

Policy: MBP 311.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Xacduro (sulbactam and durlobactam)

I. Policy:

Xacduro (sulbactam and durlobactam)

II. Purpose/Objective:

To provide a policy of coverage regarding Xacduro (sulbactam and durlobactam).

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. 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

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:

Sulbactam is a beta-lactam antibacterial and Ambler class A serine beta-lactamase inhibitor that inhibits bacterial cell wall synthesis by binding to penicillin-binding proteins 1 and 3. Durlobactam is a diazabicyclooctane beta-lactamase inhibitor that protects sulbactam from degradation by certain serine beta-lactamases.

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

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

- Medical record documentation of a diagnosis of Hospital-acquired Bacterial Pneumonia (HABP) or Ventilator-associated Bacterial Pneumonia (VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus complex* **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation that Xacduro is prescribed by or in consultation with Infectious Disease **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to preferred alternative antibiotic treatments or combination therapy depending on severity **OR**
 - Medical record documentation of history of previous intolerance to or contraindication to two (2) preferred alternative antibiotics or combination therapy depending on severity, shown to be susceptible on the culture and sensitivity.

AUTHORIZATION DURATION: 14 Days

QUANTITY LIMITS: 168 vials per 14 days

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.

Xacduro (sulbactam and durlobactam) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of Hospital-acquired Bacterial Pneumonia (HABP) or Ventilator-associated Bacterial Pneumonia (VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus complex* **AND**
- Medical record documentation that member is 18 years of age or older **AND**
- Medical record documentation that Xacduro is prescribed by or in consultation with Infectious Disease

AUTHORIZATION DURATION: 14 Days

QUANTITY LIMITS: 168 vials per 14 days

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. Xacduro [Prescribing Information]. Entasis Therapeutics Ltd & Inoviva Specialty Therapeutics. December 2023
2. Kaye KS, Shorr AF, Wunderink RG, et al. Efficacy and safety of sulbactam-durlobactam versus colistin for the treatment of patients with serious infections caused by *Acinetobacter baumannii-calcoaceticus* complex: a multicentre, randomised, active-controlled, phase 3, non-inferiority clinical trial (ATTACK). *Lancet Infect Dis.* 2023;23(9):1072-1084. doi:10.1016/S1473-3099(23)00184-6
3. Tamma PD, Aitken SL, Bonomo RA, Mathers AJ, van Duin D, Clancy CJ. Infectious Diseases Society of America Antimicrobial-Resistant Treatment Guidance: Gram-Negative Bacterial Infections. Infectious Diseases Society of America 2023; Version 3.0. Available at <https://www.idsociety.org/practice-guideline/amr-guidance/>. Accessed December 20, 2023.

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

Devised: 1/16/24

Revised:

Reviewed:

MA UM Committee approval: Pending