Policy Title: Xenleta (lefamulín) (Intravenous)

Department: PHA

Effective Date: 10/01/2020

Review Date: 6/29/2020, 3/25/2021

Revision Date: 6/29/2020

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

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
    - Dyspsnia
  - 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:**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
<th>Maximum dose (1 billable unit = 1 mg)</th>
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</thead>
<tbody>
<tr>
<td>Community Acquired Bacterial Pneumonia</td>
<td>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</td>
<td>3000 billable units every 10 days</td>
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</tbody>
</table>

**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:

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J0691</td>
<td>Injectable, lefamulin, 1mg</td>
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**References:**