Azactam(aztreonam)
Policy Number: C10143-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
2/1/2017	11/18/2020	1/26/2022
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
S0073-injection, aztreonam, 500mg	RxPA	Q1 2021 20210127C10143-A

PRODUCTS AFFECTED:
Azactam (aztreonam)
*Cayston (aztreonam inhalation) - SEE CAYSTON (AZTREONAM) (C611-A)

DRUG CLASS:
Monobactams

ROUTE OF ADMINISTRATION:
Intramuscular or Intravenous

PLACE OF SERVICE:
Retail Pharmacy, Buy and Bill
The recommendation is that medications in this policy will be for medical benefit coverage and the product is administered in a place of service that is a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the therapy/member meets the Site of Care exceptions. (See appendix for excerpt from Specialty Medication Administration Site of Care Policy)

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

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

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COVERAGE CRITERIA: INITIAL AUTHORIZATION

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:

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

DURATION OF APPROVAL:

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

QUANTITY:

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

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with an infectious disease specialist

AGE RESTRICTIONS:

None

CONTINUATION OF THERAPY:

NA

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

BACKGROUND:

None

APPENDIX:

None

Molina Healthcare, Inc. covers injectable/infused treatment in a hospital outpatient setting or at a hospital-affiliated infusion suite* when the level of care is determined to be medically necessary. Considerations used to determine if an alternative level of care is not suitable may include the following findings:

1. The member is clinically unstable based on documented medical history and susceptible to complication with drug administration (e.g., cardiopulmonary or renal dysfunction, risk for fluid overload)
2. The requested medication is administered as part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer or with dialysis
3. The member exhibits physical or cognitive impairment and a capable caregiver is not available to assist with safe administration of prescribed medication in the home
4. It is the patient's first dose of the medication or it is being re-initiated after at least 12 months*
5. The member has experienced adverse events with past administration of the drug and cannot be managed by premedication or resources available at an non-hospital facility based location (NHFBL)
6. Documented history of difficulty establishing and maintaining patent vascular access, or is not a candidate for a mode of long-term vascular access during the duration of prescribed treatment

Note: a hospital outpatient setting, or a hospital-affiliated infusion suite is expected to have immediate access to specific services of a medical center/hospital setting, including having emergency resuscitation equipment and personnel (ACLS protocol), emergency services, and inpatient admission or intensive care, if necessary

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.

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 College of Physicians, 2007.
2. Azactam (aztreonam) injection [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; September 2018.
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]