



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

LEFAMULIN

Generic	Brand	HICL	GCN	Exception/Other
LEFAMULIN	XENLETA		46826	

**GUIDELINES FOR USE**

1. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) and meet **ALL** of the following criteria?
  - The patient is 18 years of age or older
  - Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, or *Chlamydia pneumoniae*

If yes, continue to #2.

If no, do not approve.

**DENIAL TEXT:** See the denial text at the end of the guideline.

2. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

If yes, **approve Xenleta 600mg tablet for one fill by GPID (46826) with a quantity limit of #10 tablets per 5 days.**

If no, continue to #3.

3. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
  - The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
  - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Xenleta

If yes, **approve Xenleta 600mg tablet for one fill by GPID (46826) with a quantity limit of #10 tablets per 5 days.**

If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
  - Antimicrobial susceptibility results are unavailable
  - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

If yes, **approve Xenleta 600mg tablet for one fill by GPID (46826) with a quantity limit of #10 tablets per 5 days.**

If no, do not approve.

**DENIAL TEXT:** See the denial text at the end of the guideline.

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LEFAMULIN

GUIDELINES FOR USE (CONTINUED)

**DENIAL TEXT:** The guideline named **LEFAMULIN (Xenleta)** requires a diagnosis of community-acquired bacterial pneumonia (CABP). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, or *Chlamydia pneumoniae*
- The patient meets **ONE** of the following criteria:
  - Therapy is prescribed by or given in consultation with an Infectious Disease (ID) specialist
  - Antimicrobial susceptibility test is available, and the infection site culture results indicate pathogenic organism(s) with 1) resistance to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid), **AND** 2) the culture is susceptible to Xenleta
  - Antimicrobial susceptibility test is unavailable, and the patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

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**RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenleta.

**REFERENCES**

- Xenleta [Prescribing Information]. Ireland DAC: Nabriva Therapeutics US, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/09/19

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