XENLETA® (lefamulin) BILLING AND CODING GUIDE

Effective November 15, 2021

Disclaimer

The information provided in this guide contains general reimbursement information only and is not legal advice, nor is it advice about how to code, complete, or submit any particular claim for payment. Information provided is not intended to increase or maximize reimbursement by the health plan. The information provided represents Nabriva Therapeutics' understanding of current coding and reimbursement policies. Nabriva Therapeutics disclaims all responsibility related to provider billing. It is the provider's responsibility to determine appropriate codes, charges, and modifiers, and submit claims for the services consistent with the patient insurer requirements and clinical work up. Third-party insurers' policies and coding requirements vary and are updated routinely. Such policies can change over time. Providers should check and verify current policies and requirements with the health plan for any particular patient.

Current Procedural Terminology (CPT®) Disclaimer

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

Coding for XENLETA: Hospital Outpatient Department

Healthcare Common Procedure Coding System (HCPCS) Level II Code

HCPCS	Description
J0691	Injection, lefamulin, 1 mg

Note on reporting J0691: Each vial of XENLETA IV contains 150 mg. Only bill the patient's health plan the amount of XENLETA administered to the patient. The discarded amount may also be billed as long as the JW Modifier is used. For more information about billing wastage and proper use of the JW modifier, please refer to the Medicare Claims Processing Manual, Chapter 17, Drugs and Biologicals; Section 40, Discarded Drugs and Biologicals.

National Drug Code (NDC)

Product Strength Size	XENLETA 10-Digit NDC	XENLETA 11-Digit NDC	Reporting on Claim Form
Xenleta® (lefamulin) Tablets, 600 mg Blister pack of 10 tablets	72000-110-10	72000-0110-10	72000011010
Xenleta® (lefamulin) Tablets, 600 mg Bottle of 30 tablets	72000-110-30	72000-0110-30	72000011030
Xenleta® (lefamulin) Injection, 150 mg Carton of 6 vials	72000-120-06	72000-0120-06	72000012006
Diluent for Xenleta® (lefamulin), 250 mL Carton of 6 bags	72000-030-06	72000-0030-06	72000003006

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Transitional Pass-through Payment

XENLETA Granted Transitional Pass-through Status, Effective January 1, 2020

Transitional pass-through status is a temporary payment policy granted by the Centers for Medicare & Medicaid Services (CMS), the federal agency that administers the Medicare program. When a drug is granted pass-through status by CMS, hospital outpatient departments are eligible to receive separate payment for the drug, in addition to the payment received for the patient encounter for Medicare patients. Providers must bill using the HCPCS C-code J0691 to obtain payment for XENLETA. Pass-through status remains in effect for 3 years. Pass-through status is applicable to Medicare patients only. However, some Medicaid and commercial payers may recognize Medicare's pass-through status policy and allow for separate payment.

Coding for Infusion Services

Potential Current Procedural Terminology (CPT®) Codes

CPT	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)

Note: Per CPT guidelines and the CMS National Correct Coding Initiative (NCCI) Policy Manual, the CPT codes for infusion services (96365, 96366) are not intended to be reported by the physician in the facility setting. Thus, the physician will bill the appropriate E/M service(s). As reimbursement policies vary by health plan, it is important to check with the health plan provider to understand specific guidelines for billing physician infusion services.

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Coding for XENLETA: Inpatient Hospital

New Technology Add-on Payment (NTAP) for XENLETA (lefamulin), Effective October 1, 2020

NTAP is an additional payment made to the hospital, on top of the MS-DRG payment for the hospital stay. This additional payment is provided to offset some of the costs of new drugs and devices when certain criteria are met. For the fiscal year 2021, add-on payments for qualified infection disease products (QIDPs) are limited to the lesser of 75 percent of the average cost of the product, or 75 percent of the amount by which the costs of the case exceed the standard Medicare Severity Diagnosis Related Group (MS–DRG) payment. NTAP designation lasts no more than three years for a specific indication. Beginning on October 1, 2020, the Centers for Medicare and Medicaid Services (CMS) will provide an additional maximum payment of $1,275.75 for XENLETA, when used in the inpatient hospital setting for fiscal year 2021. This add-on payment will be incremental to the MS-DRG payment for qualifying Medicare inpatient cases.

