Clinical Policy: Delafloxacin (Baxdela)

Reference Number: CP.PMN.115
Effective Date: 12.01.17
Last Review Date: 08.23
Line of Business: Commercial, HIM, 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

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® 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 clinically significant adverse effects are experienced or all are contraindicated;
         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 clinically significant adverse effects are experienced or all are contraindicated;
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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a, b, or c):

a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
c. 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and 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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and 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
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 for all relevant lines of business 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

- 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 2021. Available at: www.baxdela.com. Accessed April 12, 2023.
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
J3490	Unclassified drugs
J8499	Prescription drug, oral, non chemotherapeutic, nos

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
HIM line of business added.	05.21.19	08.19
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; references to HIM.PHAR.21 revised to HIM.PA.154; updated HCPCS code; references reviewed and updated.	11.11.20	02.21
1Q 2022 annual review: added Commercial line of business to policy (retire CP.CPA.316); references reviewed and updated.	09.15.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.03.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	10.04.22	02.23
3Q 2023 annual review: no significant changes; added HCPCS code J8499; references reviewed and updated.	04.12.23	08.23

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.