CareSource

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Xenleta (lefamulin)
BILLING CODE	J0691
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Xenleta is a pleuromutilin antibacterial initially approved by the FDA in 2019. It was indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus*, *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae.* To reduce the development of drug resistant bacteria and maintain the effectiveness of Xenleta and other antibacterial drugs, Xenleta should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Community-acquired bacterial pneumonia (CABP) accounts for over 4.5 million outpatient and emergency room visits annually. CABP is the second most common cause of hospitalization and the most common infectious cause of death.

Xenleta (lefamulin) will be considered for coverage when the following criteria are met:

Community-Acquired Bacterial Pneumonia (CABP)

For **initial** authorization:

1. Member must be at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an infectious disease specialist; AND
3. Member has diagnosis of CABP, or is strongly suspected to be positive for CABP, confirmed by a chest radiograph; AND
4. Culture and sensitivity results are submitted if available or chart notes indicating intent to empirically treat are submitted; AND
5. Member has trialed and had an inadequate response to at least one preferred alternative regimen (with organism susceptibility): levofloxacin, moxifloxacin, beta-lactam + doxycycline, beta-lactam + macrolide; AND
6. Member is not concomitantly using any other CYP3A substrates that prolong the QT interval (contraindication); AND
7. For tablets requests ONLY: Member does not have moderate (Child-Pugh Class B) or severe hepatic impairment.
8. **Dosage allowed/Quantity limit:** 150 mg IV every 12 hours (infused over 60 minutes) for 5 - 7 days or 600 mg orally every 12 hours for 5 days; dosage of IV infusion should be reduced to 150 mg IV every

24 hours (infused over 60 minutes) in members with severe hepatic impairment. Quantity limit: 10 tablets per 5 days; 14 vials per 7 days.

If all the above requirements are met, the medication will be approved for 7 days.

For **reauthorization**:
1. Medication will not be reauthorized.

CareSource considers Xenleta (lefamulin) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/22/2019	New policy for Xenleta created.
04/18/2022	Transferred to new template. Updated references. Added Quantity Limits; Added Age Limits. Added a J code.

References:

1. Xenleta [package insert]. Fort Washington, PA: Nabriva Therapeutics; 2021.
2. Metley JP et al. Diagnosis and Treatment of Adults with Community-acquired Pneumonia. An Official Clinical Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America. Am J Respir Crit Care Med. 2019 Oct 1;200(7): e45-e67.
3. 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 Infect Dis. 2018;5(Suppl 1):S761. Published 2018 Nov 26. doi:10.1093/ofid/ofy229.2180. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6253245/. Accessed September 12, 2019.
4. File T, Goldberg L, Das A, et al. Efficacy and Safety of IV-to-Oral Lefamulin, a Pleuromutilin Antibiotic, for Treatment of Community-Acquired Bacterial Pneumonia: The Phase 3 LEAP 1 Trial. Clin Infect Dis. 2019 Feb 4. doi: 10.1093/cid/ciz090.
5. New Drug Approval: Xenleta (lefamulin). IPD Analytics. September 2019.

Effective date: 01/01/2023
Revised date: 04/18/2022