Original Effective Date: 06/01/2016
Current Effective Date: 12/01/2025
Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C6481-A

Cayston (aztreonam)

PRODUCTS AFFECTED

Cayston (aztreonam)

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:
Cystic fibrosis

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. CYSTIC FIBROSIS:
1. Documented diagnosis of cystic fibrosis
   AND
2. Documentation of pseudomonas aeruginosa in at least one airway [DOCUMENTATION REQUIRED]

AND

3. Documentation the member has a forced expiratory volume in one second (FEV1) between 25% and 75% predicted [DOCUMENTATION REQUIRED]
   AND
4. Prescriber attests (or the clinical reviewer has found) that the member is not colonized with Burkholderia cepacia
   AND
5. Member has an inhaled bronchodilator [e.g., Advair, Albuterol, Brovana, Dulera, Duoneb, Foradil, Perforomist, ProAir, Proventil, Serevent, Striverdi, Symbicort, Ventolin, Xopenex] available to use prior to administration of Cayston (aztreonam)
   AND
6. (a) Documented treatment failure, serious side effects or clinical contraindication to inhaled tobramycin
   OR
   (b) Antibiotic susceptibility testing indicates that aztreonam would be more effective than tobramycin
   AND
7. (a) Documentation that therapeutic plan does NOT include concurrent or alternating use of Cayston with TOBI/TOBI Podhaler or tobramycin inhalation
   OR
   (b) If concurrent therapy is requested: Documentation member has tried and failed monotherapy with Cayston (aztreonam) AND tobramycin separately prior to using concurrent alternating therapy [DOCUMENTATION REQUIRED]
   AND
8. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Cayston (aztreonam) include: patients with a known allergy to aztreonam]

CONTINUATION OF THERAPY:

A. CYSTIC FIBROSIS:

1. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms
   AND
2. Adherence to therapy at least 85% of the time as verified by the Prescriber or member medication fill history
   AND
3. If inhaled Cayston (aztreonam) is prescribed concurrently (or for alternating use) with inhaled tobramycin (Bethkis, Kitabis Pak, TOBI, TOBI Podhaler), documentation supports inadequate response to both agents alone (e.g., deteriorating pulmonary status, recurrent pulmonary exacerbations) [DOCUMENTATION REQUIRED]
   AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a pulmonologist, infectious disease specialist, cystic fibrosis specialist or physician from a CF center accredited by the Cystic Fibrosis Foundation [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
6 years of age and older

QUANTITY:
One 28-day kit per 56 days (28 days on, 28 days off)

PLACE OF ADMINISTRATION:
The recommendation is that inhalation medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Inhalation

DRUG CLASS:
Monobactams

FDA-APPROVED USES:
Indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with Pseudomonas aeruginosa.
Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV1 <25% or >75% predicted, or patients colonized with Burkholderia cepacia.
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cayston and other antibacterial drugs, Cayston should be used only to treat patients with CF known to have Pseudomonas aeruginosa in the lungs.

COMPENDIAL APPROVED OFF-LABELED USES:
Treatment of Pseudomonas aeruginosa in respiratory culture in CF transmembrane conductance regulator (CFTR)-related metabolic syndrome/cystic fibrosis screen-positive, inconclusive diagnosis (Green et al., 2024)

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
The sweat chloride test is the gold standard of CF diagnosis since it remains the most discriminatory test for this disorder. Values of chloride greater than 60 mEq/L in a sweat chloride concentration analysis are considered positive. CF can also be diagnosed by DNA analysis; however, a negative analysis result does not exclude the diagnosis of the disease.
Sputum culture and susceptibility testing performed periodically will provide information on changing microbial flora and the possible emergence of bacterial resistance. The use of continuous alternating therapy (i.e., alternating different inhaled antibiotics in order to provide continuous therapy) lacks sufficient evidence. The efficacy of this practice was evaluated in a randomized, double-blind, phase 3 trial. Ninety patients received 28-days inhaled tobramycin alternating with either 28-days inhaled aztreonam or placebo. Although the study found reduced exacerbation and respiratory hospitalization rates with the alternating tobramycin/aztreonam regimen compared to tobramycin/placebo, it was underpowered, and these results were not statistically significant.

The age minimum of 6 years of age is supported by the registration trial AIR-CF1. In this trial, a patient began the trial at 6 years of age and turned 7 during the course of the trial. The European and Canadian

drug applications accepted the age limit of 6, while the FDA accepted with an age limit of 7. Since this trial, other data sets have included patients less than and through 6 years of age including ALPINE, ALPINE-2, and PALS.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Cayston (aztreonam) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Cayston (aztreonam) include: patients with a known allergy to aztreonam.

OTHER SPECIAL CONSIDERATIONS:

Cayston is administered by inhalation using an Altera® Nebulizer System. Patients should use a bronchodilator before administration of Cayston.

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 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
NA	

AVAILABLE DOSAGE FORMS:

Cayston SOLR 75MG

REFERENCES

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3. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines: Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. April 1,2013; 187 (7): 680- 689.
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6. Mogayzel, P., Naureckas, E., Robinson, K., Brady, C., Guill, M., & Lahiri, T. et al. (2014). Cystic Fibrosis Foundation Pulmonary Guideline. Pharmacologic Approaches to Prevention and Eradication of Initial Pseudomonas aeruginosa Infection. Annals Of The American Thoracic Society,11(10), 1640- 1650. doi: 10.1513/annalsats.201404-166oc
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11. Green, D. M., Lahiri, T., Raraigh, K. S., Ruiz, F., Spano, J., Antos, N., … Self, S. (2024). Cystic Fibrosis Foundation Evidence-Based Guideline for the Management of CRMS/CFSPID. Pediatrics. https://doi.org/10.1542/peds.2023-064657

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Compendial Approved Off-Labeled Uses References	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Duration of Approval	Q4 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Other Special Considerations	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Age Restrictions FDA-Approved Uses Background Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file