ICD-10-PCS Procedure Codes for XENLETA Administration

The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) procedure codes are used by hospitals to report procedures performed in the hospital inpatient setting only. In order to facilitate NTAP to hospitals, CMS established two new ICD-10-PCS procedure codes to identify XENLETA administration during inpatient hospital stays. Hospitals must bill the following ICD-10-PCS codes to identify XENLETA on claims to ensure eligibility for NTAP.

ICD-10-PCS	Description
XW03366	Introduction of lefamulin anti-infective into peripheral vein, percutaneous approach, new technology group 6
XW04366	Introduction of lefamulin anti-infective into central vein, percutaneous approach, new technology group 6
XW0DX66	Introduction of lefamulin anti-infective into mouth and pharynx, external approach, new technology group 6

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Diagnosis Coding

Potential International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes

ICD-10-CM	Description
J18.8	Other pneumonia, unspecified organism
J18.9	Pneumonia, unspecified organism
Z16.10*	Resistance to unspecified beta lactam antibiotics
Z16.11*	Resistance to penicillins
Z16.19*	Resistance to other specified beta lactam antibiotics
Z16.20*	Resistance to unspecified antibiotic
Z16.21*	Resistance to vancomycin
Z16.22*	Resistance to vancomycin related antibiotics
Z16.23*	Resistance to quinolones and fluoroquinolones
Z16.24*	Resistance to multiple antibiotics
Z16.29*	Resistance to other single specified antibiotic
Z16.30*	Resistance to unspecified antimicrobial drugs
Z16.35*	Resistance to multiple antimicrobial drugs
Z16.39*	Resistance to other specified antimicrobial drug

ICD-10-CM	Description
A481	Legionnaires' disease
J13	Pneumonia due to Streptococcus pneumoniae
J14	Pneumonia due to Haemophilus influenzae
J15.20	Pneumonia due to staphylococcus, unspecified
J15.211	Pneumonia due to methicillin susceptible Staphylococcus aureus
J15.7	Pneumonia due to Mycoplasma pneumoniae
J15.8	Pneumonia due to other specified bacteria
J15.9	Unspecified bacterial pneumonia
J16.0	Chlamydial pneumonia
J16.8	Pneumonia due to other specified infectious organisms
J17	Pneumonia in diseases classified elsewhere
J18.0	Bronchopneumonia, unspecified organism
J18.1	Lobar pneumonia, unspecified organism
J18.2	Hypostatic pneumonia, unspecified organism

*Note: Effective October 1, 2019, the Centers for Medicare and Medicaid Services (CMS) has designated certain antimicrobial drug resistance ICD-10-CM diagnosis codes as a complication or comorbidity (CC), which generally results in assignment to a higher severity MS-DRG (and higher payment) for inpatient stays. For more information, please refer to the Inpatient Prospective Payment System (IPPS) Final Rule for Fiscal Year 2020 (CMS-1716-F).

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Sample UB-04 (CMS 1450)

