

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## Xenleta (lefamulin)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 month

Medications	Quantity Limit
Xenleta (lefamulin)	10 tablets per fill; 1 fill per 30 days

### APPROVAL CRITERIA

Requests for Xenleta (lefamulin) may be approved if the following criteria are met:

- I. Individual has been diagnosed with community-acquired bacterial pneumonia (CABP) confirmed by chest radiograph findings (File, 2019); **AND**
- II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one alternative antibiotic that the microorganism is susceptible to [examples of alternative antibiotics include but are not limited to: moxifloxacin; levofloxacin; beta-lactam (amoxicillin-clavulanate, cefuroxime, ceftriaxone, cefotaxime) plus macrolide (azithromycin, clarithromycin); beta-lactam plus doxycycline] (ATS/IDSA, 2019);

**OR**

- III. Individual started treatment with antibiotic(s) in the hospital and requires continued outpatient therapy for a microorganism susceptible to Xenleta (lefamulin).

Xenleta (lefamulin) may not be approved for the following:

- I. Individual with known prolongation of the QT interval; **OR**
- II. Individual with ventricular arrhythmias including torsades de pointes; **OR**
- III. Concomitant administration with class IA (including quinidine and procainamide) or class III (including amiodarone and sotalol) antiarrhythmic agents; **OR**
- IV. Concomitant administration with agents that prolong the QT interval (including antipsychotics, erythromycin, pimozide, moxifloxacin and tricyclic antidepressants); **OR**
- V. Concomitant administration with strong CYP3A inhibitors or P-gp inhibitors (including clarithromycin, ketoconazole); **OR**
- VI. Individual with moderate or severe hepatic impairment (Child-Pugh Class B or C).

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**Key References:**

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 13, 2020.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. File TM, Goldberg L, Das A, et al. Efficacy and Safety of Intravenous-to-oral Lefamulin, a Pleuromutilin Antibiotic, for the Treatment of Community-acquired Bacterial Pneumonia: The Phase III Lefamulin Evaluation Against Pneumonia (LEAP 1) Trial. *Clin Infect Dis*. 2019;69(11):1856–67.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. 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 (ATS) and Infectious Diseases Society of America (IDSA). *Am J Respir Crit Care Med*. 2019 Oct;200(7):e45-467.
6. US Food and Drug Administration. Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Last updated: March 10, 2020. Available at <https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm093664.htm>. Accessed: March 14, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.