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

*Effective: February 15, 2021*

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| 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
MM: 888.415.9055
PRECERT: 617.972.9409

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

## OVERVIEW

Xenleta (lefamulin acetate) is 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:

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

**OR**

2. 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**

Documentation of contraindication or resistance of the isolate pathogen to at least two alternative generic antibiotics (such as moxifloxacin, amoxicillin, etc.)

## LIMITATIONS

1. The plan does not provide coverage of Xenleta for any condition not listed above in this Pharmacy Medical Necessity Guidelines.
2. Duration of approval is limited to 30 days.

## CODES

None

## REFERENCES

1. Xenleta (lefamulin acetate) injection and coated tablets [package insert]. King of Prussia, PA: Nabriva Therapeutics US, Inc.; October 2019.

## APPROVAL HISTORY

February 11, 2020: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. February 9, 2021: Updated criteria to indicate that Xenleta will be approved if injection or tablets were initiated in the inpatient setting.

## 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.