BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/15/18**
SECTION: DRUGS	**LAST REVIEW DATE: 11/15/18**
	LAST CRITERIA REVISION DATE:
	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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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 Pulmonologist or is in consultation with 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:
     - Receiving treatment with other inhaled/nebulized antibiotics or inhaled/nebulized anti-infective agents, including alternating treatment schedules or as part of a cyclic rotation with inhaled tobramycin
     - Individual with FEV < 25% or > 75% predicted
     - 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:
     - Baseline FEV_1

  8. There are **NO** contraindications.
     - Contraindications include:
       - Known allergy to aztreonam

  Initial approval duration: 12 months
  84 vials per 56 days
  Dosing is 28 days 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 Pulmonologist or is in consultation with Infectious Disease Specialist

  2. Individual's condition has responded while on therapy
     - Response is defined as **ONE** of the following:

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- Reduction in symptoms of cough, wheezing, and sputum production on the last day of treatment with Cayston
- Achieved and maintains at least a 10% improvement in FEV_1 on the last day of treatment with Cayston
- Decrease in pulmonary exacerbations due to Pseudomonas aeruginosa

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
   - Contraindications as listed in the criteria for initial therapy section
   - Significant adverse effect such as:
     - Severe bronchospasm immediately following administration
     - Reduction in FEV_1 of $\geq$ 15% immediately following administration

Renewal duration: 12 months
84 vials per 56 days
Dosing is 28 days 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

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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.

Resources:

Cayston. Package Insert. Revised by manufacturer 5/2014. Accessed 11/02/18.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.