Clinical Policy: Aztreonam (Cayston)

Reference Number: PA.CP.PHAR.209
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

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

FDA Approved Indication(s)
Cayston is indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa*.

Limitation(s) of use:
- Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with forced expiratory volume in one second (FEV_1) < 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.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness that Cayston is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cystic Fibrosis (must meet all)**:**
1. Diagnosis of CF;
2. Age ≥ 6 years;
3. Pseudomonas aeruginosa is present in at least one airway culture;
4. Member meets one of the following (a or b):
   a. Failure of a trial of TOBI® inhalation solution or TOBI® Podhaler™ unless contraindicated or clinically significant adverse effects are experienced;
   b. Antibiotic susceptibility testing indicates that aztreonam would be more effective than tobramycin;
5. Member meets one of the following (a or b):
   a. Cayston is not prescribed concurrently (or for alternating use) with inhaled tobramycin (Bethkis®, Kitabis® Pak, TOBI, TOBI Podhaler);
   b. If member is currently receiving inhaled tobramycin (Bethkis, Kitabis Pak, TOBI, TOBI Podhaler), documentation supports inadequate response to tobramycin alone (e.g., deteriorating pulmonary status, recurrent pulmonary exacerbations);
6. Dose does not exceed 225 mg/day administered on a 28 days on/28 days off cycle.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If Cayston is prescribed concurrently (or for alternating use) with inhaled tobramycin (Bethkis, Kitabis Pak, TOBI, TOBI Podhaler), documentation supports inadequate response to either agent alone (e.g., deteriorating pulmonary status, recurrent pulmonary exacerbations);
4. If request is for a dose increase, new dose does not exceed 225 mg/day administered on a 28 days on/28 days off cycle.

Approval duration: 12 months

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

1. Currently, receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

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

2. Refer to PA.CP.PMN.53

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).

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
Modified age restriction from ≥ 7 to ≥ 6 years per ATS guideline recommendations. Removed baseline FEV requirement. Added allowance for concurrent/alternating use with tobramycin pending supportive documentation of inadequate response to either agent alone. References reviewed updated.	02/18	

References
1. Cayston Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; May 2014. Available at www.cayston.com. Accessed October 27, 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. 2013; 187(7): 680-689.
4. Flume PA, Clancy JP, Retsch-Bogart GZ, et al. Continuous alternating inhaled antibiotics for chronic pseudomonal infection in cystic fibrosis. J Cyst Fibrosis. 2016; 15(6): 809-815.