Effective Date: 02/01/2017
Last P&T Approval/Version: 01/26/2022
Next Review Due By: 01/2023
Policy Number: C10143-A

Azactam (aztreonam)

PRODUCTS AFFECTED

Azactam (aztreonam)
*Cayston (aztreonam inhalation) - SEE CAYSTON (AZTREONAM) (C611-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 bacilli

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

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 a continuation of therapy that was started at an in-patient 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:
NA

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

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with an infectious disease specialist [If prescribed in consultation, consultationnotes must be submitted within initial request and reauthorization requests]

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 benefitcoverage 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:
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 bacilli

COMPENDIAL APPROVED OFF-LABELED USES:
Meningitis, bacterial; Osteomyelitis, native vertebral; 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.

OTHER SPECIAL CONSIDERATIONS:
None

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
S0073	Injection, aztreonam, 500 mg

AVAILABLE DOSAGE FORMS:
Aztreonam SOLR 1GM, Aztreonam SOLR 2GM, Azactam SOLR 2GM, Aztreonam SOLR 2GM, Azactam SOLR 1GM

REFERENCES

1. Aronoff GR, Bennett WM, Berns JS, et al, Drug Prescribing in Renal Failure: Dosing Guidelines for Adults and Children, 5th ed, Philadelphia, PA: American Collegeof Physicians, 2007.
2. Azactam (aztreonam) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; received April 2021
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]