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