UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Baxdela

Program	Prior Authorization
Medication	Baxdela (delafloxacin) oral tablets
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	1/2020
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

1. Background:

Baxdela is indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: *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.*

Baxdela is also indicated in adults for the treatment of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: S*treptococcus 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.*

2. Coverage Criteria:

A. <u>Community-acquired bacterial pneumonia</u>

1. **Baxdela** will be approved based on the following:

a. **<u>One</u>** of the following:

(1) For continuation of therapy upon hospital discharge

-OR-

(2) As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

-OR-

(3) All of the following:

(a) Diagnosis of community-acquired bacterial pneumonia (CABP)

-AND-

(b) Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Baxdela

-AND-

(c) History of failure, contraindication, or intolerance to **three** of the following antibiotics or antibiotic regimens:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Authorization will be issued for up to 10 days.

B. Acute Bacterial Skin and Skin Structure Infections

1. **Baxdela** will be approved based on the following:

a. **One** of the following:

(1) For continuation of therapy upon hospital discharge

-OR-

(2) As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

-OR-

(3) All of the following:

(a) One of the following diagnoses:

i. Both of the following:
- Acute bacterial skin and skin structure infections
- Infection caused by methicillin-resistant *Staphylococcus aureus* (MRSA) documented by culture and sensitivity report

-OR-

ii. Both of the following:
- Empirical treatment of patients with acute bacterial skin and skin structure infections
- Presence of MRSA infection is likely

-AND-

(b) History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

-AND-

(c) History of failure, contraindication, or intolerance to **one** of the following antibiotics:
- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline
- Clindamycin

-OR-

(4) All of the following:

(a) Diagnosis of acute bacterial skin and skin structure infections

-AND-

(b) Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Baxdela

-AND-

(c) History of failure, contraindication, or intolerance to **three** of the following antibiotics:
- A penicillin
- A cephalosporin
- A tetracycline
- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- Clindamycin

Authorization will be issued for up to 14 days.

C. Off-Label Uses

1. **Baxdela** will be approved based on one of the following:

a. For continuation of therapy upon hospital discharge

-OR-

b. As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

-OR-

c. The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)

Authorization duration based on provider and IDSA recommended treatment durations, up to 6 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Baxdela [package insert]. Lincolnshire, Illinois: Melinta Therapeutics, Inc.; October 2020.
2. Metlay JP, Waterer GW, Long AC et al. Diagnosis and Treatment of Adults with Community-acquired Pneumonia: An Official Clinical Practice Guideline of the

American Thoracic Society and Infectious Disease Society of America, *Am J Respir Crit Care Med*. 2019 Oct; 200(7): e45-67.
3. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 Update by the Infectious Diseases Society of America. Clin Infect Dis. 2014;59(2):e10-52.

Program	Prior Authorization –Baxdela (delafloxacin)
Change Control	
Date	Change
1/2020	New policy
1/2021	Annual review, updated references.