MEDICAL MUTUAL®

Drug Policy

Policy:	Cayston (aztreonam inhalation solution)	Annual Review Date: 04/17/2025 Last Revised Date: 04/17/2025

OVERVIEW

Cayston (aztreonam) is a monobactam antibiotic which inhibits bacterial cell wall synthesis by binding to penicillin-binding proteins in susceptible organisms, including *Pseudomonas aeruginosa*, leading to cell death. The presence of cystic fibrosis (CF) lung secretions does not reduce the activity of aztreonam.

POLICY STATEMENT

This policy involves the use of Cayston. Prior authorization is recommended for pharmacy benefit coverage of Cayston. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below.

Automation: When available, the ICD-10 codes for Cystic Fibrosis (ICD-10: E84.*) AND claims history of generic tobramycin inhaled solution within the previous 730 days will be used for automation to allow approval of the requested medication.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cayston is recommended in those who meet the following criteria:

1. **Cystic Fibrosis**
   - **A) Criteria.** *Approve if the member has tried or has a contraindication to generic tobramycin inhaled solution or Tobi Podhaler.*

Initial Approval/ Extended Approval.
A) *Initial Approval: 365 days*
B) *Extended Approval: 365 days*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Cayston has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Nasal Rinse**. Cayston is not approvable for compounding of aztreonam nasal rinse.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Cayston inhalation solution [prescribing information]. Foster City, CA: Gilead Sciences; November 2019.
2. Flume PK, O'Sullivan BP, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. *Am J Respir Crit Care Med*. 2007;176:957-969.
3. Le J, Ashley ED, Neuhauser MM, et al and the Society of Infectious Diseases Pharmacists Aerosolized Antimicrobials Task Force. Consensus summary of aerosolized antimicrobial agents: application of guideline criteria. Insights from the Society of Infectious Diseases Pharmacists. *Pharmacotherapy*. 2010;30(6):562-584.
4. Geller DE. Aerosol antibiotics in cystic fibrosis. *Respir Care*. 2009;54(5):658-669.
5. Tiddens HAWM, De Boeck K, Clancy JP, et al. Open label study of inhaled aztreonam for *Pseudomonas* eradication in children with cystic fibrosis: The ALPINE study. *J Cyst Fibros*. 2015;14:111-119.
6. 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;187:680-689.
7. Mogayzel PJ, Naureckas ET, Robinson KA, et al; and the Cystic Fibrosis Foundation Pulmonary Clinical Practice Guidelines Committee. Pharmacologic approaches to prevention and eradication of initial *Pseudomonas aeruginosa* infection. *Ann Am Thorac Soc*. 2014;11(10):1640-1650.