

Commercial/Healthcare Exchange PA Criteria

Effective: November 13, 2019

Prior Authorization: Xenleta

Products Affected: Xenleta (lefamulin) oral tablets

Medication Description: Xenleta is a first-in-class semi-synthetic pleuromutilin antibiotic that inhibits bacterial protein synthesis.

Covered Uses: Treatment of adults with community-acquired bacterial pneumonia (CABP) caused by susceptible organisms (*Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae* and *Chlamydia pneumoniae*).

Exclusion Criteria:

1. Patients with known hypersensitivity to lefamulin, pleuromutilin class drugs
2. Concomitant use of Xenleta with CYP3A substrates that prolong the QT interval

Required Medical Information:

1. Diagnosis
2. Culture and susceptibility results
3. History of previous therapy tried/failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an infectious disease specialist.

Coverage Duration: 5 days

Other Criteria:

- A. Patient has a diagnosis of community acquired bacterial pneumonia (CABP); AND
- B. Culture and Sensitivity (C&S) testing shows isolated pathogen that is susceptible to lefamulin [documentation required]: *S. pneumoniae*, *S. aureus* (methicillin-susceptible isolates), *H. influenzae*, *L. pneumophila*, *M. pneumoniae* and *C. pneumoniae*; AND
- C. The C&S report shows resistance of the isolated pathogen to ALL formulary antibiotics FDA approved for member's diagnosis

References:

1. Product Information: XENLETA(TM) oral tablets, intravenous injection, lefamulin oral tablets, intravenous injection. Nabriva Therapeutics US Inc (per FDA), King of Prussia, PA, 2019.

Policy Revision history:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	11/8/2019

