Original Effective Date: 02/01/2017
Current Effective Date: 03/07/2024
Last P&T Approval/Version: 01/31/2024
Next Review Due By: 01/2025
Policy Number: C10143-A

Azactam (aztreonam)

PRODUCTS AFFECTED

Azactam (aztreonam), aztreonam
*Cayston (aztreonam inhalation) - SEE CAYSTON (AZTREONAM) (C6481-A)

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:
Urinary tract infections, Lower respiratory tract infections, Septicemia, Skin/skin structure infections, Intra-abdominal infections, Bacterial meningitis, Native vertebral osteomyelitis, and Gynecological infections caused by susceptible gram-negative microorganisms

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.

Drug and Biologic Coverage Criteria

A. FOR ALL INDICATIONS:

1. (a) 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 or compendia supported
   OR
   (b) 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
2. Member does NOT have an allergy to beta-lactam antibiotics OR Prescriber has acknowledged the beta-lactam allergy and has documented medical necessity for utilization with caution

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
Initial authorization: 28 days OR DISCHARGE NOTE END DATE, whichever is shorter, Continuation of therapy: N/A

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:
None

QUANTITY:
Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the intramuscular injectable products be administered in a place of service that is a non-hospital facility-based location.

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:
Intramuscular or Intravenous

DRUG CLASS:
Monobactams

FDA-APPROVED USES:
Indicated for the treatment of patients with urinary tract infections, lower respiratory tract infections, septicemia, skin/skin structure infections, intra-abdominal infections, and gynecological infections caused by susceptible gram- negative microorganisms.

Urinary Tract Infections (complicated and uncomplicated), including pyelonephritis and cystitis (initial and recurrent) caused by Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas

aeruginosa, Enterobacter cloacae, Klebsiella oxytoca*, Citrobacter species*, and Serratia marcescens*.
Lower Respiratory Tract Infections, including pneumonia and bronchitis caused by Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Haemophilus influenzae, Proteus mirabilis, Enterobacter species, and Serratia marcescens*.
Septicemia caused by Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Proteus mirabilis*, Serratia marcescens*, and Enterobacter species.
Skin and Skin-Structure Infections, including those associated with postoperative wounds, ulcers, and burns, caused by Escherichia coli, Proteus mirabilis, Serratia marcescens, Enterobacter species, Pseudomonas aeruginosa, Klebsiella pneumoniae, and Citrobacter species*.
Intra-abdominal Infections, including peritonitis caused by Escherichia coli, Klebsiella species including K. pneumoniae, Enterobacter species including E. cloacae*, Pseudomonas aeruginosa, Citrobacter species* including C. freundii*, and Serratia species* including S. marcescens*.
Gynecologic Infections, including endometritis and pelvic cellulitis caused by Escherichia coli, Klebsiella pneumoniae*, Enterobacter species* including E. cloacae*, and Proteus mirabilis*.
Azactam is indicated for adjunctive therapy to surgery in the management of infections caused by susceptible organisms, including abscesses, infections complicating hollow viscus perforations, cutaneous infections, and infections of serous surfaces. Azactam is effective against most of the commonly encountered Gram-negative aerobic pathogens seen in general surgery.
* Efficacy for this organism in this organ system was studied in fewer than 10 infections

COMPENDIAL APPROVED OFF-LABELED USES:
Bacterial Meningitis; native vertebral osteomyelitis; Surgical prophylaxis (perioperative), febrile neutropenia

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Azactam (aztreonam) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Azactam (aztreonam) include: known hypersensitivity to aztreonam or any other component in the formulation.

OTHER SPECIAL CONSIDERATIONS:
Both animal and human data suggest that Azactam (aztreonam for injection, USP) is rarely cross-reactive with other beta-lactam antibiotics and weakly immunogenic. However, this drug should be administered with caution to any patient with a history of hypersensitivity to beta-lactams (e.g., penicillins, cephalosporins, and/or carbapenems). Treatment with aztreonam can result in hypersensitivity reactions in patients with or without prior exposure to aztreonam. If an allergic reaction to aztreonam occurs, discontinue the drug and institute supportive treatment as appropriate (e.g., maintenance of ventilation, pressor amines, antihistamines, corticosteroids). Serious hypersensitivity reactions may require epinephrine and other emergency measures.

Clostridium difficile–associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Azactam, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile. C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin-producing strains of C.

difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J0457	Injection, aztreonam, 100 mg

AVAILABLE DOSAGE FORMS:
Azactam SOLR 1GM single dose vial
Azactam SOLR 2GM single dose vial
Aztreonam SOLR 1GM single dose vial
Aztreonam SOLR 2GM single dose vial

REFERENCES

1. Azactam (aztreonam) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2023.
2. Aronoff GR, Bennett WM, Berns JS, et al, Drug Prescribing in Renal Failure: Dosing Guidelines for Adults and Children, 5th ed, Philadelphia, PA: American College of Physicians, 2007.
3. Berbari EF, Kanj SS, Kowalski TJ, et al; Infectious Diseases Society of America. 2015 Infectious Diseases Society of America (IDSA) Clinical Practice Guidelines for the diagnosis and treatment of native vertebral osteomyelitis in adults. Clin Infect Dis. 2015;61(6):e26-e46. [PubMed 26229122]10.1093/cid/civ482
4. Bosso JA and Black PG, “The Use of Aztreonam in Pediatric Patients: A Review,” Pharmacotherapy, 1991, 11(1):20-5. [PubMed 1902290]
5. Tamma, P. D., Aitken, S. L., Bonomo, R. A., Mathers, A. J., Van Duin, D., & Clancy, C. J. (2022). Infectious diseases society of America 2022 guidance on the treatment of extended-spectrum β-lactamase producing Enterobacterales (ESBL-e), carbapenem-resistant enterobacterales (CRE), and pseudomonas aeruginosa with difficult-to-treat resistance (dtr-P. aeruginosa). Clinical Infectious Diseases, 75(2), 187-212. doi:10.1093/cid/ciac268

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Other Special Considerations Coding/Billing Information Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Products Affected Diagnosis FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file