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Effective Date: 11/07/2019

Xenleta® (lefamulin) intravenous injection

FDA approval: 08/19/2019

HCPCS: C9054

Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA-approved indications
 - b. FDA approved age recommendations
 - c. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's prior authorization and step therapy documents
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: FDA approved dosing
 - b. Authorization Period: FDA approved treatment duration

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

- A. **FDA approved indication/Diagnosis**
 - a. Treatment of adults with community acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae*.

**Please refer to most recent prescribing information.*

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

B. Background Information

- a. According to the Centers for Disease Control and Prevention (CDC), in the U.S. there are approximately 5 million cases of pneumonia each year, causing pneumonia to be the fifth leading cause of hospitalization and one of the leading causes of infection-related death
- b. The CDC estimates that approximately 50,000 people die from pneumonia each year in the United States
- c. Many antibacterial drug classes are recommended for treatment of CABP, some of which are also available in both IV and oral formulations.
- d. The Infectious Disease Society of America (ISDA) and the American Thoracic Society (ATS) have developed the Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults (2007) which outlines the recommendations for treatment of CABP
- e. Preferred regimens for the outpatient management of CABP in otherwise healthy individuals include azithromycin, clarithromycin, or erythromycin with doxycycline as an alternative. Doxycycline, with maintenance doses of twice daily, is available in both IV and oral formulations
- f. In the presence of comorbidities, in regions with macrolide-resistant *Streptococcus pneumoniae*, risk for drug-resistant *S. pneumoniae*, or for the inpatient non-intensive care (ICU) unit treatment of CABP, the guidelines recommend the use of a respiratory fluoroquinolone (moxifloxacin, gemifloxacin, or levofloxacin). Moxifloxacin and levofloxacin are available in both IV and oral formulations

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. Dosing and administration

- a. Injection: 150 mg/15mL vial diluted in 250 mg of 0.9% normal saline infused over 60 minutes every 12 hours for 5-7 days with the option to switch to Xenleta tablets to complete the treatment course

**Please refer to most recent prescribing information.*

F. How supplied

- a. Injection: 150 mg/15mL vial

References:

1. Xenleta (lefamulin) [prescribing information] King of Prussia, PA: Nabriva Therapeutics. 2019.
2. Manufacturer press release. Available at: <http://investors.nabriva.com/news-releases/news-release-details/nabriva-therapeutics-receives-us-fda-approval-xenleta>. Accessed August 20th, 2019.
3. FDA news release: FDA approves new antibiotic to treat community acquired bacterial pneumonia. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-new-antibiotic-treat-community-acquired-bacterial-pneumonia>. Accessed August 20th, 2019.
4. Centers for Disease Control and Prevention. Pneumonia. <https://www.cdc.gov/pneumonia/index.html>. Accessed August 20th, 2019.
5. Mandell LA, Wunderink RG, Anzueto A, et al. Infectious Diseases Society of America/American Thoracic Society consensus guidelines on the management of community-acquired pneumonia in adults. Clin Infect Dis 2007; 44 Suppl 2:S27.

6. File TM, Goldberg L, Das A, et al. 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. Clin Infect Diseases. 2019 Feb 4. Epub ahead of print. <https://doi.org/10.1093/cid/ciz090>.
7. Alexander E, Goldberg L, Das A, et al. 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(1): S761. November 2018. <https://doi.org/10.1093/ofid/ofy229.2180>.

Policy History		
#	Date	Change Description
1.0	Effective Date: PBDC: 10/07/19 P&T: 11/07/19	Full Drug Review

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.