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 ≥ 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_1 is ≥ 25% to ≤ 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_1 <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_1: 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. 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

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.