Clinical Policy: Delafloxacin (Baxdela)

Reference Number: PA.CP.PMN.115
Effective Date: 10.17.18
Last Review Date: 01.19

Coding Implications
Revision Log

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 susceptible isolates of the following:

- 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*.

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.

It is the policy of health plans affiliated with PA Health & Wellness® that Baxdela is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Bacterial Skin and Skin Structure Infection (must meet all)**:**

1. Diagnosis of ABSSSI;
2. 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 a gram-positive or gram-negative organism 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 obtain 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;

3. 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 or up to 14 days 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): PA.CP.PMN.53

II. Continued Therapy

A. Acute Bacterial Skin and Skin Structure Infection (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   b. Request is for continuation of therapy initiated in an acute care hospital from which member was discharged;
2. Member has not received ≥ 14 days of therapy for current infection;
3. 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 of total treatment

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   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): PA.CP.PMN.53

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 policies – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ABSSSI: acute bacterial skin and skin structure infection
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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Therapeutic alternatives include formulary 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	Maximum Dose
ABSSSI	Oral dosage: 450 mg PO every 12 hours for a total duration of 5 to 14 days IV dosage: 300 mg IV every 12 hours for a total duration of 5 to 14 days	PO: 900 mg/day IV: 600 mg/day

VI. Product Availability

- Tablets: 450 mg
- Lyophilized powder in a single dose vial for injection: 300 mg

VII. References

1. Baxdela Prescribing Information. Lincolnshire, IL. Melinta Therapeutics, Inc.; May 2018. Available at: www.baxdela.com. Accessed October 30, 2018.
2. Infectious Diseases Society of America. Available at: http://www.idsociety.org/Organ_System/. Accessed October 30, 2018.
3. .

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	P&T Approval Date
Policy created	10/18	
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/availability of antibiotics for the susceptible pathogen/member's indication; 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.	01/19	