Effective Date **1/15/2024**
Next Review Date… **1/15/2025**
Coverage Policy Number **IP0373**

Delafloxacin

Table of Contents

Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for oral delafloxacin (Baxdela®).

The use of intravenous delafloxacin is not addressed in this coverage policy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Delafloxacin (Baxdela) is considered medically necessary when ONE of the following is met:

1. **Treatment of Adults with Acute Bacterial Skin and Skin Structure Infections (ABSSSI).** Individual meets the following criteria:
    A. Documentation of failure, contraindication, or intolerance to an appropriate first-line therapy (for example: ceftriaxone, cefazolin, cephalexin, clindamycin, linezolid, piperacillin-tazobactam, sulfamethoxazole-trimethoprim (SMX-TMP), vancomycin)

2. **Treatment of Adults with Community-Acquired Bacterial Pneumonia (CABP).** Individual meets the following criteria:
    A. Documentation of failure, contraindication, or intolerance to an appropriate first-line therapy [for example: amoxicillin, doxycycline, macrolide (i.e., azithromycin or clarithromycin), respiratory fluoroquinolone (i.e., levofloxacin or moxifloxacin) or combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline]

3. **Continuation of Delafloxacin (Baxdela) Therapy.** Individual meets **ONE** of the following criteria:
    A. Individual is transitioning from intravenous (IV) delafloxacin to oral therapy
    B. The individual was started on oral delafloxacin in an inpatient facility and is continuing therapy

---

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

Authorization Duration

Initial approval duration:
1. Acute bacterial skin and skin structure infections (ABSSSI): up to 14 days
2. Community-acquired bacterial pneumonia (CABP): up to 10 days

Reauthorization approval duration: not applicable

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
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: 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.

The prescribing information notes, to reduce the development of drug-resistant bacteria and maintain the effectiveness of Baxdela and other antibacterial drugs, Baxdela should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the

absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Safety
As with other fluoroquinolones, there is a Boxed Warning regarding disabling and potentially irreversible serious adverse reactions including tendinitis and tendon rupture, peripheral neuropathy, and central nervous system (CNS) effects. Fluoroquinolones may also exacerbate muscle weakness in patients with myasthenia gravis.

References

1. Baxdela™ [prescribing information]. Melinta Therapeutics, Inc; 2021. Assessed October 2, 2023. https://www.baxdela.com/docs/baxdela-prescribing-information.pdf