BlueCross BlueShield Arizona

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PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**11/16/2017**
LAST REVIEW DATE:	**11/18/2021**
LAST CRITERIA REVISION DATE:	**11/19/2020**
ARCHIVE DATE:	

BAXDELA™ (delafloxacin meglumine)

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)

Criteria:

- **Criteria for therapy:** Baxdela (delafloxacin meglumine) 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. A confirmed diagnosis of **ONE** of the following:
    a. Acute bacterial skin and skin structure infections (ABSSSI)
    b. Community acquired bacterial pneumonia (CABP)

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 or for an out-patient infection ONE** of the following:
        i. **If C&S is feasible**, *one* of the following:
            1. Failure, contraindication or intolerance of at least 2 formulary antibiotics, 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** formulary antibiotics but is susceptible to Baxdela (delafloxacin) only

        ii. **If C&S report is not feasible,** documentation from the provider that the member has failure, contraindication or intolerance to 2 formulary antibiotics indicated for member'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. Individual does not have end stage renal disease (eGFR < 15 mL/min/1.73 m^2) or is on hemodialysis

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

7. There are **NO** FDA-label contraindications, such as
    a. Known hypersensitivity to any fluoroquinolone

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Approval duration:
For ABSSSI: Maximum duration 14 days only regardless of route of administration
For CABP: Maximum duration 10 days only regardless of route of administration
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 a Non-cancer Medications**
2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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:

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

Resources:

Baxdela (delafloxacin meglumine) product information, revised by Melinta Therapeutics Inc 06-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed September 09, 2021.

Spelman D, Baddour LM. Cellulitis and skin abscess in adults: Treatment. In: UpToDate, Lowry FD, Baron EL (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed September 09, 2021.

Lowry FD. Methicillin-resistant Staphylococcus aureus (MRSA) in adults: Treatment of skin and soft tissue infections. In: UpToDate, Spelman D, Baron L (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed September 09, 2021.

Lowry FD. Methicillin-resistant Staphylococcus aureus (MRSA) in adults: Treatment of bacteremia. In: UpToDate, Spelman D, Baron L (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed September 09, 2021.

Ramirez JA. Overview of community-acquired pneumonia in adults. In: UpToDate, File TM, Bond S (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed September 09, 2021.

File TM. Treatment of community-acquired pneumonia in adults in the outpatient setting. In: UpToDate, Ramirez JA, Bond S (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed September 09, 2021.