ALASKA MEDICAID
Prior Authorization Criteria

Baxdela™ (delafloxacin)

FDA INDICATIONS AND USAGE[1]

Baxdela is a fluoroquinolone antibiotic used to treat susceptible gram-positive and gram-negative acute bacterial skin and skin structure infections (ABSSSI). This includes the Gram-positive organisms Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillinsusceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis and the Gram-negative organisms Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa.

APPROVAL CRITERIA[1,2]

1. Patient is 18 years of age or older **AND;**
2. Patient has a confirmed diagnosis of acute bacterial skin and skin structure infection **AND;**
3. A culture report showing that the pathogen is one listed in the FDA indications above or provides documentation that a culture is not feasible **AND;**
4. Patient has tried and failed at least two other antibiotics, one of which must be a fluoroquinolone, indicated for the patient diagnosis **OR**;
5. Patient has a contraindication or intolerance to all other Alaska Medicaid covered antibiotics used to treat ABSSSI.

DENIAL CRITERIA[1,2]

1. Patient is less than 18 years of age **OR**;
2. Patient does not have confirmed diagnosis of acute bacterial skin and skin structure infection **OR**;
3. A culture report showing that the pathogen is not one listed in the FDA indications above or has not provided documentation that a culture is not feasible **OR**;
4. Patient has not tried and failed at least two other antibiotics, one of which must be a fluoroquinolone, indicated for the patient diagnosis **OR**;
5. Patient does not have a contraindication or intolerance to all other Alaska Medicaid covered antibiotics used to treat ABSSSI.

CAUTIONS[1]

- Fluoroquinolones have known to cause tendon rupture, peripheral neuropathy, and central nervous system effects.
- Baxdela should be avoided in patients with a known history of myasthenia gravis.
- Baxdela should be discontinued at the first sign of rash or other sign of hypersensitivity reaction.

DURATION OF APPROVAL

- Approval: 14 days

QUANTITY LIMITS

- 28 - 450mg tablets (twice daily dosing)
- IV Baxdela should be billed through the medical benefit.

REFERENCES / FOOTNOTES:

1. Baxdela [Package Insert]. Lincolnshire, IL. Melinta Therapeutics, Inc.; 2017. Available at: www.baxdela.com. Accessed December 7, 2018.
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.