BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/16/17**
SECTION: DRUGS	**LAST REVIEW DATE: 11/16/17**
	LAST CRITERIA REVISION DATE:
	ARCHIVE DATE:

BAXDELA™ (delafloxacin meglumine) oral tablet and intravenous infusion

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

BAXDELA™ (delafloxacin meglumine) oral tablet and intravenous infusion (cont.)

Description:

- **Baxdela** is a fluoroquinolone that exhibits activity against both gram-positive and gram-negative pathogens.
- To reduce the development of drug-resistant bacteria and maintain the effectiveness of Baxdela and other antibacterial drugs, Baxdela should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.
- When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
- The safety and efficacy of Baxdela were based on two phase 3, non-inferiority trials in 1,510 patients with ABSSSI. In both studies, the comparator was the intravenous (IV) combination of vancomycin and aztreonam. The primary endpoint was the objective clinical response at 48 to 72 hours post initiation of treatment, defined as ≥ 20% decrease in lesion size.

  In both studies, Baxdela IV and oral monotherapy was statistically non-inferior to the combination of vancomycin plus aztreonam for the primary endpoint.
- Similar to other fluoroquinolones, Baxdela carries a boxed warning for serious adverse reactions, including tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis.
- Baxdela is contraindicated in patients with known hypersensitivity to delafloxacin or any of the fluoroquinolone class of antibacterial drugs, or any of the components of Baxdela.
- Warnings and precautions of Baxdela include hypersensitivity reactions, *Clostridium difficile*-associated diarrhea, and development of drug-resistant bacteria.
- The most common adverse reactions (incidence ≥ 2%) with Baxdela use were nausea, diarrhea, headache, transaminase elevations, and vomiting.
- The recommended dosage of Baxdela is 300 mg by IV infusion over 60 minutes, every 12 hours or the 450 mg tablet administered orally every 12 hours for 5 to 14 days total duration.
- Baxdela may be initiated as an IV infusion and then switched to the tablet formulation at the discretion of the physician.

  Dose adjustments may be necessary for patients with renal impairment.

Baxdela (delafloxacin meglumine)

Medication class:
Fluoroquinolones

FDA-approved indication(s):
- 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.*

Recommended Dose:
- Administer Baxdela for injection 300 mg by intravenous infusion over 60 minutes, every 12 hours, or a 450-mg Baxdela tablet orally every 12 hours for 5 to 14 days total duration.
- Dosage for patients with renal impairment is based on the estimated glomerular filtration rate (eGFR)

Available Dosage Forms:
- Oral Tablets: 450 mg delafloxacin (equivalent to 649 mg delafloxacin meglumine).
- For Injection: 300 mg of delafloxacin (equivalent to 433 mg delafloxacin meglumine) as a lyophilized powder in a single dose vial for reconstitution and further dilution before intravenous infusion.

Limitations of use:
- To reduce the development of drug-resistant bacteria and maintain the effectiveness of Baxdela and other antibacterial drugs, Baxdela should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

Warnings and Precautions:
- Hypersensitivity Reactions: May occur after first or subsequent doses of Baxdela. Discontinue Baxdela at the first sign of a skin rash or any other sign of hypersensitivity.
- *Clostridium difficile*-associated diarrhea: Evaluate if diarrhea occurs.

BAXDELA™ (delafloxacin meglumine) oral tablet and intravenous infusion (cont.)

Criteria:

- **Criteria for initial therapy:** Baxdela is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 18 years of age or older

  2. A confirmed diagnosis of acute bacterial skin and skin structure infections (ABSSSI)

  3. Current culture and sensitivity (C&S) report shows isolated pathogen is gram- positive or gram-negative organism susceptible to delafloxaicn (unless provider submits valid documentation that obtaining a C&S report is not feasible)

  4. Member meets one of the following:
     a. If **C&S is feasible**, one of the following:
        i. Failure, contraindication or intolerance of at least 2 formulary antibiotics, one of which is fluoroquinolone, to which the isolated pathogen is susceptible
        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 providers: The member has failure, contraindication or intolerance to 2 formulary antibiotics indicated for member's diagnosis, one of which is a fluoroquinolone

Initial approval duration: 300 mg twice daily (IV infusion) for up to 14 days only (MEDICAL BENEFIT ONLY)
450 mg twice daily (28 tablets) for 14 days only
Maximum duration for 14 days only regardless of route of administration

Resources:

Baxdela. Package Insert. Revised by manufacturer 6/2017. Accessed 10/12/17.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.