Pharmacy Medical Necessity Guidelines: Baxdela™ (delafloxacin) tablets

Effective: February 11, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

The fluoroquinolone Baxela (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 methilcillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates) • *Staphylococcus haemolyticus* • *Staphylococcus lugdenesis* • *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 pneomoniae*

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:

1. Member has been started on Baxdela injection and is switching to Baxdela tablet

OR

2. Member has a diagnosis of Acute Bacterial Skin and Skin Structure Infection (ABSSSI) of community-acquired bacterial pneumonia (CABP)

AND

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

Upon renewal,

1. The Member has had an office visit and 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; October 2019.

APPROVAL HISTORY

April 10, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. March 12, 2019: Administrative changes made to template.
2. February 11, 2020: Added the indication of community acquired bacterial pneumonia (CABP) to the MNG.

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