

Xenleta (lefamulin) Oral Tablets
Effective 04/01/2025

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Xenleta (lefamulin) 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*
- *Chlamydophila pneumoniae*

Xenleta is available as an intravenous infusion or oral tablets.

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted all of the following criteria are met:

1. Member meets ONE of the following:
 - a. Member initiated Xenleta IV or tablets in the inpatient setting and is transitioning to outpatient treatment
 - b. Member meets ALL of the following:
 - i. Diagnosis of 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*
 - ii. Member has had previous use, contraindication, or resistance to at least one alternative generic antibiotic (ex. moxifloxacin etc.)

Limitations

Mass General Brigham Health Plan includes Mass General Brigham Health Plan, Inc. and Mass General Brigham Health Insurance Company.

1. Requests will be approved for 1 month.
2. Requests for reauthorization must meet initial criteria.
3. The following quantity limits apply:

Drug Name	Quantity Limit
Xenleta 600mg	10 tablets per 5 days

References

1. Xenleta (lefamulin) [prescribing information]. King of Prussia, PA: Nabriva Therapeutics US Inc., June 2021.

Review History

05/20/2020 – Created and Reviewed P&T Mtg. Effective 7/1/20

11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.

01/08/2025 – Reviewed and updated at December P&T. Updated verbiage for new members. Updated criteria to allow for approval if member was started in the inpatient setting and is transitioning to outpatient treatment. Removed age requirement. Effective 04/01/2025.

