# 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 Chlamydophila 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 |