RX.PA.079.CCH XENLETA (LEFAMULIN)

The purpose of this policy is to define the prior authorization process for Xenleta (Lefamulin) for the treatment of adults 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.*

DEFINITIONS

CABP = Community-Acquired Bacterial Pneumonia

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Xenleta (Lefamulin), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed below:

- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must be prescribed by, or in consultation with, an infectious disease specialist
- Must be at least 18 years old
- Must have a diagnosis of pneumonia confirmed with chest x-ray, chest radiograph or other imaging technique.
- Must have a diagnosis of CABP that is possibly caused by the following microorganisms:
    - *Streptococcus pneumoniae*
    - *Staphylococcus aureus* (methicillin-susceptible isolates)
    - *Haemophilus influenzae*
    - *Legionella pneumophila*
    - *Mycoplasma pneumoniae*

  - *Chlamydophila pneumoniae*
- Must meet ONE of the following:
  - Culture and sensitivity report indicates pathogenic organism(s) resistance to at least TWO standard of care medications for CABP (e.g., amoxicillin, azithromycin, ceftriaxone, doxycycline, levofloxacin, linezolid, moxifloxacin) AND indicates susceptibility to Xenleta
  - Member has tried and failed at least TWO standard of care medications for CABP or has a contraindication to all medications

Reauthorization Criteria:

All prior authorization renewals are reviewed, and initial criteria must be met again for approval.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 week
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J0691	Xenleta	Injection, lefamulin, 1 mg

REFERENCES

1. FDA approves new antibiotic to treat community-acquired bacterial pneumonia. (2019, August 19). Retrieved October 5, 2019, from https://www.fda.gov/news-events/press-announcements/fda-approves-new-antibiotic-treat-community-acquired-bacterial-pneumonia.
2. File, T. M. (2019, May 2). Treatment of community-acquired pneumonia in adults in the outpatient setting. Retrieved October 5, 2019, from https://www-uptodate-com.suproxy.su.edu/contents/treatment-of-community-acquired-pneumonia-in-adults-in-the-outpatient-setting?search=community acquired pneumonia treatment&source=search_result&selectedTitle=3~150&usage_type=default&display_rank=3.
3. Nabriva Therapeutics Receives U.S. FDA Approval of Xenleta™ (lefamulin) to Treat Community-Acquired Bacterial Pneumonia (CABP). (2019, August 19). Retrieved October 5, 2019, from https://investors.nabriva.com/news-releases/news-release-details/nabriva-therapeutics-receives-us-fda-approval-xenleta.

4. Study to Compare Lefamulin to Moxifloxacin (With or Without Linezolid) for the Treatment of Adults With Pneumonia (LEAP). (2015, September 24). Retrieved October 5, 2019, from https://clinicaltrials.gov/ct2/show/NCT02559310.

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	XX/XX

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

Disclaimer

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