BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

BAXDELA™ (delafloxacin meglumine) Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for therapy:** Baxdela (delafloxacin meglumine) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with Infectious Disease, Dermatologist, Podiatrist, or Pulmonologist

2. Individual is 18 years of age or older

3. Individual has a confirmed diagnosis of **ONE** of the following:

a. Acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible microorganisms (see Definitions section)

b. Community acquired bacterial pneumonia (CABP) caused by susceptible microorganisms (see Definitions section)

4. Individual meets **ONE** of the following:
   a. **When applicable, to facilitate a hospital discharge**: Individual is transitioning from intravenous Baxdela (delafloxacin) to oral Baxdela (delafloxacin) (the number of days of intravenous use must be documented on the request)
   b. **Non-hospital discharge for an out-patient infection ONE** of the following:
      i. **If C&S is available**, **ONE** of the following:
         1. Failure, contraindication per FDA label, intolerance, or is not a candidate for at least 2 oral formulary antibiotics indicated for individual's diagnosis, one of which was a fluoroquinolone and the isolated pathogen was shown to be resistant to formulary antibiotics but is susceptible to Baxdela (delafloxacin) only
         2. The C&S report shows resistance of the isolated pathogen to **ALL** oral formulary antibiotics indicated for individual's diagnosis but is susceptible to Baxdela (delafloxacin) only
      ii. **If C&S report is not available:,** Documentation from the provider that the individual has failure, contraindication per FDA label, intolerance, or is not a candidate for 2 oral formulary antibiotics indicated for individual's diagnosis, one of which is a fluoroquinolone and that the infection is strongly suspected to be caused by a pathogen that would be susceptible to Baxdela (delafloxacin) only

5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual **does not have ANY** of the following:
   a. A history of myasthenia gravis
   b. Tendinitis or tendon rupture from previous use of any fluoroquinolone
   c. Arthralgia from previous use of any fluoroquinolone
   d. Myalgia from previous use of any fluoroquinolone
   e. Peripheral neuropathy from previous use of any fluoroquinolone
   f. Hallucinations, anxiety, insomnia, severe headaches, and confusion from previous use of any fluoroquinolone
   g. End stage renal disease (eGFR < 15 mL/min/1.73 m^2) or is on hemodialysis

7. Individual is not currently taking any other drug(s) which cause severe adverse reactions or any drug interaction(s) requiring discontinuation

8. There are **NO** FDA-label contraindications such as known hypersensitivity to any fluoroquinolone

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Approval duration:

For ABSSSI: Maximum duration 14 days only regardless of route of administration (includes any in-patient days)

For CABP: Maximum duration 10 days only regardless of route of administration (includes any in-patient days)

IV infusions or injections: MEDICAL BENEFIT ONLY: 14 days for ABSSSI and 10 days for CABP

No refills will be authorized

Any request for refill will be reviewed as a new request

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

Description:

Baxdela (delafloxacin meglumine) is indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: *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*, *Enterococcus faecalis*, *Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* and *Pseudomonas aeruginosa.*

Baxdela (delafloxacin meglumine) is also indicated in adults for the treatment of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible [MSSA] isolates only), *Klebsiella pneumoniae*, *Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae*, *Chlamydia pneumoniae*, *Legionella pneumophila,* and *Mycoplasma pneumoniae.*

Baxdela (delafloxacin meglumine) 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 (meglumine) and other antibacterial drugs, Baxdela (meglumine) 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.

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Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Acute bacterial skin and skin structure infection (ABSSSI):

- A bacterial infection of the skin with a lesion size area of at least 75 cm^2 (measured by the area of redness, edema, or induration).
- The following infections are defined as ABSSSIs:
  - *Cellulitis/erysipelas*: a diffuse skin infection characterized by spreading areas of redness, edema, and/or induration
  - *Wound infection*: an infection characterized by purulent drainage from a wound with surrounding redness, edema, and/or induration
  - *Major cutaneous abscess*: an infection characterized by a collection of pus within the dermis or deeper that is accompanied by redness, edema, and/or induration

Susceptible microorganisms:

- ABSSSI
  - *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*, *Enterococcus faecalis*, *Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* and *Pseudomonas aeruginosa*
- CABP
  - *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible [MSSA] isolates only), *Klebsiella pneumoniae*, *Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae*, *Chlamydia pneumoniae*, *Legionella pneumophila,* and *Mycoplasma pneumoniae*

Oral antimicrobial therapy for treatment of skin and soft tissue infections due to methicillin-resistant Staphylococcus aureus (MRSA)	
Treatment	Adult dose
Preferred agents - choice between the preferred oral antibiotic agents is guided by clinical circumstances that includes local antibiotic resistance patterns, allergy history, and use of other medications	
Trimethoprim-Sulfamethoxazole	1 or 2 DS twice daily (with normal renal function)
Clindamycin	450 mg three times daily
Doxycycline	100 mg once daily
Minocycline	200 mg once, then 100 mg twice daily
Alternative agents - should be reserved for patients who do not respond to or cannot tolerate the preferred agents	
Linezolid	600 mg twice daily

Tedizolid	200 mg once daily
Delafloxacin	450 mg twice daily
Omadacycline	300 mg once daily

Resources:

Baxdela (delafloxacin meglumine) product information, revised by Melinta Therapeutics Inc 06-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed June 26, 2025.

Spelman D, Baddour LM. Acute cellulitis and erysipelas in adults: Treatment. In: UpToDate, Nelson S, Hall KK (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through July 2025. Topic last updated June 13, 2025. Accessed August 14, 2025.

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