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Xenleta (lefamulin) Oral Tablets Effective 07/01/2020 ☐ MassHealth UPPL Plan □ Prior Authorization □ Commercial/Exchange **Program Type** ☐ Quantity Limit □ Pharmacy Benefit **Benefit** ☐ Step Therapy ☐ Medical Benefit Specialty This medication has been designated specialty and must be filled at a contracted Limitations specialty pharmacy. **Medical and Specialty Medications** Phone: 877-519-1908 All Plans Fax: 855-540-3693 Contact Information **Non-Specialty Medications All Plans** Phone: 800-711-4555 Fax: 844-403-1029

Overview

Xenleta (lefamulin) is a first-in-class, semi-synthetic pleuromutilin antibiotic for the treatment of community-acquired bacterial pneumonia (CABP). Xenleta is available as an intravenous infusion or oral tablets

Coverage Guidelines

Exceptions

Authorization may be granted for members who are currently receiving Xenleta IV as an in-patient treatment and will be transitioning to Xenleta oral tablets, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when the member meets all following criteria and documentation has been submitted:

- 1. The member using Xenleta to treat community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila
- 2. The member is 18 years of age or older.
- 3. The member has had previous use, contraindication, or resistance to at least one alternative generic antibiotic (ex. moxifloxacin etc.)

Limitations

The following quantity limits apply:

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Xenleta 600mg	10 tablets per 5 days

References

- 1. Xenleta (lefamulin) [prescribing information]. King of Prussia, PA: Nabriva Therapeutics US Inc., August 2019.
- 2. Avelox (moxifloxacin) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; May

Review History

05/20/2020 – Created and Reviewed P&T Mtg. Effective 7/1/20 11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.

