

Commercial/Healthcare Exchange PA Criteria

Effective: January 31, 2018

Prior Authorization: Baxdela

Products Affected: Baxdela (delafloxacin) oral tablets

Medication Description:

Baxdela (delafloxacin) is indicated for the treatment of acute bacterial skin and skin structure infections in adult patients caused by susceptible organisms, including *Staphylococcus aureus* (methicillin-resistant and methicillin-susceptible isolates), *S haemolyticus*, *S lugdunensis*, *Streptococcus agalactiae*, *S anginosus* group (including *S anginosus*, *S intermedius*, and *S constellatus*), *S pyogenes*, *Enterococcus faecalis*, *Escherichia coli*, *Enterobacter cloacae*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*.

Covered Uses:

1. Acute bacterial skin and skin structure infections (ABSSI) in adult patients caused by susceptible organisms.
2. Community-acquired bacterial pneumonia (CABP) in adult patients caused by susceptible organisms.

Exclusion Criteria:

1. Patients with known hypersensitivity to delafloxacin or any of the fluoroquinolone class of antibacterial drugs

Required Medical Information:

1. Diagnosis
2. Previous therapy tried/failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, an infectious disease specialist.

Coverage Duration: 14 days

Other Criteria:

- A. Patient has a diagnosis of ABSSI or CABP; **AND**
- B. Culture and Sensitivity (C&S) testing shows isolated pathogen that is susceptible to delafloxacin **[documentation required]**:
 - a. **ABSSI:** *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*.
 - b. **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*; **AND**
- C. The C&S report shows resistance of the isolated pathogen to ALL formulary antibiotics FDA approved for member's diagnosis

References:

1. Product Information: BAXDELA(TM) oral tablets, intravenous injection, delafloxacin oral tablets, intravenous injection. Melinta Therapeutics, Inc (per FDA), Lincolnshire, IL, 2017.
2. Kingsley J, Mehra P, Lawrence LE, et al: A randomized, double-blind, Phase 2 study to evaluate subjective and objective outcomes in patients with acute bacterial skin and skin structure infections treated with delafloxacin, linezolid or vancomycin. J Antimicrob Chemother 2016; 71(3):821-829.

Policy Revision history:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	1/19/2016
2	Annual Review	No changes	N/A	01/2018
2	Update	Updated criteria to reflect FDA label	Covered Uses Exclusion Criteria Other Criteria	1/14/2020

