Sample Letter of Medical Necessity

[Provider Letterhead]

[Insert date]

[Payer name]
[Street address]
[City, state and ZIP code]

Subscriber ID: [Insert Subscriber ID]
Patient: [Insert Patient Name]
DOB: [Insert Patient Date of Birth]
Physician TIN: [Insert Physician Tax ID Number]
Physician NPI: [Insert Physician NPI Number]
NDC Code: 72000-0110-30

RE: Documentation to Support Medical Necessity for XENLETA (lefamulin) 600 mg tablets

To Whom It May Concern,

I am writing to request coverage for XENLETA (lefamulin) 600 mg tablets for my patient, [Patient Name], who has been diagnosed with community acquired bacterial pneumonia (CABP).

Pneumonia is among the most common causes of hospitalization and is a leading cause of death due to an infectious disease (approximately 50,000 in the United States each year)[1]. Current first-line CABP treatment includes a macrolide, β-lactam, a combination of β-lactam and macrolide, or fluoroquinolone.

High rates of bacterial resistance to commonly used first-line CABP therapies combined with increasing fluoroquinolone-associated safety concerns (tendinitis and tendon rupture, peripheral neuropathy, central nervous system effects, and hypoglycemia), have created a need for new treatment options. For these reasons, along with the specific deteails documented in the patient's medical history outlined below, I believe that XENLETA is the most appropriate treatment option for my patient.

Patient Medical History

[Insert relevant information about the patient's condition and medical history that you believe support the medical necessity for XENLETA. For example the patient's age, duration and severity of the patient's symptoms, history or prior infections or medical comorbidities, lab testing and outcomes, pathogen type (e.g. *Streptococcus pneumoniae, Staphylococcus*

[1] See Centers for Disease Control and Prevention, National Center for Health Statistics: Pneumonia. Available at https://www.cdc.gov/nchs/fastats/pneumonia.htm.

aureus, Haemophilus influenzae, and the atypical pathogens *Mycoplasma pneumoniae, Chlamydophila pneumoniae, or Legionella pneumophila). Also list any prior* medications that the patient has tried and failed, or therapies that would be clinically inappropriate for the patient (and why).]

Given the patient's symptoms and medical history, it is my expert clinical opinion that the patient should receive XENLETA immediately to treat [his/her] CABP. [Insert any additional information to express the urgency related to the need for approval of XENLETA].

About XENLETA

XENLETA (lefamulin) is a first-in-class semi-synthetic pleuromutilin antibiotic for systemic administration in humans. It is designed to inhibit the synthesis of bacterial protein, which is required for bacteria to grow. XENLETA's binding occurs with high affinity, high specificity and at molecular sites that are different than other antibiotic classes. Based on results from its two global, Phase 3 clinical trials (LEAP1 and LEAP 2), XENLETA is well-positioned for use as a first-line monotherapy for the treatment of CABP.

In LEAP 1 and LEAP 2 (pooled), the median age of patients treated with XENLETA was 61 (range 19-97) years; 42% of patients were 65 years or older and 18% of patients were 75 years or older. In both trials, approximately half of XENLETA-treated patients had impaired renal function and the most common other comorbidities included hypertension, asthma/COPD and diabetes mellitus. These baseline characteristics were broadly representative of the adult patient population with CABP.

In LEAP 1, XENLETA demonstrated non-inferiority compared to moxifloxacin, with or without linezolid, for the FDA primary endpoint of early clinical response (ECR) assessed 72 to 120 hours following initiation of therapy in the intent to treat (ITT) patient population (ECR rate = 87.3% for XENLETA and 90.2% for moxifloxacin, with or without linezolid; treatment difference -2.9 [95% confidence interval (CI) -8.5, 2.8]).

In LEAP 2, 5-days of oral XENLETA also demonstrated non-inferiority to 7-days of oral moxifloxacin for the ECR endpoint in the ITT population (ECR rate = 90.8% for XENLETA and 90.8% moxifloxacin; treatment difference 0.1 [95% confidence interval (CI) -4.4, 4.5]). Importantly, high-risk patients 65 years and older achieved a similar ECR rate as those less than 65 years of age. The most common adverse reactions in patients receiving XENLETA in LEAP 1 (IV and oral) were administration site reactions, hepatic enzyme elevation, nausea, hypokalemia, insomnia, and headache in LEAP 1, and in LEAP 2 (oral only) diarrhea, nausea, vomiting and hepatic enzyme elevation. Few discontinuations due to adverse reactions were reported (3.3% in both treatment arms) and the 28-day mortality was low and balanced between treatment groups [8 patients (1.2%)] and [7 patients (1.1%)] for XENLETA and comparator, respectively from pooled data for LEAP 1 and LEAP 2.

In summary, I believe XENLETA is medically necessary for the treatment of [insert patient's name]'s CABP and request approval of coverage for this medication. Thank you for your time and consideration regarding this matter.

Respectfully,

[Provider Name]
[Name of Practice]
[Contact Information]

Attachments:

1. Medical records
2. XENLETA Prescribing Information

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