

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2023 P 1016-11
Program	Prior Authorization/Notification
Medication	Cayston® (aztreonam for inhalation solution)
P&T Approval Date	11/2011, 5/2012, 5/2013, 2/2014, 2/2015, 2/2016, 2/2017, 2/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023
Effective Date	5/1/2023; Oxford only: 5/1/2023

### 1. Background:

Cayston (aztreonam solution for inhalation) is a monobactam antibacterial indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa*. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with forced expiratory volume (FEV<sub>1</sub>) < 25% or > 75% predicted, or patients colonized with *Burkholderia cepacia*.<sup>1</sup>

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

Members will be required to meet the coverage criteria below.

### 2. Coverage Criteria<sup>a</sup>:

#### A. Initial Authorization

1. **Cayston** will be approved based on **both** of the following criteria:

a. Diagnosis of cystic fibrosis (CF)

**-AND-**

b. Lung infection with positive culture demonstrating *Pseudomonas aeruginosa* infection

**Authorization will be issued for 12 months**

#### B. Reauthorization

1. **Cayston** will be approved based on the following criterion:

a. Documentation of positive clinical response to Cayston therapy

**Authorization will be issued for 12 months**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### 3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

### 4. References:

1. Cayston [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019.

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<b>Change Control</b>	
2/2014	Updated Background. Removed reauthorization criteria and increased authorization to 60 months.
2/2015	Annual review with no change to coverage criteria. Updated background and references.
2/2016	Annual review with no changes to clinical content. Changed authorization period to 12 months and added re-authorization period for 12 months.
2/2017	Annual review. No changes to coverage criteria.
2/2018	Annual review. No changes to coverage criteria.
2/2019	Annual review. No changes to coverage criteria.
2/2020	Annual review. Update to background. No changes to coverage criteria.
2/2021	Annual review. No changes to coverage criteria.
2/2022	Annual review with no changes to coverage criteria.
2/2023	Annual review with no changes to coverage criteria. Added state mandate.