Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 207.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Xenleta IV (lefamulin)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Xenleta IV (lefamulin)

II. Purpose/Objective:
To provide a policy of coverage regarding Xenleta IV (lefamulin)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Xenleta IV (lefamulin) is a pleuromutilin antibiotic that inhibits bacterial protein synthesis through interactions (hydrogen bonds, hydrophobic interactions, and Van der Waals forces) with the A- and P- sites of the peptidyl transferase center in domain V of the 23s ribosomal RNA of the 50S subunit. The binding pocket of the bacterial ribosome closes around the mutilin core for an induced fit that prevents correct positioning of transfer RNA.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Xenleta IV (lefamulin) will be considered medically necessary for the commercial, exchange, CHIP, and Medicaid lines of business when ALL of the following criteria are met:

- Prescription is written by or in consultation with Infectious Disease **AND**
- Medical record documentation of a diagnosis of 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* **AND**
- Medical record documentation that patient is ≥18 years of age **AND**
- Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to three (3) alternative antibiotics shown to be susceptible on the culture and sensitivity **OR**
- Medical record documentation that treatment with Xenleta was initiated within an inpatient setting

QUANTITY LIMIT: Facets RX count: up to 2100 units, QL: 14 vials per 7 days and RX count of 1.

AUTHORIZATION DURATION: Approvals will be given for up to 7 days of total treatment.

Xenleta IV (lefamulin) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Prescription is written by or in consultation with Infectious Disease **AND**
- Medical record documentation of a diagnosis of 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* **AND**
- Medical record documentation that patient is ≥18 years of age

QUANTITY LIMIT: Facets RX count: up to 2100 units, QL: 14 vials per 7 days

AUTHORIZATION DURATION: Approvals will be given for up to 7 days of total treatment.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Xenleta [prescribing information]. Fort Washington, PA: Nabriva Therapeutics US Inc; June 2021.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/21/20

Revised: 11/26/22 (Medicaid PARP statement), 10/26/23 (LOB carve out, Medicaid business segment), 12/28/23 (references added), 10/16/24 (LOB table, taglines)

Reviewed: 1/1/21, 11/29/21 (clarified Darwin QL)

MA UM Committee approval: 12/31/23, 12/31/24

DHS PARP approval: 11/19/24