Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 169.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Baxdela IV (delafloxacin)

I. Policy:
Baxdela IV (delafloxacin)

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

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
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:
Baxdela IV (delafloxacin) is a fluoroquinolone antibiotic that inhibits DNA gyrase (topoisomerase II) and topoisomerase IV enzymes, which are required for bacterial DNA replication, transcription, repair, and recombination.

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

Baxdela IV (delafloxacin) 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 that patient is greater than or equal to 18 years of age **AND**
- Medical record documentation of one of the following:
    - A diagnosis of acute bacterial skin and skin structure infections (ABSSSI)* caused by: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group* (including S*treptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus*), *Streptococcus pyogenes*, *Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae*, and *Pseudomonas aeruginosa* **OR**
    - A diagnosis of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus (methicillin susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila, and Mycoplasma pneumoniae*

AND

- Prescription written by or in consultation with Infectious Disease **AND**
- If Baxdela was initiated during an inpatient stay, medical record documentation of 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**
- Medical record documentation of therapeutic failure on, intolerance to, contraindication to Baxdela tablets.

*Note to reviewer: ABSSSI is defined as a skin infection with a lesion surface area of at least 75 cm^2 and includes the three following types of infection: (1) cellulitis/erysipelas, (2) wound infections, and (3) major cutaneous abscesses.

AUTHORIZATION DURATION:
If approved for ABSSI, Baxdela IV will be authorized for 14 days, with a maximum of 28 doses.
If approved for CABP, Baxdela IV will be authorized for 10 days, with a maximum of 20 doses.

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

- Medical record documentation that patient is greater than or equal to 18 years of age **AND**
- Medical record documentation of one of the following:
    - A diagnosis of acute bacterial skin and skin structure infections (ABSSSI)* caused by: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group* (including S*treptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus*), *Streptococcus pyogenes*, *Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae*, and *Pseudomonas aeruginosa* **OR**
    - A diagnosis of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus (methicillin susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila, and Mycoplasma pneumoniae*

AND

- Prescription written by or in consultation with Infectious Disease

*Note to reviewer: ABSSSI is defined as a skin infection with a lesion surface area of at least 75 cm^2 and includes the three following types of infection: (1) cellulitis/erysipelas, (2) wound infections, and (3) major cutaneous abscesses.

AUTHORIZATION DURATION:
If approved for ABSSI, Baxdela IV will be authorized for 14 days, with a maximum of 28 doses.
If approved for CABP, Baxdela IV will be authorized for 10 days, with a maximum of 20 doses.

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. Baxdela [prescribing information]. Lincolnshire, IL: Melinta Therapeutics LLC; June 2021.

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

Devised: 3/20/18

Revised: 3/17/20 (CABP), 1/19/23 (LOB carve out, Medicaid PARP statement, Medicaid business segment), 12/30/23 (references added)

Reviewed: 1/30/19, 11/1/19, 1/28/21, 1/21/22, 1/15/24

MA UM Committee approval: 12/31/23