PRIOR AUTHORIZATION POLICY

POLICY: Antibiotics (Inhaled) – Cayston Prior Authorization Policy
- Cayston® (aztreonam inhalation solution – Gilead)

REVIEW DATE: 03/29/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Cayston. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Cayston as well as the monitoring required for adverse events and long-term efficacy, approval requires Cayston to be prescribed by or in consultation with a physician who specializes in the condition being treated.

- **Cayston® (aztreonam inhalation solution – Gilead)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Cystic Fibrosis.** Approve for 1 year if the patient meets the following criteria (A and B):
   - **A)** Patient has *Pseudomonas aeruginosa* in culture of the airway; AND
     Note: Examples of culture of the airway include 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.

Other Uses with Supportive Evidence

2. **Continuation of Cayston**. Approve for 1 month if the patient was started on Cayston and is continuing a course of therapy.

CONDITIONS NOT COVERED

- **Cayston® (aztreonam inhalation solution – Gilead)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Cystic fibrosis:** Moved examples of culture of the airway to a Note.	04/06/2022
Annual Revision	No criteria changes.	03/29/2023