Clinical Policy: Delafloxacin (Baxdela)

Reference Number: CP.PMN.115
Effective Date: 08.01.17
Last Review Date: 11.17
Line of Business: 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
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 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.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® 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 ≥ 18 years;
3. Current culture and sensitivity (C&S) report 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;
4. Member meets one of the following (a or b):
   a. If C&S report is feasible, one of the following:
      i. Failure of ≥ 2 preferred drug list (PDL) antibiotics, one of which must be a fluoroquinolone, to which the isolated pathogen is susceptible, unless all are contraindicated or clinically significant adverse effects are experienced;
      ii. The C&S report shows resistance of the isolated pathogen to ALL PDL antibiotics FDA approved for member's diagnosis;

b. If a C&S report is not feasible via documentation from the provider: The member has tried and failed 2 PDL antibiotic indicated for member's diagnosis, one of which must be a fluoroquinolone, unless all are contraindicated or clinically significant adverse effects are experienced;

5. Dose does not exceed the following:
   a. Intravenous (IV): 600 mg per day;
   b. Oral tablets: 900 mg per day (2 tablets per day).

Approval duration: Duration of request or 14 days (whichever is less)

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member has not received ≥ 14 days of therapy for current/existing infection;
3. If request is for a dose increase, new dose does not exceed the following:
   a. Intravenous (IV): 600 mg per day;
   b. Oral tablets: 900 mg per day (2 tablets per day).

Approval duration: Up to 14 days of therapy (total)

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 CP.PMN.53 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 – 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
IV: intravenous

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	PO: 900 mg per day (2 tablets per day)

	IV dosage: 300 mg IV every 12 hours for a total duration of 5 to 14 days	IV: 600 mg per 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.; June 2017. Available at: www.baxdela.com. Accessed July 23, 2017.
2. Infectious Diseases Society of America. Available at: http://www.idsociety.org/Organ_System/. Accessed July 24, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.01.17	11.17

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.