

## **Clinical Policy: Delafloxacin (Baxdela)**

Reference Number: CP.PMN.115

Effective Date: 08.01.17

Last Review Date: 02.19

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<sup>®</sup>) 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 Centene Corporation<sup>®</sup> 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. Age  $\geq$  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 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  $\geq$  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  $\geq 2$  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 or up to 14 days of total treatment, whichever is less**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

**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 Centene 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  $\geq 14$  days of therapy for current infection;
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 of total treatment**

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

1. Currently receiving medication via Centene 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 for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.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 policies – CP.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	MRSA: methicillin-resistant <i>Staphylococcus aureus</i>
C&S: culture & sensitivity	MSSA: methicillin-susceptible <i>Staphylococcus aureus</i>
FDA: Food and Drug Administration	

*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<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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](http://www.baxdela.com). Accessed October 30, 2018.

2. Infectious Diseases Society of America. Available at:  
[http://www.idsociety.org/Organ\\_System/](http://www.idsociety.org/Organ_System/). Accessed October 30, 2018.

**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	08.01.17	11.17
4Q 2018 annual review: no significant changes; references reviewed and updated.	08.14.18	11.18
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.	10.30.18	02.19

**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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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