

## Clinical Policy: Aztreonam (Cayston)

Reference Number: CP.PHAR.209

Effective Date: 05/16

Last Review Date: 05/17

[Coding Implications](#)  
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for aztreonam solution for inhalation (Cayston®).

### Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that Cayston is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Cystic Fibrosis (must meet all):

1. Age  $\geq$  7 years;
2. Diagnosis of cystic fibrosis (CF);
3. Pseudomonas aeruginosa is present in at least one airway culture;
4. Member has a contraindication to, or has failed a trial of, TOBI® inhalation solution or TOBI® Podhaler™; or antibiotic susceptibility testing indicates that aztreonam would be more effective than tobramycin;
5. Therapeutic plan does NOT include concurrent or alternating use of Cayston with TOBI/TOBI Podhaler;
6. Prescribed daily dose of Cayston does not exceed 225 mg aztreonam on a 28 days on/28 days off cycle;
7. FEV<sub>1</sub> is  $\geq$  25% to  $\leq$  90 % of predicted.

**Approval duration: 6 months**

##### B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

#### II. Continued Approval

##### A. Cystic Fibrosis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Therapeutic plan does NOT include concurrent or alternating use of Cayston with TOBI/TOBI Podhaler;
3. Prescribed total daily dose of Cayston does not exceed 225 mg aztreonam on a 28 days on/28 days off cycle;
4. Member is responding positively to therapy (e.g.: stable or improved pulmonary function, improved quality of life, reduced hospitalization).

**Approval duration: 12 months**

**B. Other diagnoses/indications (1 or 2):**

1. Currently, receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to CP.PHAR.57 - Global Biopharm Policy.

**Background***Description/Mechanism of Action:*

The active ingredient in Cayston is aztreonam, a monobactam antibacterial. The monobactams are structurally different from beta-lactam antibiotics (e.g., penicillins, cephalosporins, carbapenems) due to a monocyclic nucleus. This nucleus contains several side chains; sulfonic acid in the 1-position activates the nucleus, an aminothiazolyl oxime side chain in the 3-position confers specificity for aerobic Gram-negative bacteria including *Pseudomonas* spp., and a methyl group in the 4-position enhances beta-lactamase stability.

*Formulations:*

Cayston (kit): Inhalation solution (preservative and arginine free)

- 84 vials, each containing lyophilized aztreonam (75 mg) and lysine (46.7 mg);
- 88 ampules, each containing 1 mL sterile diluent (0.17% sodium chloride).

*FDA-Approved Indications:*

Cayston is a monobactam antibacterial/inhalation solution indicated to:

- Improve respiratory symptoms in CF patients with *Pseudomonas aeruginosa*. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV<sub>1</sub> <25% or >75% predicted, or patients colonized with *Burkholderia cepacia*.

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*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.*

**Appendices****Appendix A: Abbreviation Key**

CF: cystic fibrosis

FEV<sub>1</sub>: forced expiratory volume in one second

FVC: forced vital capacity

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Policy split from CP.PHAR.54 CF Treatments. Concurrent use of Cayston with TOBI/TOBI Podhaler is restricted per 2015 expert review citing lack of evidence. Appendix C (clinical reasons to continue CF therapy) is replaced by “Member continues to respond positively to Cayston therapy in one or more of the following areas: pulmonary function, quality of life, pulmonary exacerbations”. Approval periods are extended from 3 to 6 and 6 to 12 months.	05/16	5/16
FEV1 delineation of ≤90% added to initial criteria. Allergy contraindication removed. B. cepacia restriction removed as it is not a contraindication. Efficacy statement edited to indicate a general positive response to therapy.	05/17	05/17

**References**

1. Cayston Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; May 2014. Available at [http://www.gilead.com/~media/files/pdfs/medicines/respiratory/cayston/cayston\\_pi.pdf?la=en](http://www.gilead.com/~media/files/pdfs/medicines/respiratory/cayston/cayston_pi.pdf?la=en). Accessed May 1, 2017.
2. Flume PA, Mogayzel PJ, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Treatment of pulmonary exacerbations. *Am J Respir Crit Care Med.* 2009; 180: 802-808.
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.

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence

of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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