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Policy Number: C16332-A

Baxdela (delafloxacin)

PRODUCTS AFFECTED

Baxdela (delafloxacin)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Acute bacterial skin and skin structure infection (ABSSSI), Community-acquired bacterial pneumonia (CABP)

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION AND COMMUNITY ACQUIRED PNEUMONIA:

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1. Documentation member has an infection caused by or strongly suspected to be caused by a type of pathogen and site of infection within the FDA label
AND
2. (a) FOR COMMUNITY ACQUIRED PNEUMONIA (CABP): Documentation of inadequate treatment response, serious side effects, contraindication, or non- susceptibility to a first-line antibiotic treatment, such as a macrolide, alternative fluoroquinolone, beta-lactam, or tetracycline
OR
(b) FOR ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION (ABSSSI): Documentation of inadequate treatment response, serious side effects, contraindication, or non- susceptibility to a first-line antibiotic treatment for the site of infection such as a beta-lactam, tetracycline, clindamycin, trimethoprim-sulfamethoxazole, alternative fluoroquinolone, or vancomycin
OR
(c) Request is for continuation of therapy that was started at an inpatient setting (within the last 14 days) and member is at time of request transitioning to an outpatient site of care [DISCHARGE DOCUMENTATION REQUIRED WHICH INCLUDES INFECTIOUS DISEASE PRESCRIBER RECOMMENDED DURATION OF THERAPY, START AND END DATE]
AND
3. FOR IV REQUESTS ONLY: Documentation of medically necessary use of IV Baxdela (delafloxacin) for the current active infection instead of oral Baxdela (delafloxacin)

CONTINUATION OF THERAPY:

N/A: Each new infection treatment should be a new review

DURATION OF APPROVAL:

Initial authorization: Up to a total treatment duration of 14 days, Continuation of Therapy: NA

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with an infectious disease specialist. [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

ABSSSI: 300mg IV every 12 hours OR 450mg orally every 12 hours for 5 to 14 days

CABP:

300mg IV every 12 hours OR 450mg orally every 12 hours for 5 to 10 days

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral, Intravenous

DRUG CLASS:

Fluoroquinolone

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FDA-APPROVED USES:

Indicated for the treatment of adults with the following infections caused by designated susceptible bacteria:

- Acute Bacterial Skin and Skin Structure Infections (ABSSSI)
- Community-Acquired Bacterial Pneumonia (CABP)

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 bacteria.

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 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*.

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Efficacy

The PROCEED studies were two phase III, multicenter, multinational, double-blind, double-dummy, non-inferiority trials that assessed the efficacy of Baxdela versus vancomycin 15 mg/kg actual body weight plus aztreonam in adults with ABSSSI. Patients in Trial 1 received 300 mg Baxdela via intravenous infusion every 12 hours for five to 14 days. The mean duration of treatment with delafloxacin was 5 days, and 5.5 days in the vancomycin plus aztreonam group. In Trial 2, patients received Baxdela 300 mg via intravenous infusion for six doses then made a mandatory switch to oral Baxdela 450 mg every 12 hours for a total treatment duration of five to 14 days. The primary efficacy outcome for both trials was the clinical response at 48 to 72 hours after treatment was initiated, which was defined as a 20% or greater decrease in lesion size measured at the leading edge of erythema. In Trial 1, 78.2% (259/331) of patients in the Baxdela group had a clinical response at 48 to 72 hours compared to 80.9% (266/329) of patients in the vancomycin plus aztreonam group. In Trial 2, 83.7% (354/423) of patients in the Baxdela group had a clinical response at 48 to 72 hours compared to 80.6% (344/427) of patients in the vancomycin plus aztreonam group. Baxdela met non-inferiority criteria with similar clinical response rates in either treatment arm of both trials. The secondary endpoint was investigator-assessed success, defined as complete or near resolution of signs and symptoms with no further antibacterial needed, at the follow-up visit (Day 14 ± 1) and late follow-up visit (Days 21–28). Success rates were similar between Baxdela and vancomycin plus aztreonam. In Trial 1, the Baxdela group had an 81.6% (270/331) success rate compared to 83.3% (274/329) in the vancomycin plus aztreonam group. In Trial 2, the Baxdela group had an 87.2% (369/423)

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success rate compared to 84.8% (362/427) in the vancomycin plus aztreonam group.

