Clinical Policy: Delafloxacin (Baxdela)
Reference Number: ERX,NPA,54
Effective Date: 08.01.17
Last Review Date: 11.17

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 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 (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 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 (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 or ii):
            i. Failure of ≥ 2 formulary 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 formulary 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 formulary 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 ERX,PA,01 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 a health plan affiliated with Envolve Pharmacy Solutions 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 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      FDA: Food and Drug Administration
C&S: culture & sensitivity                          IV: intravenous

Appendix B: Therapeutic Alternatives

Therapeutic alternatives include formulary antibiotics that are indicated for member’s diagnosis and/or have sufficient activity against the offending pathogen at the site of infection. Examples include the following:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>nafcillin</td>
<td>Infection of skin and/or subcutaneous tissue: MSSA: 1-2 g IV every 4 hours; Streptococcal: 1-2 g IV every 4 to 6 hours</td>
<td>12 g</td>
</tr>
<tr>
<td>doxycycline</td>
<td>Infection of skin and/or subcutaneous tissue: 100 mg BID PO</td>
<td>200 mg</td>
</tr>
<tr>
<td>vancomycin</td>
<td>Infection of the skin and/or subcutaneous tissue MRSA: 30 mg/kg/day IV in 2 divided doses</td>
<td>Not to exceed maximum adult daily dose</td>
</tr>
<tr>
<td>trimethoprim/sulfamethoxazole</td>
<td>Infection of the skin and soft tissue: 1-2 DS tablets PO BID</td>
<td>Sulfamethoxazole: 1600 mg  Trimethoprim: 320 mg</td>
</tr>
<tr>
<td>clindamycin</td>
<td>Severe infection of skin and/or subcutaneous tissue: 150 to 300 g orally every 6 hours; use 300 to 450 mg orally every 6 hours for more severe infections</td>
<td>1800 mg</td>
</tr>
<tr>
<td>ciprofloxacin</td>
<td>PO/IVSevere or complicated infection of skin and/or subcutaneous tissue: 400 mg IV every 8 hours for 7 to 14 days</td>
<td>1200 mg</td>
</tr>
<tr>
<td>ivofloxacin</td>
<td>Complicated infection of skin and/or subcutaneous tissue: 750 mg IV/orally every 24 hours for 7 to 14 days</td>
<td>750 mg</td>
</tr>
</tbody>
</table>
Delafloxacin

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>moxifloxacin</td>
<td>Complicated infection of skin and/or subcutaneous tissue: 400 mg orally or IV infusion over 60 minutes every 24 hours for 7 to 21 days</td>
<td>400 mg</td>
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</tbody>
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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.

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSSSI</td>
<td>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</td>
<td>PO: 900 mg per day (2 tablets per day) IV: 600 mg per day</td>
</tr>
</tbody>
</table>

VI. Product Availability

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

VII. References


Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Policy created</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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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.

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