

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

Xenleta (lefamulin) tablets and intravenous injection

POLICY

I. 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.

II. PHARMACY BENEFIT QUANTITY LIMIT

- 2 tablets per day, 10 tablets per treatment course

III. 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) 600mg PO every 12 hours x 5 days	3000 billable units every 10 days

The following HCPCS/CPT codes are:

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

IV. COVERAGE DURATION

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- 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).

References:

1. Xenleta [package insert]. Ireland DAC: Nabriva Therapeutics US, Inc.; December 2022.
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.