Patient Enrollment Form & Prescription

Xenleta™ (lefamulin)
150 mg injection | 600 mg tablets

Instructions and Description of Services

Note: If additional information or assistance is needed, please contact Nabriva RX Connect™ for an assessment of what services may be needed and the steps required.

DESCRIPTION OF SERVICES

Benefit Investigation

A Nabriva RX Connect reimbursement specialist will contact the patient's insurance company to collect information regarding the patient's coverage and benefits for XENLETA.

Please complete sections 1-3 and 5-8 when requesting this service.

Prior Authorization Support

Designated specialty pharmacies or a Nabriva RX Connect reimbursement specialist will contact the patient's insurance company to collect information on whether a prior authorization is required, and any specific requirements. They may also help the healthcare provider follow up on the status and outcome of a healthcare provider–submitted prior authorization request for XENLETA.

Please complete sections 1-3 and 5-8 when requesting this service.

Specialty Retail and Specialty Pharmacy Locator

A Nabriva RX Connect reimbursement specialist will assist the healthcare provider in identifying a designated specialty pharmacy to dispense XENLETA.

For more information, please contact Nabriva RX Connect via phone at 1-855-5NABRIVA (Option 3) or visit Xenleta.com/pharmacy.

Patient Assistance Program (PAP)

Available for eligible patients. Nabriva Therapeutics US, Inc. will provide assistance (through in-kind product donations) to uninsured or underinsured patients who meet specific income requirements.

Eligibility requirements include the following:

- Patient has provided consent to participate in the program by signing the Patient Enrollment Form
- Patient has a valid prescription for XENLETA
- Patient has no prescription coverage, or not enough coverage, to pay for XENLETA
- Patient resides in the US or a US territory
- Patient has an on-label diagnosis
- Patient has been treated by a healthcare provider licensed in the US or a US territory
- Patient has provided income verification information
- Terms and conditions apply

Please complete sections 1-8 when requesting this service.

Copay Assistance

Available for eligible patients with commercial insurance, patients pay no more than $50 for each XENLETA prescription.

For more information, please contact Nabriva RX Connect via phone at 1-855-5NABRIVA (Option 3) or visit Xenleta.com/copay.

INSTRUCTIONS

Complete all applicable sections of the Patient Enrollment Form & Prescription.

Ensure all applicable signature fields are complete.

Fax the completed Patient Enrollment Form & Prescription and all required documentation to Nabriva RX Connect at 1-866-867-9868.

Patient Confidentiality

Patient confidentiality is of primary importance to us. All patient information will remain confidential.

Important Reminder

Please be certain that all applicable pages of the Patient Enrollment Form & Prescription are completed and include all appropriate documentation when submitting this form. Incomplete forms slow the review process and, in some cases, may require the healthcare provider to reapply for the program(s).

Nabriva RX Connect™

Nabriva RX Connect
Eastpoint Parkway, Louisville, KY 40223 | Phone number: 1-855-5NABRIVA (Option 3) | Fax: 1-866-867-9868

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1 Requested Services

(Check all that apply. See page 1 for a description of available services.)

- ☐ Benefit Investigation
- ☐ Prior Authorization Support
- ☐ Patient Assistance Program (PAP)
- ☐ Designated Specialty Pharmacy Locator

2 Patient Information

Name *(First, Last, Suffix)* _____

Date of Birth _____ Gender ☐ Male ☐ Female

Home Address _____

City _____ State _____ Zip _____

Authorized Representative _____ Relationship to Patient _____

Home Phone _____ Cell Phone _____

Best Time to Contact ☐ Morning *(8 am-12 pm EST)* ☐ Afternoon *(12 pm-4 pm EST)*

☐ Evening *(4 pm-8 pm EST)* ☐ Other _____

3 Patient Insurance Information

Does the patient have health insurance? ☐ Yes ☐ No

Insurance Type: ☐ Commercial ☐ Government ☐ Other

Primary Medical Insurance Provider _____

Beneficiary/Cardholder Name _____

ID# _____ Group# _____

Prescription Insurance Provider _____

ID# _____ Group# _____

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Patient Financial Information *[Required only if applying for Patient Assistance Program (PAP)]*

Current Annual Household Income $ _____

Number of People in Household _____

If there is no household income, indicate how the patient/household is being supported

_____

_____

_____

_____

_____

PAP Support Services Patient Application and Authorization *(Signature Required)*

I authorize Nabriva Therapeutics US, Inc. ("Nabriva") and companies working with Nabriva to provide me with support services related to Nabriva products (collectively called "Support Services"). I understand, agree and authorize that any individual providing Support Services is not employed by my healthcare provider. I authorize Nabriva and companies working with Nabriva to contact me to provide Support Services and information by mail, e-mail, fax, telephone call, text message, and other means. If I provided my cell phone number on this form, I agree to receive calls/texts at that number, from or on behalf of Nabriva. I understand and agree that these calls/texts may be deemed telemarketing under applicable law. I understand that my consent to receive these calls/texts is not a condition of receiving the Support Services. I further understand that I do not have to agree to receive the Support Services and that I can still receive XENLETA as prescribed by my healthcare professional. I understand that I am under no obligation to purchase XENLETA.