Safety

Serious adverse reactions occurred in 3/741 (0.4%) of patients treated with Baxdela and in 6/751 (0.8%) of patients treated with vancomycin plus aztreonam. Baxdela was discontinued due to an adverse reaction in 7/741 (0.9%) patients and vancomycin plus aztreonam was discontinued due to an adverse reaction in 21/751 (2.8%) patients. The most commonly reported adverse reactions leading to study discontinuation in the Baxdela arm included urticaria (2/741; 0.3%) and hypersensitivity (2/741; 0.3%). Among both trials, there was one death in the Baxdela treatment arm and three deaths in the vancomycin plus aztreonam arm; none of the deaths were considered related to treatment. Among all patients in the Baxdela treatment arm (N=741), the most common adverse reactions were nausea (8%), diarrhea (8%), headache (3%), transaminase elevations (3%), and vomiting (2%). Baxdela has a black box warning as fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including tendinitis and tendon rupture, peripheral neuropathy, and central nervous system effects. Baxdela should be discontinued immediately, and fluoroquinolones should be avoided in patients who have experienced these adverse reactions. Baxdela should be avoided in patients with a known history of myasthenia gravis.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Baxdela (delafloxacin) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Baxdela (delafloxacin) include: known hypersensitivity to Baxdela or other fluoroquinolones.

OTHER SPECIAL CONSIDERATIONS:

Patients with renal impairment (eGFR 15-29 ml/min) should have their IV dose reduced to 200mg every 12 hours, or 400 mg per day. No adjustment is needed with the oral dosage form.

Baxdela (delafloxacin) has a black box warning for serious adverse reactions including tendonitis, tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis. Fluoroquinolones are associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including tendinitis and tendon rupture, peripheral neuropathy, and CNS effects. Discontinue delafloxacin immediately and avoid the use of fluoroquinolones in patients who experience any of these serious adverse reactions. Exacerbation of myasthenia gravis: Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid delafloxacin in patients with known history of myasthenia gravis.

Clostridium difficile-associated diarrhea (CDAD) has been reported in users of nearly all systemic antibacterial drugs, including Baxdela, with severity ranging from mild diarrhea to fatal colitis. Treatment with antibacterial agents can alter the normal flora of the colon and may permit overgrowth of C. difficile. If CDAD is suspected or confirmed, ongoing antibacterial use not directed against C. difficile should be discontinued, if possible. Appropriate measures such as fluid and electrolyte management, protein supplementation, antibacterial treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

CODING/BILLING INFORMATION

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical

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Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
J3490	Unclassified drugs (Baxdela)

AVAILABLE DOSAGE FORMS:

Baxdela TABS 450MG

Baxdela SOLR 300MG single dose vial

REFERENCES

1. Baxdela (delafloxacin) tablets, for oral use, for injection, for intravenous use [prescribing information]. Lincolnshire, IL: Melinta Therapeutics LLC; June 2021.
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3. Pullman J, Gardovskis J, Farley B, Sun E, Quintas M, Lawrence L, Ling R, Cammarata S; PROCEED Study Group. Efficacy and safety of delafloxacin compared with vancomycin plus aztreonam for acute bacterial skin and skin structure infections: a Phase 3, double-blind, randomized study. J Antimicrob Chemother. 2017 Dec 1;72(12):3471-3480. doi:10.1093/jac/dkx329.
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5. Metlay, J. P., Waterer, G. W., Long, A. C., Anzueto, A., Brozek, J., Crothers, K., . . . Whitney, C. G. (2019). Diagnosis and treatment of adults with community-acquired pneumonia. an official clinical practice guideline of the American Thoracic Society and Infectious Diseases Society of America. American Journal of Respiratory and Critical Care Medicine, 200(7). doi:10.1164/rccm.201908- 1581st
6. Stevens, D. L., Bisno, A. L., Chambers, H. F., Dellinger, E. P., Goldstein, E. J., Gorbach, S. L., . . . Wade, J. C. (2014). Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the Infectious Diseases Society of America. Clinical Infectious Diseases, 59(2). doi:10.1093/cid/ciu296

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Quantity Coding/Billing Information References	Q1 2025
REVISION- Notable revisions: Required Medical Information Duration of Approval Drug Class FDA-Approved Uses Coding/Billing Information	Q1 2024

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REVISION- Notable revisions: Required Medical Information Age Restrictions FDA-Approved Uses Background Contraindications/Exclusions/Discontinuation Other Special Considerations HCPCS Code and Description Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file