UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Xenleta

Program	Prior Authorization
Medication	Xenleta (lefamulin) oral tablets
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	1/2020
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

1. Background:

Xenleta is indicated for the treatment of adult patients with 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 pneumoniae*.

2. Coverage Criteria:

A. <u>Community-acquired bacterial pneumonia</u>

1. **Xenleta** will be approved based on the following:

a. **<u>One</u>** of the following:

(1) For continuation of therapy upon hospital discharge

-OR-

(2) As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication.

-OR-

(3) All of the following:

(a) Diagnosis of community-acquired bacterial pneumonia (CABP)

-AND-

(b) Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Xenleta

-AND-

(c) History of failure, contraindication, or intolerance to **three** of the following antibiotics:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Authorization will be issued for up to 7 days.

B. Off-Label Uses

1. **Xenleta** will be approved based on one of the following:

a. For continuation of therapy upon hospital discharge

-OR-

b. As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

-OR-

c. The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA).

Authorization duration based on provider and IDSA recommended treatment durations, up to 6 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Xenleta [package insert]. King of Prussia, PA: Nabriva Therapeutics US, Inc.; October 2019.
2. Metlay JP, Waterer GW, Long AC et al. Diagnosis and Treatment of Adults with Community-acquired Pneumonia: An Official Clinical Practice Guideline of the American Thoracic Society and Infectious Disease Society of America, *Am J Respir Crit Care Med*. 2019 Oct; 200(7): e45-67.

Program	Prior Authorization –Xenleta (lefamulin)
Change Control	
Date	Change
1/2020	New policy
1/2021	Annual review, updated references.