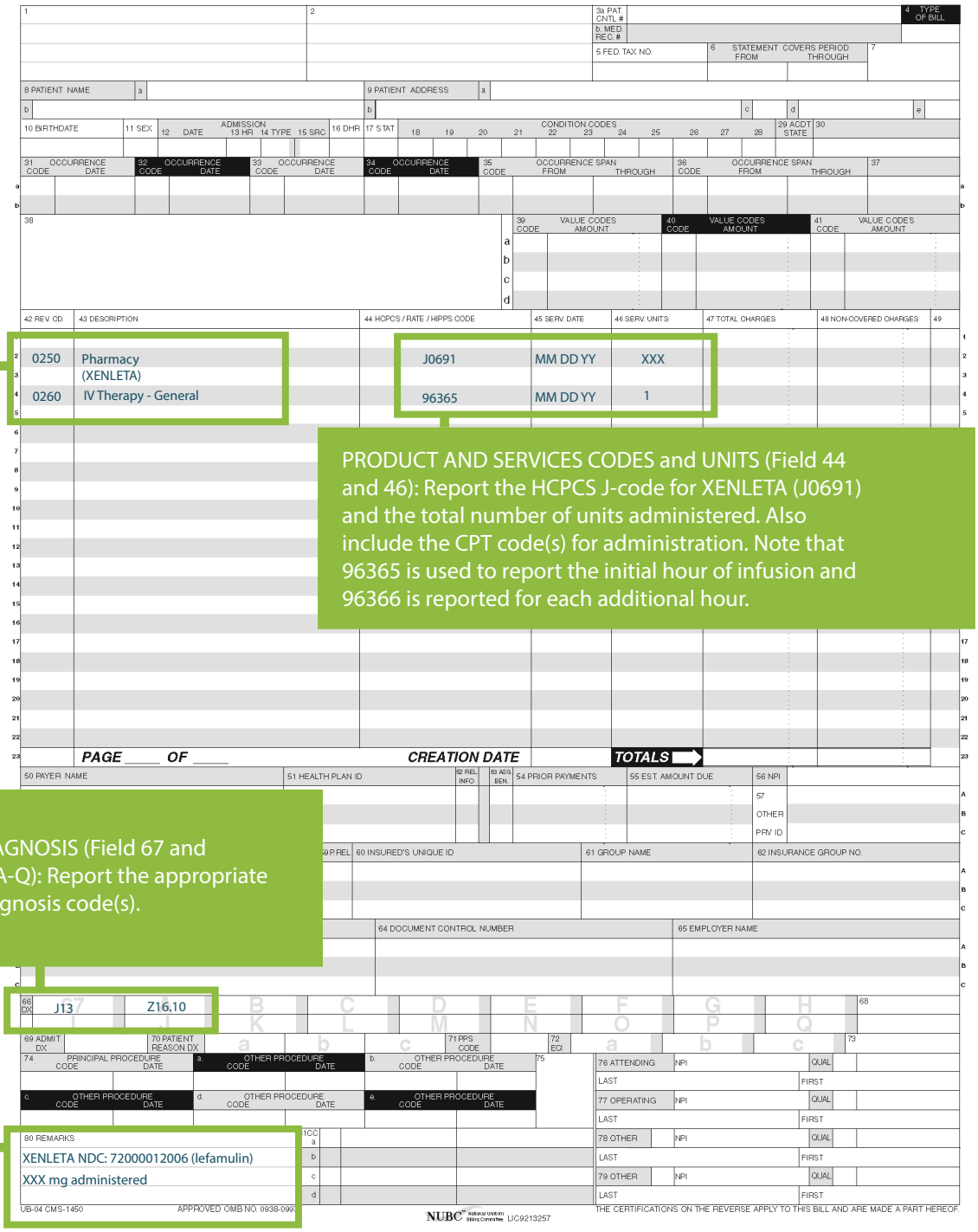
Hospital Outpatient Department Administration

REVENUE CODES (Field 42 and 43): Report the most appropriate revenue codes and descriptions of items and services for the cost center. Revenue codes may vary by payer.

PRODUCT AND SERVICES CODES and UNITS (Field 44 and 46): Report the HCPCS J-code for XENLETA (J0691) and the total number of units administered. Also include the CPT code(s) for administration. Note that 96365 is used to report the initial hour of infusion and 96366 is reported for each additional hour.

DIAGNOSIS (Field 67 and 67A-Q): Report the appropriate diagnosis code(s).

REMARKS (Field 80): Identify the drug being administered and include the NDC number. Some payers require the NDC to be listed in addition to the HCPCS J-code.



