

ALASKA MEDICAID
Prior Authorization Criteria

Baxdela™ (delafloxacin)

FDA INDICATIONS AND USAGE¹

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 methicillin-susceptible [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.

CAUTIONS¹

- 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.

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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.