

Effective Date: 01/01/2021
Reviewed: 6/2020, 3/2021, 2/2022, 3/2023, 12/2023, 01/2024, 03/2025
Pharmacy Scope: Medicaid
Medical Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Xenleta (lefamulin) tablets and intravenous injection

POLICY

I. SUMMARY OF EVIDENCE

Xenleta (lefamulin) is a pleuromutilin antibacterial indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by susceptible microorganisms. In the LEAP 1 and LEAP 2 trials Xenleta was compared to moxifloxacin, a fluoroquinolone antibiotic, for the treatment of CABP. The trials showed that Xenleta was non-inferior to moxifloxacin in achieving early clinical response and clinical success rates. Early clinical response was defined as improvement in clinical signs and symptoms of pneumonia within 72 hours of treatment initiation. Common adverse reactions being gastrointestinal-related, including nausea, vomiting, and diarrhea.

II. CRITERIA FOR APPROVAL

An authorization may be granted when all the following criteria are met:

- A. The member has a diagnosis of Community Acquired Bacterial Pneumonia (CABP) confirmed by the following:
 - a. Having at least 3 of the 4 symptoms consistent with CABP (cough, sputum production, chest pain and/or dyspnea).
 - b. Diagnosis of CABP has been confirmed through chest radiograph.
- B. Member is at least 18 years of age.
- C. Documentation of culture and sensitivity results.
- D. Member has tried and failed OR had an intolerance to one alternative antibiotic to which the organism is susceptible (i.e., moxifloxacin, levofloxacin, beta-lactam + macrolide, beta-lactam + doxycycline, etc.), **OR**
- E. For Xenleta tablet requests, the medication was initiated in the hospital and is a continuation of therapy upon discharge.
- F. MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

III. PHARMACY BENEFIT QUANTITY LIMIT

- 2 tablets per day, 10 tablets per treatment course

IV. MEDICAL DOSING

Indication	Dose	Maximum dose (1 billable unit = 1 mg)
Community Acquired Bacterial Pneumonia	150mg IV every 12 hours x 5-10 days (minimum of 3 days of IV therapy before transitioning to oral treatment)	3000 billable units every 10 days

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	600mg PO every 12 hours x 5 days	
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The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0691	Injectable, lefamulin, 1mg

V. COVERAGE DURATION

- Xenleta tablets: 1 month
- Xenleta IV: 10 days

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:

Xenleta was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Xenleta according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

References:

1. Xenleta [package insert]. Ireland DAC: Nabriva Therapeutics US, Inc.; March 2025.
2. File, T., Goldberg, L., Das, A., et al, 2019. Efficacy and Safety of Intravenous-to-oral Lefamulin, a Pleuromutilin Antibiotic, for the Treatment of Community-acquired Bacterial Pneumonia: The Phase III Lefamulin Evaluation Against Pneumonia (LEAP 1) Trial. *Clinical Infectious Diseases*, 69(11), pp.1856-1867.
3. Alexander, E., Goldberg, L., Das, A., et al, 2018. LB6. Oral Lefamulin Is Safe and Effective in the Treatment of Adults With Community-Acquired Bacterial Pneumonia (CABP): Results of Lefamulin Evaluation Against Pneumonia (LEAP 2) Study. *Open Forum Infectious Diseases*, 5(suppl_1), pp.S761-S761.