

<b>Policy Title:</b>	Xenleta (lefamulin) (Intravenous)		
		<b>Department:</b>	PHA
<b>Effective Date:</b>	10/01/2020		
<b>Review Date:</b>	6/29/2020		
<b>Revision Date:</b>	6/29/2020		

**Purpose:** To support safe, effective and appropriate use of Xenleta (lefamulin).

**Scope:** Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

**Policy Statement:**

Xenleta is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:**

Coverage of Xenleta will be reviewed prospectively via the prior authorization process based on criteria below.

***Initial Criteria:***

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

- Authorization may be granted to members 18 years of age or older when all of the following criteria are met:
  - Member has at least 3 of the 4 symptoms consistent with CABP:
    - Cough
    - Sputum production
    - Chest pain
    - Dyspnea
  - Diagnosis of CABP has been confirmed via chest radiograph; **AND**
- Documentation of culture and sensitivity results, **AND**
- 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.)

**Coverage durations:**

- Initial coverage: 10 days
- Continuation of therapy coverage: coverage will not be renewed

\*\*\* Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.\*\*\*

#### Dosage/Administration:

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

**Investigational use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

#### Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

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

#### References:

1. Xenleta [package insert]. Ireland DAC: Nabriva Therapeutics US, Inc.; August 2019.
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.