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

Xenleta (lefamulin acetate) is a pleuromutilin antibacterial indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae*.

Xenleta (lefamulin acetate) is available as tablets for oral administration and solution for intravenous use. The following prior authorization guidelines apply to the oral formulation.

COVERAGE GUIDELINES

The plan may authorize coverage of **Xenleta (lefamulin acetate**) oral tablets when the following criteria are met:

The member meets **ONE** of the following:

1. The member has been stable on intravenous Xenleta (lefamulin) or tablets in an inpatient setting

OR

2. The member meets both of the following:
    a. The member has a diagnosis of community-acquired bacterial pneumonia (CABP) caused by one of the following susceptible microorganisms:
        - Streptococcus pneumoniae
        - Staphylococcus aureus (methicillin-susceptible isolates)
        - Haemophilus influenzae
        - Legionella pneumophila
        - Mycoplasma pneumoniae
        - Chlamydophila pneumoniae

    AND

    b. Documentation of contraindication or resistance to the isolate pathogen to at least two alternative generic antibiotics (such as moxifloxacin, amoxicillin, etc.) or clinical rationale why treatment with two alternative generic antibiotics is not appropriate for the member

LIMITATIONS

1. Duration of approval is limited to 30 days.

CODES

None

REFERENCES

1. File TM. Treatment of community-acquired pneumonia in adults in the outpatient setting. Available at: www.uptodate.com. Accessed 30 May 2023.
2. Xenleta (lefamulin acetate) injection and coated tablets [package insert]. Fort Washington, PA: Nabriva Therapeutics US, Inc.; October 2024.

APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:

1. June 13, 2023: Effective August 1, 2023, updated previous trial language to include clinical rationale why treatment with two alternative generic antibiotics is not appropriate for the member.
2. March 12, 2024: Effective April 1, 2024, updated RxUM fax number.

3. March 11, 2025: No changes
4. May 12, 2026: 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.

Provider Services