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Sample UB-04 (CMS 1450)

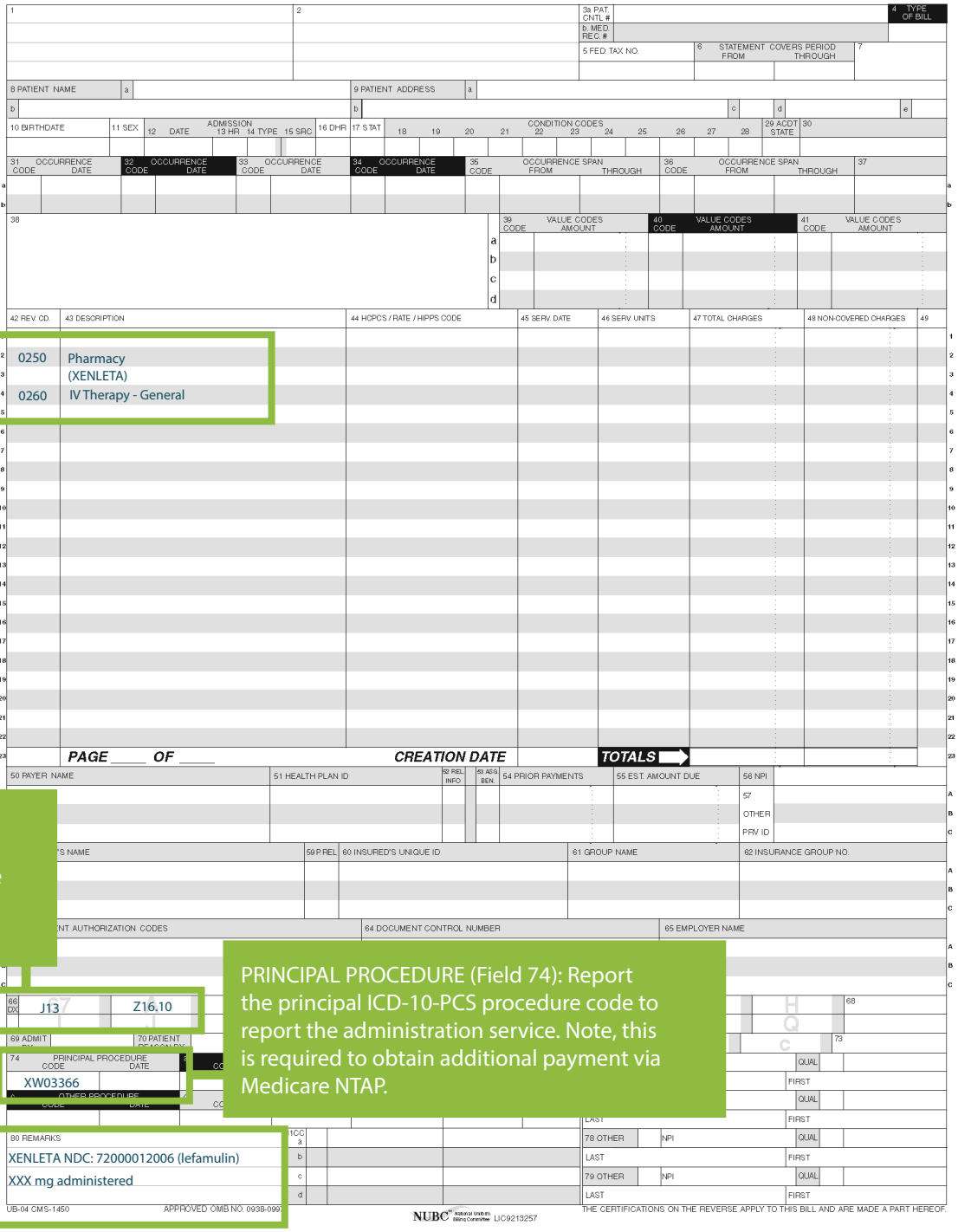
Inpatient Hospital Administration

REVENUE CODES (Field 42 and 43): Report the most appropriate revenue codes and descriptions of items and services for the cost center. Revenue codes may vary by payer.

DIAGNOSIS (Field 67 and 67A-Q): Report the appropriate diagnosis code(s).

PRINCIPAL PROCEDURE (Field 74): Report the principal ICD-10-PCS procedure code to report the administration service. Note, this is required to obtain additional payment via Medicare NTAP.

REMARKS (Field 80): Identify the drug being administered and include the NDC number. Some payers require the NDC to be listed in addition to the HCPCS J-code.



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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.

Clostridioides 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.

PM-US-LEF-0281 v4 JUL 2022

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