BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

**PHARMACY COVERAGE GUIDELINES**
**SECTION: DRUGS**

**ORIGINAL EFFECTIVE DATE: 11/15/2018**
**LAST REVIEW DATE: 11/19/2020**
**LAST CRITERIA REVISION DATE: 11/19/2020**
**ARCHIVE DATE:**

# CAYSTON® (aztreonam) oral inhalation solution

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.**

**This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Pharmacy Coverage Guidelines are subject to change as new information becomes available.**

**For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.**



This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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# CAYSTON® (aztreonam) oral inhalation solution

**Criteria**:

- **Criteria for initial therapy:** Cayston (aztreonam) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Pulmonologist or Infectious Disease Specialist

  2. Individual is 7 years of age or older

  3. A confirmed diagnosis of ***Pseudomonas aeruginosa* infection in the lungs of an individual with cystic fibrosis (CF)**

  4. Cultures of airway demonstrating *Pseudomonas aeruginosa* is sensitive to aztreonam (*copy of culture report must be sent*)

  5. Individual has failure, contraindication, intolerance, or organism is resistance to Bethkis (tobramycin inhalation solution)

  6. There is no evidence of the following:
     a. Individual with FEV < 25% or > 75% predicted
     b. Individual colonized with *Burkholderia cepacia*

  7. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Baseline $FEV_1$

  **Initial approval duration**: 12 months
  Dosing is 28 day treatment followed by 28 days off
  Aztreonam is administered by inhalation using an *Altera Nebulizer System*

- **Criteria for continuation of coverage (renewal request):** Cayston (aztreonam) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Pulmonologist or Infectious Disease Specialist

  2. Individual's condition has responded while on therapy
     a. Response is defined as **ONE** of the following:
        i. Reduction in symptoms of cough, wheezing, and sputum production on the last day of treatment with Cayston
        ii. Achieved and maintains at least a 10% improvement in $FEV_1$ on the last day of treatment with Cayston

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3. Individual has been adherent with the medication

4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
    a. Significant adverse effect such as:
        i. Severe bronchospasm immediately following administration
        ii. Reduction in $FEV_1$ of $\geq$ 15% immediately following administration

**Renewal duration**: 12 months
Dosing is 28 day treatment followed by 28 days off
Aztreonam is administered by inhalation using an *Altera Nebulizer System*

**Description:**

Cayston (aztreonam) is indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa (P. aeruginosa)*. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV < 25% or > 75% predicted, or patients colonized with *Burkholderia cepacia*.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cayston (aztreonam) and other antibacterial drugs, Cayston (aztreonam) should be used only to treat patients with CF known to have *P. aeruginosa* in the lungs.

Cayston (aztreonam) is a monobactam antibacterial that is structurally different from beta-lactam antibiotics (e.g., penicillins, cephalosporins, carbapenems). Aztreonam exhibits *in vitro* activity against Gram-negative aerobic pathogens including *P. aeruginosa*. Aztreonam binds to penicillin-binding proteins of susceptible bacteria, which leads to inhibition of bacterial cell wall synthesis and death of the cell. Aztreonam activity is not decreased in the presence of CF lung secretions.

A single sputum sample from a patient with cystic fibrosis may contain multiple morphotypes (a group of different types of individuals within the same species) of *P. aeruginosa*, and each morphotype may have a different level of in vitro susceptibility to aztreonam. There are no in vitro susceptibility test interpretive criteria for isolates of *P. aeruginosa* obtained from the sputum of patients with cystic fibrosis

Aztreonam inhibits bacterial cell wall synthesis by binding to one or more of the penicillin-binding proteins (PBPs), which in turn inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis. Bacteria eventually lyse due to ongoing activity of cell wall autolytic enzymes (autolysins and murein hydrolases), while cell wall assembly is arrested. Monobactam structure makes cross-allergenicity with beta-lactams unlikely No cross-resistance to other classes of antibiotics, including aminoglycosides, quinolones, and beta-lactams have been reported.

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**Resources:**

Cayston (aztreonam) inhalation product information, revised by manufacturer Gilead 11-2019, at DailyMed http://dailymed.nlm.nih.gov accessed September 13, 2020.

Simon RH. Cystic fibrosis: Antibiotic therapy for chronic pulmonary infection. In: UpToDate, Mallory GB, Hoppin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on September 15, 2020.