I certify that all of the information provided in this application, including household income, is complete and accurate. I understand that PAP Support Services will terminate if the PAP becomes aware of any fraud or if this medicine is no longer prescribed for me. I understand that completing this PAP application does not ensure that I will qualify for patient assistance. If I receive free medicine through the PAP, I certify that I will not seek reimbursement or credit for this medication from any insurance company, health plan, or government program. I understand that the PAP reserves the right to modify or discontinue this PAP or terminate assistance at any time and without notice. I authorize the PAP and its administrator to forward my prescription to a dispensing Designated Specialty Pharmacy on my behalf.

I certify that I am at least eighteen (18) years of age. I understand that I may opt out of receiving the PAP Support Services by notifying Nabriva RX Connect, Eastpoint Parkway, Louisville, KY 40223.

By signing below (required), I have read and agree to **the authorization above.**

Patient Printed Name *(First, Last)* _____

Relationship to Patient ☐ Patient ☐ Authorized Representative ☐ Caregiver

Patient/Authorized Representative/Caregiver Signature **X** _____

Date _____

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5 Clinical Information & Prescription

☐ **PRESCRIPTIONS: XENLETA 600 MG ORAL ANTIBIOTIC**
(fill in) _____ Days *(fill in)* _____ Total Pills. No Refills.

Primary Diagnosis *(ICD-10 Code)* _____ Secondary Diagnosis *(ICD-10 Code)* _____

Current Medications _____

Allergies _____

Patient Discharge Date *(MM/DD/YYYY)* _____

6 Discharge Planner/Requestor Information

Name *(First, Last)* _____

Hospital Organization Name _____

Address _____

City _____ State _____ Zip _____

Primary Phone _____ Secondary Phone _____

Fax _____

Best Time to Contact ☐ Morning *(8 am-12 pm EST)* ☐ Afternoon *(12 pm-4 pm EST)*
☐ Evening *(4 pm-8 pm EST)* ☐ Other _____

7 Prescriber Information

Prescriber Name _____ Prescriber NPI Number _____

Address _____

City _____ State _____ Zip _____

Primary Phone _____ Secondary Phone _____

Fax _____

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8 Prescriber Declaration *(Signature Required)*

I certify that the patient and prescriber information contained in this Patient Enrollment Form & Prescription is complete and accurate to the best of my knowledge. I have prescribed XENLETA and certify that this prescription medication is medically necessary for the patient and that it will be used as directed. I certify that I will be supervising the patient's treatments and verify that the information provided is complete and accurate to the best of my knowledge. I certify that I have received the appropriate permission from the patient and met any other applicable requirements imposed under the Health Insurance Portability and Accountability Act of 1996 and/or state law needed to release the above information to Nabriva RX Connect for the purposes of verifying the patient's insurance coverage, seeking prior authorization if needed, on my patient's behalf, and providing information on appeals for denials of claims.

I authorize the forwarding of this prescription to a dispensing Designated Specialty Pharmacy on behalf of myself and the patient. I understand that neither I nor the patient should seek reimbursement for any free medicine received under the PAP and my team has informed the patient of this requirement.

By signing below (required), I have read and agree to **Section 8. Prescriber Declaration.**
(NOTE: Patient Enrollment Form & Prescription requests cannot be processed without signed Prescriber Declaration. Prescriber actual signature required, no signature stamp.)

Prescriber Printed Name *(First, Last)* _____

Prescriber Signature **X** _____ Date _____

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Indication and Important Safety Information

Indication

XENLETA is a pleuromutilin antibacterial indicated 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*.

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of XENLETA and other antibacterial drugs, XENLETA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Important Safety Information

CONTRAINDICATIONS

XENLETA is contraindicated in patients with known hypersensitivity to XENLETA or pleuromutilins.

XENLETA tablets are contraindicated for use with CYP3A4 substrates that prolong the QT interval.

WARNINGS AND PRECAUTIONS

XENLETA has the potential to prolong the QT interval. Avoid XENLETA in patients with known QT prolongation, ventricular arrhythmias, and patients receiving drugs that may prolong the QT interval.

Based on animal studies, XENLETA may cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception.

Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including XENLETA, with severity ranging from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

ADVERSE REACTIONS

The most common adverse reactions (≥2%) for (a) XENLETA Injection are administration site reactions, hepatic enzyme elevation, nausea, hypokalemia, insomnia, and headache and (b) XENLETA Tablets are diarrhea, nausea, vomiting, and hepatic enzyme elevation.

USE IN SPECIFIC POPULATIONS

In patients with severe hepatic impairment, reduce the dosage of XENLETA Injection to 150 mg infused over 60 minutes every 24 hours. XENLETA Tablets are not recommended in patients with moderate or severe hepatic impairment due to insufficient information to provide dosing recommendations.

Avoid XENLETA Injection and Tablets with concomitant strong or moderate CYP3A or P-gp inducers. Monitor for reduced efficacy of XENLETA.

Avoid XENLETA Tablets with strong CYP3A or P-gp inhibitors.

Monitor for adverse reactions of sensitive CYP3A substrates administered with XENLETA Tablets.

XENLETA has not been studied in pregnant women. Verify pregnancy status in females prior to initiating XENLETA and advise females to use contraception during treatment and for 2 days after the final dose. Lactating women should pump and discard milk for the duration of treatment with XENLETA and for 2 days after the final dose.

To report SUSPECTED ADVERSE REACTIONS, or administration during pregnancy, contact Nabriva Therapeutics US, Inc. at 1-855-5NABRIVA or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Full Prescribing Information for XENLETA.

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