Clinical Policy: Delafloxacin (Baxdela)

Reference Number: ERX.NPA.54
Effective Date: 12.01.17
Last Review Date: 02.21
Line of Business: Commercial, Medicaid

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

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 one of the following (a or b):
   a. IV: 600 mg (2 vials) per day;
   b. PO: 900 mg (2 tablets) 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 a health plan affiliated with Envolve Pharmacy Solutions 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 one of the following (a or b):
   a. IV: 600 mg (2 vials) per day;
   b. PO: 900 mg (2 tablets) 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 14 days (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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 not be a formulary agent and 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	• PO: 450 mg PO q12h • IV: 300 mg IV q12h • IV/PO: 300 mg IV q12h, then *switch* to 450 mg PO q12h	5 to 14 days	PO: 900 mg/day IV: 600 mg/day
CABP		5 to 10 days	

VI. Product Availability
- Tablet: 450 mg
- 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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.01.17	11.17
1Q 2019 annual review: clarified that requirement for C&S report is for the current infection; clarified that pathogen susceptibility to antibiotics be demonstrated via C&S report; clarified that requirement for failure of antibiotics is contingent upon existence of antibiotics for the susceptible pathogen/member's indication; added 'lack of susceptibility' as an alternative to demonstrating resistance on C&S; added criterion to allow member to continue treatment if it was started in an acute care hospital and member was discharged; references reviewed and updated.	10.30.18	02.19
1Q 2020 annual review: criteria added for new FDA approved indication: CABP; updated dosage and administration table to distinguish between treatment durations for ABSSSI and CABP; references reviewed and updated.	12.03.19	02.20
1Q 2021 annual review: no significant changes; updated Appendix B; references reviewed and updated.	11.11.20	02.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.