UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1016-13
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, 2/2024, 2/2025
Effective Date	5/1/2025

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 in 1 second (FEV_1) < 25% or > 75% predicted, or patients colonized with *Burkholderia cepacia*.

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[a]:

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

[a] 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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Change Control	
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.
2/2024	Annual review. Updated background. No changes to coverage criteria.
2/2025	Annual review. No changes to coverage criteria.