Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 215.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Recarbrio (imipenem/cilastatin/relebactam)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Recarbrio (imipenem/cilastatin/relebactam)

II. Purpose/Objective:
To provide a policy of coverage regarding Recarbrio (imipenem/cilastatin/relebactam)

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:
Recarbrio (imipenem/cilastatin/relebactam) is a carbapenem antimicrobial that contains imipenem, which inhibits penicillin-binding proteins and leads to the disruption of bacterial cell wall synthesis. Recarbio also contains cilastatin, which is a renal dehydropeptidase inhibitor that limits the renal metabolism of imipenem, and relebactam, which is a beta-lactamase inhibitor that protects imipenem from degradation by beta-lactamases.

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

Recarbrio (imipenem/cilastatin/relebactam) 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 that the member is greater than or equal to 18 years of age **AND**
- Medical record documentation of one of the following:
    - Diagnosis of Complicated Urinary Tract Infection (including Pyelonephritis) (cUTI) caused by the following susceptible gram-negative microorganisms: *Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae, or Pseudomonas aeruginosa* **OR**
    - Diagnosis of Complicated Intra-abdominal Infection (cIAI) caused by the following susceptible gram-negative microorganisms*: Bacteroides caccae, Bacteroides fragilis, Bacteroides ovatus, Bacteroides stercoris, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Fusobacterium nucleatum, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Parabacteroides distasonis, or Pseudomonas aeruginosa* **OR**
    - Diagnosis of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by the following susceptible gram-negative microorganisms: *Acinetobacter calcoaceticus-baumannii complex, Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, 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 **AND**
- Medical record documentation of a therapeutic failure on imipenem/cilastatin OR medical rationale of why imipenem/cilastatin cannot be used.

AUTHORIZATION DURATION: If approved, Recarbrio will be authorized for up to 14 days.

QUANTITY LIMITS: 4 vials per day (Facets RX Count of 7000 units)

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.

Recarbrio (imipenem/cilastatin/relebactam) 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 that the member is greater than or equal to 18 years of age **AND**
- Medical record documentation of one of the following:
    - Diagnosis of Complicated Urinary Tract Infection (including Pyelonephritis) (cUTI) caused by the following susceptible gram-negative microorganisms: *Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae, or Pseudomonas aeruginosa* **OR**
    - Diagnosis of Complicated Intra-abdominal Infection (cIAI) caused by the following susceptible gram-negative microorganisms*: Bacteroides caccae, Bacteroides fragilis, Bacteroides ovatus, Bacteroides stercoris, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Fusobacterium nucleatum, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Parabacteroides distasonis, or Pseudomonas aeruginosa* **OR**
    - Diagnosis of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by the following susceptible gram-negative microorganisms: *Acinetobacter calcoaceticus-baumannii complex, Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa, or Serratia marcescens*

AUTHORIZATION DURATION: If approved, Recarbrio will be authorized for up to 14 days.

QUANTITY LIMITS: 4 vials per day (Facets RX Count of 7000 units)

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. Recarbrio [prescribing information]. Rahway, NJ: Merck Sharp & Dohme LLC; May 2022.

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

Devised: 5/19/20

Revised: 11/17/20 (pneumonia), 10/4/22 (Medicaid PARP statement), 10/2/23 (LOB carve out, Medicaid business segment), 12/28/23 (references added), 10/1/24 (LOB table, taglines)

Reviewed: 10/4/21

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

DHS PARP approval: 11/19/24