

**Policy: MBP 205.0**

**Section: Medical Benefit Pharmaceutical Policy**

**Subject: Zerbaxa (ceftolozane/tazobactam)**

**Applicable line of business:**

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

**I. Policy:**

Zerbaxa (ceftolozane/tazobactam)

**II. Purpose/Objective:**

To provide a policy of coverage regarding Zerbaxa (ceftolozane/tazobactam)

**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

**Commercial**

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**Medicare**

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

**CHIP**

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**Medicaid**

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

## 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:

Zerbaxa (ceftolozane/tazobactam) is a cephalosporin combination. Ceftolozane inhibits bacterial cell wall synthesis by binding to one or more of the penicillin-binding proteins (PBPs); which in turn inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis. Ceftolozane is an inhibitor of PBPs of *Pseudomonas aeruginosa* (eg, PBP1b, PBP1c, and PBP3) and *Escherichia coli* (eg, PBP3). Tazobactam irreversibly inhibits some beta-lactamases (eg, certain penicillinases and cephalosporinases), and can covalently bind to some plasmid-mediated and chromosomal bacterial beta-lactamases.

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

Zerbaxa (ceftolozane/tazobactam) 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 one of the following:
    - Diagnosis of Complicated Intra-abdominal Infection (cIAI) caused by: *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Bacteroides fragilis*, *Streptococcus anginosus*, *Streptococcus constellatus*, or *Streptococcus salivarius*
- OR**
- Diagnosis of Complicated Urinary Tract Infection (including Pyelonephritis) (cUTI) caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, or *Pseudomonas aeruginosa*
- OR**
- Medical record documentation that the member is greater than or equal to 18 years of age **AND**
  - Diagnosis of Hospital-acquired Bacterial Pneumonia or Ventilator-associated Bacterial Pneumonia (HABP/VABP) caused by *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, or *Serratia marcescens*.
- AND**
- Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to preferred alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to three (3) preferred alternative antibiotics shown to be susceptible on the culture and sensitivity

## AUTHORIZATION DURATION:

For cUTI: 7 days

For cIAI or HABP/VABP: up to 14 days

## QUANTITY LIMITS:

For cUTI: 3 vials per day, Facets RX Count: 420 units (J0695)

For cIAI: 3 vials per day, Facets RX Count: 840 units (J0695)

For HABP/VABP: 6 vials per day, Facets RX Count: 1680 units (J0695)

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Zerbaxa (ceftolozane/tazobactam) 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 one of the following:
  - Diagnosis of Complicated Intra-abdominal Infection (cIAI) caused by: *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Bacteroides fragilis*, *Streptococcus anginosus*, *Streptococcus constellatus*, or *Streptococcus salivarius*

**OR**

- Diagnosis of Complicated Urinary Tract Infection (including Pyelonephritis) (cUTI) caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, or *Pseudomonas aeruginosa*

**OR**

- Medical record documentation that the member is greater than or equal to 18 years of age **AND**
- Diagnosis of Hospital-acquired Bacterial Pneumonia or Ventilator-associated Bacterial Pneumonia (HABP/VABP) caused by *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, or *Serratia marcescens*.

**AUTHORIZATION DURATION:**

For cUTI: 7 days

For cIAI or HABP/VABP: up to 14 days

**QUANTITY LIMITS:**

For cUTI: 3 vials per day, Facets RX Count: 420 units (J0695)

For cIAI: 3 vials per day, Facets RX Count: 840 units (J0695)

For HABP/VABP: 6 vials per day, Facets RX Count: 1680 units (J0695)

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. Zerbaxa [prescribing information]. Syracuse, NY: Steri-Pharma LLC; May 2022.

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

**Devised:** 11/19/19

**Revised:** 8/25/22 (Pediatric cIAI/cUTI, Medicaid PARP statement), 8/22/23 (LOB carve out, Medicaid business segment), 12/28/23 (references added), 8/19/24 (removed Darwin, LOB table, taglines)

**Reviewed:** 11/2/20, 10/4/21

**MA UM Committee approval:** 12/31/23