ALASKA MEDICAID
Prior Authorization Criteria

Baxdela™ (delafloxacin)

FDA INDICATIONS AND USAGE
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. 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. 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
• 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: