**Effective Date** ..... **9/1/2023**
**Next Review Date…** ..... **9/1/2024**
**Coverage Policy Number** ..... **IP0485**

# Aztreonam Inhalation Solution

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## Related Coverage Resources

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## Overview

This policy supports medical necessity review for aztreonam inhalation solution (**Cayston**®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Medical Necessity Criteria

**Aztreonam inhalation solution (Cayston) is considered medically necessary when ONE of the following is met (1 or 2):**

1. **Cystic Fibrosis.** Individual meets **BOTH** of the following criteria (A and B):
   A. Documentation of *Pseudomonas aeruginosa* in airway cultures (for example, sputum culture, oropharyngeal culture, bronchoalveolar lavage culture)
   B. The medication is prescribed by, or in consultation with, a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

2. **Continuation of Aztreonam Inhalation Solution (Cayston) Therapy.** Individual meets **BOTH** of the following criteria (A and B):
    A. Individual was started on aztreonam inhalation solution (Cayston) and is continuing the course of therapy
    B. The medication is prescribed by, or in consultation with, a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

## Reauthorization Criteria

Aztreonam inhalation solution (Cayston) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

## Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

## Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

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

## Background

**OVERVIEW**
Cayston, a monobactam antibiotic, is indicated to improve respiratory symptoms in **cystic fibrosis** (CF) patients with *Pseudomonas aeruginosa*.[1] Safety and efficacy have not been established in pediatric patients < 7 years of age, in patients with forced expiratory volume in 1 second ($FEV_1$) < 25% or > 75% predicted, or in patients colonized with *Burkholderia cepacia*.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cayston and other antibiotics, Cayston should be used to treat patients with CF known to have *P. aeruginosa* in the lungs.[1]

**Clinical Efficacy**
An open-label study assessed inhaled aztreonam for the eradication of newly acquired *P. aeruginosa* in children aged 3 months to < 18 years of age (n = 105).[2] In total, 49 patients < 6 years of age were included in the study. Patients received inhaled aztreonam 75 mg three times daily for 28 days. At the end of treatment with inhaled aztreonam, 91.5% of the patients (n = 43/47) < 6 years of age were culture-negative for *P. aeruginosa* and 76.6% of patients (n = 36/47) < 6 years of age remained culture-negative 4 weeks after completing the course of therapy.

**Guidelines**
The Cystic Fibrosis Foundation (CFF) Pulmonary Therapeutics Committee provides recommendations for the use of chronic medications in the management of CF lung disease (2013).[3] In patients ≥ 6 years of age with CF and moderate-to-severe lung disease with *P. aeruginosa* persistently present in cultures of the airways, the chronic use of inhaled aztreonam is strongly recommended to improve lung function and quality of life (QoL). For mild disease, the Committee recommends chronic use of inhaled aztreonam for patients ≥ 6 years of age with CF and *P. aeruginosa* persistently present in cultures of the airways, to improve lung function and QoL.

The CFF published a systematic review of the literature regarding eradication of initial *P. aeruginosa* infections to develop guidelines for effective prevention (2014).[4] The recommendations pertaining to inhaled antibiotics are as follows: 1) Inhaled antibiotic therapy is recommended for the treatment of initial or new growth of *P. aeruginosa* (the favored antibiotic regimen is tobramycin [300 mg twice daily {BID}] for 28 days); and 2) Prophylactic antipseudomonal antibiotics to prevent the acquisition of *P. aeruginosa* are not recommended.

## References


1. Cayston® inhalation solution [prescribing information]. Foster City, CA: Gilead; November 2019.
2. 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.
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;187:680-689.
4. 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.