PHARMACY POLICY STATEMENT **Georgia Medicaid**	
DRUG NAME	Xenleta (lefamulin)
BILLING CODE	For Pharmacy: Must use valid NDC code For Medical: J3490
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products/regimens include: levofloxacin, moxifloxacin, beta-lactam + doxycycline, beta-lactam + macrolide QUANTITY LIMIT— 150mg IV every 12 hours for 5 – 7 days or 600mg orally every 12 hours for 5 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Xenleta (lefamulin) is a **non-preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP)

For **initial** authorization:

1. Medication must be prescribed by or in consultation with an infectious disease specialist; AND
2. Member has diagnosis of CABP, or is strongly suspected to be positive for CABP, confirmed by consistent chest radiograph; AND
3. Culture and sensitivity results are submitted if available or chart notes indicating intent to empirically treat are submitted; AND
4. 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
5. Member is not concomitantly using any other CYP3A substrates that prolong the QT interval (contraindication); AND
6. For tablets requests ONLY: Member does not have moderate (Child-Pugh Class B) or severe hepatic impairment.
7. **Dosage allowed:** 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.

If member meets all the requirements listed above, the medication will be approved for up to 7 days.

For **reauthorization**:

1. Medication will not be reauthorized.

CareSource considers Xenleta (lefamulin) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
10/22/2019	New policy for Xenleta created.

References:

1. New Drug Approval: Xenleta (lefamulin). IPD Analytics. September 2019.
2. Xenleta [package insert]. Ireland DAC: Nabriva Therapeutics; 2019.

Effective date: 04/01/2020
Revised date: 10/22/2019