CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Cayston (aztreonam inhalation solution)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Cayston (aztreonam inhalation solution) is a monobactam antibacterial indicated to improve respiratory symptoms in cystic fibrosis patients with *Pseudomonas aeruginosa,* initially approved by the FDA in 2010. Cystic fibrosis is an autosomal recessive disease in which patients can have abnormal airways secretions, chronic endobronchial infection, and progressive airway obstruction.

Cayston (aztreonam inhalation solution) will be considered for coverage when the following criteria are met:

Cystic Fibrosis

For **initial** authorization:

1. Member is at least 7 years of age; AND
2. