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5.01.054

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Anti-infective Agents	**Original Policy Date:**	November 1, 2019
Subject:	Baxdela	**Page:**	1 of 5

Last Review Date: June 13, 2024

Baxdela

Description

Baxdela (delafloxacin)

Background
Baxdela (delafloxacin) belongs to the fluoroquinolone class of antibacterial drugs and is anionic in nature which treats specific bacterial infections. The antibacterial activity of Baxdela is due to the inhibition of both bacterial topoisomerase IV and DNA gyrase (topoisomerase II) enzymes which are required for bacterial DNA replication, transcription, repair, and recombination. Baxdela exhibits a concentration-dependent bactericidal activity against gram-positive and gram-negative bacteria in vitro (1).

Regulatory Status
FDA-approved indications: Baxdela is a fluoroquinolone antibacterial indicated for the treatment of adults with the following infections caused by designated susceptible bacteria:

1. Acute Bacterial Skin and Skin Structure Infections (ABSSSI)
2. Community-Acquired Bacterial Pneumonia (CABP)

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 (1).

Baxdela is a fluoroquinolone. Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions from different body systems that can occur together in the same patient. Commonly seen adverse reactions include tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion). These

reactions could occur within hours to weeks after starting a fluoroquinolone. Patients of any age or without pre-existing risk factors have experienced these adverse reactions. Discontinue Baxdela immediately at the first signs or symptoms of any serious adverse reaction. In addition, avoid the use of fluoroquinolones, including Baxdela, in patients who have experienced any of these serious adverse reactions associated with fluoroquinolones (1).

Fluoroquinolones also have neuromuscular blocking activity and may exacerbate muscle weakness in persons with myasthenia gravis. Post-marketing serious adverse reactions, including death and requirement for ventilator support, have been associated with fluoroquinolone use in persons with myasthenia gravis. Avoid Baxdela in patients with known history of myasthenia gravis (1).

Clostridium difficile-associated diarrhea (CDAD) has been reported in users of nearly all systemic antibacterial drugs, including Baxdela, with severity ranging from mild diarrhea to fatal colitis. Treatment with antibacterial agents can alter the normal flora of the colon and may permit overgrowth of *C. difficile*. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against *C. difficile* should be discontinued, if possible. Appropriate measures such as fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated (1).

The safety and efficacy of Baxdela formulations given for longer than 14 days for acute bacterial skin and skin structure infections have not been evaluated in controlled clinical trials (1).

The safety and efficacy of Baxdela formulations given for longer than 10 days for community acquired bacterial pneumonia have not been evaluated in controlled clinical trials (1).

The safety and effectiveness of Baxdela in pediatric patients less than 18 years of age have not been established (1).

Related policies
Nuzyra, Sivextro, Xenleta, Zyvox

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Baxdela may be considered **medically necessary** if the conditions indicated below are met.

Baxdela may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have an infection caused by **OR** strongly suspected to be caused by **ONE** of the following:

1. Acute Bacterial Skin and Skin Structure Infections (ABSSSI)
   - *Staphylococcus aureus* (methicillin-susceptible)
   - *Staphylococcus aureus* (methicillin-resistant)
   - *Staphylococcus haemolyticus*
   - *Staphylococcus lugdunensis*
   - *Streptococcus agalactiae*
   - *Streptococcus anginosus* (entire group)
   - *Streptococcus pyogenes*
   - *Enterococcus faecalis*
   - *Escherichia coli*
   - *Enterobacter cloacae*
   - *Klebsiella pneumoniae*
   - *Pseudomonas aeruginosa*

2. Community-Acquired Bacterial Pneumonia (CABP)
   - *Streptococcus pneumoniae*
   - *Staphylococcus aureus* (methicillin susceptible isolates only)
   - *Klebsiella pneumoniae*
   - *Escherichia coli*
   - *Pseudomonas aeruginosa*
   - *Haemophilus influenza*
   - *Haemophilus parainfluenzae*
   - *Chlamydia pneumoniae*
   - *Legionella pneumophila*
   - *Mycoplasma pneumoniae*

AND the following:

1. Inadequate treatment response, intolerance, or contraindication to a first-line

antibiotic, such as a macrolide, fluoroquinolone, beta-lactam, or tetracycline

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Duration 14 day supply every 365 days

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Baxdela is a fluoroquinolone antibacterial indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) or community-acquired bacterial pneumonia (CABP) caused by designated susceptible bacteria. 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. Baxdela belongs to the fluoroquinolone class of antibacterial drugs which have been associated with disabling and potentially irreversible serious adverse reactions from different body systems that can occur together in the same patient. Commonly seen adverse reactions include tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects. *Clostridium difficile*-associated diarrhea (CDAD) has been also reported in users of nearly all systemic antibacterial drugs, including Baxdela, with severity ranging from mild diarrhea to fatal colitis (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Baxdela while maintaining optimal therapeutic outcomes.

References

1. Baxdela [package insert]. Lincolnshire, IL: Melinta Therapeutics Inc; June 2021.

Policy History

Date	Action
November 2019	New Addition
December 2019	Annual review. Revised requirement to be infection caused by or strongly suspected to be caused by one of the following organisms per SME
March 2020	Annual review. Added requirement to t/f a first-line antibiotic per SME
March 2021	Annual review and reference update
March 2022	Annual review and reference update
March 2023	Annual review. Changed policy number to 5.01.054
June 2023	Annual review
March 2024	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.