# SENTARA COMMUNITY PLAN
# (MEDICAID)

## PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

**Directions**: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

**Drug Requested: Xenleta™** (lefamulin)

**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

**Member Name:** _____

**Member Sentara #:** _____ **Date of Birth:** _____

**Prescriber Name:** _____

**Prescriber Signature:** _____ **Date:** _____

**Office Contact Name:** _____

**Phone Number:** _____ **Fax Number:** _____

**DEA OR NPI #:** _____

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

**Drug Form/Strength:** _____

**Dosing Schedule**: _____ **Length of Therapy**: _____

**Diagnosis:** _____ **ICD Code, if applicable:** _____

**Weight:** _____ **Date:** _____

**CLINICAL CRITERIA:** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

**Initial Length: 7 days**

1. Is the member 18 years of age or older? **AND** ❑ Yes ❑ No
2. Does the member have a diagnosis of community-acquired bacterial pneumonia (CABP)? **AND** ❑ Yes ❑ No
3. Is the CABP thought to be due to organisms susceptible to lefamulin and member is not at risk for multidrug resistant organisms (e.g., Pseudomonas aeruginosa, methicillin-resistant Staphylococcus aureus)? **AND** ❑ Yes ❑ No
4. Is there confirmation that the member does NOT have known sensitivity to lefamulin, its excipients, or another pleuromutilin agents? **AND** ❑ Yes ❑ No

**(Continued on next page)**

5. Is there confirmation that the member is NOT pregnant? **AND** ❑ Yes ❑ No
6. Has the member been advised (prescriber attestation) to use effective contraception during treatment and for 2 days following treatment completion, if member is female of reproductive potential? **AND**
   ❑ Yes ❑ No
7. Is there confirmation that the member does NOT have QT prolongation or ventricular arrhythmias? **AND** ❑ Yes ❑ No
8. Do you confirm that the member is NOT taking concomitant agents that prolong the QT interval that are considered sensitive substrates of cytochrome p450 3A4 (CYP3A4) (e.g., pimozide)? **AND**
   ❑ Yes ❑ No
9. Is there confirmation that the member is NOT taking any Class IA or Class III antiarrhythmic drugs (e.g., quinidine, procainamide, amiodarone, sotalol) or other agents known to prolong the QT interval (e.g., antipsychotics, erythromycin, moxifloxacin, tricyclic antidepressants)? **AND**
   ❑ Yes ❑ No
10. Is the treatment duration in compliance with product labeling (5 to 7 days intravenous [IV], 5 days oral, and, IV to oral switch, total duration does not exceed 7 days)? **AND** ❑ Yes ❑ No
11. Does the member have severe hepatic impairment? If yes, oral lefamulin will not be used and the IV formulation is prescribed with a decreased dosing interval (every 24 hours) as per product labeling (oral formulation will not be used). **AND** ❑ Yes ❑ No
12. Is there confirmation that the member is NOT a candidate (based on member history, risk factors, comorbidities, or local antibiogram) for current treatment-guideline recommended first-line agents for CABP (e.g., macrolide, doxycycline, beta-lactam plus doxycycline or macrolide)? **AND**
    ❑ Yes ❑ No

**Medication being provided by a Specialty Pharmacy - PropriumRx**

***Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

**Previous therapies will be verified through pharmacy paid claims or submitted chart notes.***



**REVISED/UPDATED/REFORMATTED:** ~~2/19/2020;~~ **11/10/2023**