Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 247.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Kimyrsa (oritavancin)

I. Policy:
Kimyrsa (oritavancin)

II. Purpose/Objective:
To provide a policy of coverage regarding Kimyrsa (oritavancin)

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
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. 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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit 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:
Oritavancin is a lipoglycopeptide with concentration-dependent bactericidal activity. It inhibits cell wall biosynthesis by inhibiting the polymerization step by binding to stem peptides of peptidoglycan precursors, by inhibiting crosslinking by binding to bridging segments, and by disrupting bacterial membrane integrity, leading to cell death.

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

Kimyrsa (oritavancin) will be considered medically necessary when all of the following criteria are met:

1. Medical record documentation that patient is ≥ 18 years of age **AND**
2. Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: *Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus,* or *Enterococcus faecalis* (vancomycin susceptible strains) which has been diagnosed and documented with Infectious Disease consultation **AND**
3. 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 other antibiotics shown to be susceptible on the culture and sensitivity **AND**
4. Medical record documentation of intolerance to or contraindication to Orbactiv (oritavancin)

AUTHORIZATION DURATION/QUANTITY LIMIT:
Approval will be for **one (1) week** and will be limited to one (1) treatment course (up to 1,200 mg as a single dose) (Facets RX count 120, Darwin RX count 1).

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.

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

Devised: 11/16/21

Revised: 10/21/22 (Medicaid PARP statement)

Reviewed: