UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 3153-1
Program	Step Therapy
Medication	Cayston (aztreonam for inhalation solution)
P&T Approval Date	2/2021
Effective Date	5/1/2021; Oxford only: 5/1/2021

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try preferred products before providing coverage for Cayston.

Cayston (aztreonam solution for inhalation) is a monobactam antibacterial 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 forced expiratory volume (FEV_1) < 25% or >75% predicted, or patients colonized with *Burkholderia cepacia* (*B. cepacia*).[1]

Tobramycin inhalation solution is an aminoglycoside antibacterial indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with *P. aeruginosa.* Safety and effectiveness have not been established in patients under the age of 6 years, patients with FEV_1 < 25% or > 75% predicted, or patients colonized with *B. capecia.*[2]

Members currently on Cayston as documented in claims history will be allowed continued coverage of their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Cayston will be approved based on the following criteria:

1. History of failure, contraindication, or intolerance to tobramycin inhalation solution (document date of trial and list reason for therapeutic failure, contraindication, or intolerance)

Authorization will be issued for 12 months.

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[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.
- Medical Necessity, Supply Limits and/or Notification may be in place.
- Not all tobramycin products are covered. Refer to the most current UHC prescription drug list to identify covered products.

4. References:

1. Cayston [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019.
2. Tobramycin [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc. January 2019.

Program	Step Therapy – Cayston (aztreonam for inhalation solution)
Change Control	
2/2021	New program.

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