Clinical Policy: Delafloxacin (Baxdela)

Reference Number: LA.PMN.115
Effective Date:
Last Review Date: 03.21
Line of Business: Medicaid

Coding Implications Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Delafloxacin (Baxdela®) is a fluoroquinolone antibiotic.

FDA Approved Indication(s)

Baxdela is indicated in adults for the treatment of:

- **Acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms:**
  - **Gram-positive organisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus*, *Staphylococcus lugdunensis*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), *Streptococcus pyogenes*, and *Enterococcus faecalis***
  - **Gram-negative organisms: *Escherichia coli*, *Enterobacter cloacae*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa***
- **Community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms:**
  - **Gram-positive organisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible [MSSA] isolates only)**
  - **Gram-negative organisms: *Klebsiella pneumoniae*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, and *Haemophilus arainfluenzae***
  - **Other organisms: *Chlamydia pneumoniae*, *Legionella pneumophila*, and *Mycoplasma pneumoniae***

Policy/Criteria

Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Baxdela is medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Acute Bacterial Skin and Skin Structure Infection or Community-Acquired Bacterial Pneumonia (must meet all):

1. **Diagnosis of ABSSSI or CABP;**
2. **Age ≥ 18 years;**

3. **Member meets one of the following (a or b):**
   a. **Request is for continuation of therapy initiated in an acute care hospital from which member was discharged;**
   b. **Both of the following (i and ii):**
      i. **Culture and sensitivity (C&S) report for the current infection shows isolated pathogen is susceptible to delafloxacin, unless provider submits documentation that obtaining a C&S report is not feasible;**
      ii. **Member meets one of the following (a, b, or c):**
         a) **Failure of ≥ 2 formulary antibiotics, one of which must be a fluoroquinolone, to which the isolated pathogen is susceptible (if available) per C&S report, unless all are contraindicated or clinically significant adverse effects are experienced;**
         b) **C&S report shows resistance or lack of susceptibility of the isolated pathogen to all formulary antibiotics FDA-approved for member's diagnosis;**
         c) **If provider documents that obtaining a C&S report is not feasible: Failure of ≥ 2 formulary antibiotics indicated for member's diagnosis (if available), one of which must be a fluoroquinolone, unless all are contraindicated or clinically significant adverse effects are experienced;**
4. **Dose does not exceed the following:**
   a. **IV: 600 mg (2 vials) per day;**

Approval duration: Duration of request, up to 14 days (ABSSSI), or up to 10 days (CABP) of total treatment, whichever is less

B. Other diagnoses/indications
1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. Continued Therapy
A. All Indications in Section I (must meet all):
1. **Member meets one of the following (a or b):**
   a. **Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;**
   b. **Request is for continuation of therapy initiated in an acute care hospital from which member was discharged;**
2. **Member is responding positively to therapy;**
3. **Member has not received more than the indicated therapy duration for current infection (a or b):**
   a. **ABSSSI: ≥ 14 days;**
   b. **CABP: ≥ 10 days;**
4. **If request is for a dose increase, new dose does not exceed the following:**
   a. **IV: 600 mg (2 vials) per day;**

Approval duration: Up to 14 days (ABSSSI) or up to 10 days (CABP) of total treatment

B. Other diagnoses/indications (must meet 1 or 2):
1. **Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.**
   Approval duration: Duration of request or 14 days (whichever is less); or
2. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – LA.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ABSSSI: acute bacterial skin and skin structure infection
CABP: community-acquired bacterial pneumonia
C&S: culture & sensitivity
FDA: Food and Drug Administration
MRSA: methicillin-resistant *Staphylococcus aureus*
MSSA: methicillin-susceptible *Staphylococcus aureus*

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Therapeutic alternatives include formulary fluoroquinolones or other antibiotics that are indicated for member's diagnosis and have sufficient activity against the offending pathogen at the site of the infection.		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- **Contraindication(s): known hypersensitivity to Baxdela or other fluoroquinolones**
- **Boxed warning(s): serious adverse reactions including tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis**

V. Dosage and Administration

Indication	Dosing Regimen	Total Duration	Maximum Dose
ABSSSI	• **IV: 300 mg IV q12h**	**5 to 14 days**	**IV: 600 mg/day**

Indication	Dosing Regimen	Total Duration	Maximum Dose
CABP	• IV: 300 mg IV q12h, then *switch* to 450 mg PO q12h	5 to 10 days	

VI. Product Availability

- Lyophilized powder in a single dose vial for injection: 300 mg

VII. References

1. Baxdela Prescribing Information. Lincolnshire, IL: Melinta Therapeutics, Inc.; October 2020. Available at: www.baxdela.com. Accessed November 11, 2020.
2. Metley JP, Waterer GW, Long AC, et al. Diagnosis and treatment of adults with community-acquired pneumonia. An official clinical practice guideline of the American Thoracic Society and Infectious Diseases Society of America. Am J Respir Crit Care Med. 2019 Oct 1;200(7):e45-e67.
3. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the Infectious Diseases Society of America. Clin Infect Dis 2014; April 14;59(2):10-52

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9462	Injection, delafloxacin, 1 mg

Reviews, Revisions, and Approvals	Date
Converted corporate to local policy	03.2021

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical

policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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