

Pharmacy Policy Bulletin

Title: Aztreonam (Cayston®)

Policy #: Rx.01.6

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **aztreonam (Cayston®)** as provided under the member's prescription drug benefit.

Description:

Aztreonam (Cayston®) is a monobactam antibiotic, which is part of the beta-lactam class, that binds to penicillin binding proteins of susceptible bacteria and leads to inhibition of bacterial cell wall synthesis and death of the cell.

Aztreonam (Cayston®) is indicated to improve respiratory symptoms in cystic fibrosis patients with pulmonary *Pseudomonas aeruginosa* infections. Safety and effectiveness has not been established in pediatric patients below the age of 7 years, patients with FEV1 <25% or >75% predicted, or patients colonized with *Burkholderia cepacia*.

Policy:

INITIAL CRITERIA: Aztreonam (Cayston®) is approved when ALL of the following are met:

1. Member is 7 years of age or older; AND
2. Diagnosis of cystic fibrosis; AND
3. Evidence of *Pseudomonas aeruginosa* in the lungs confirmed by culture; AND
4. Susceptibility results indicating that the *Pseudomonas aeruginosa* is sensitive to aztreonam; AND
5. FEV1 that is 25% to 75% of predicted

Initial authorization: 2 years

REAUTHORIZATION CRITERIA: Aztreonam (Cayston®) is re-approved when ALL of the following are met:

1. Diagnosis of cystic fibrosis; AND
2. Evidence of *Pseudomonas aeruginosa* in the lungs confirmed by culture; AND
3. Documentation of positive clinical response to therapy (e.g. improvement in lung function demonstrated by improved FEV1)

Reauthorization: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Cayston® [package insert]. Foster City CA. Gilead Sciences. November 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=67300ca3-8c53-4ce4-8e86-2c03be1f9b8a&type=display>. Accessed July 21, 2021.

McCoy K, Quittner A, Oermann C, et al. Inhaled Aztreonam Lysine for chronic airway pseudomonas aeruginosa in cystic fibrosis. Am J Respir Crit Care 2008; 178(9): 921-928. Accessed July 21, 2021.

Oermann C, Retsch-Bogart G, Quittner A, et al. An 18 month study of the safety and efficacy of repeated courses of inhaled Aztreonam Lysine in Cystic Fibrosis. Pediatric Pulmonology 2010; 45(11): 1121-1134. Accessed July 21, 2021

Retsch-Bogart G, Quittner A, Gibson R, et al. Efficacy and Safety of inhaled Aztreonam lysine for airway pseudomonas in cystic fibrosis. Chest 2009; 135(5): 1223-1232. Accessed July 21, 2021.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Cayston®	Aztreonam

Cross References:

Rx.01.33 Off-Label Use

Policy Version Number:	13.00
P&T Approval Date:	June 10, 2021.
Policy Effective Date:	October 01, 2021
Next Required Review Date:	June 10, 2022

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.
