Pharmacy Medical Necessity Guidelines:
Baxdela™ (delafloxacin) tablets

Effective: February 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

The fluoroquinolone Baxdela (delafloxacin) tablet is approved for use in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. In order to reduce the development of drug-resistant bacteria and maintain the effectiveness of Baxdela, it should only be used to treat infections that are proven or strongly suspected to be caused by bacteria.
The following isolates are susceptible to Baxdela:

Gram-positive organisms	• *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates) • *Staphylococcus haemolyticus* • *Staphylococcus lugdunenesis* • *Streptococcus agalactiae* • *Streptococcus anginosus* Group (including *Streptococcus anginosus, Streptococcus intermedius,* and *Streptococcus constellatus*) • *Streptococcus pyogenes* • *Enterococcus faecalis*
Gram-negative organisms	• *Escherichia coli* • *Enterobacter cloacae* • *Klebsiella pneumoniae* • *Pseudomonas aeruginosa*

The oral dose of Baxdela for the treatment of ABSSSI is 450 mg every 12 hours for 5 to 14 days total duration.

Baxdela 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*
- *Mycoplasma pneumoniae*

The oral dose of Baxdela for the treatment of CABP is 450 mg every 12 hours for 5-10 days.

COVERAGE GUIDELINES

The plan may authorize coverage of Baxdela (delafloxacin) tablets for Members when the following criteria are met:

Initial Authorization:

1. Member has been started on Baxdela injection and is switching to Baxdela tablet or was stable on Baxdela in an inpatient setting

OR

2. Member meets **ALL** of the following:
    a. Member has a diagnosis of Acute Bacterial Skin and Skin Structure Infection (ABSSSI) or community-acquired bacterial pneumonia (CABP)

    AND

    b. Member has a had an inadequate response, adverse reaction, or contraindication to at least two covered generic antibiotics for the pathogen **OR** the prescriber indicates clinical inappropriateness of treatment with at least two generic covered antibiotics for the pathogen

Reauthorization:

1. The Member has been re-assessed for this condition, and continued therapy with the medication is considered medically necessary.

LIMITATIONS

1. Baxdela (delafloxacin) tablet will be approved for 14 days for the treatment of ABSSSI and 10 days for CABP. Subsequent approval will require a new authorization.

CODES

None

REFERENCES

1. Baxdela (delafloxacin) tablets [prescribing information]. Lincolnshire, IL: Melinta Therapeutics, Inc; June 2021.
2. File TM. Treatment of community-acquired pneumonia in adults who require hospitalization. UpToDate. Available at: www.uptodate.com. Accessed2 February 2026.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2023: No changes.
2. February 13, 2024: Effective March 1, 2024, updated fax number for RxUM. Updated the reauthorization criteria to remove the requirement that the member must have had an office visit.
3. February 11, 2025: No changes
4. February 10, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of

benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic. Provider Services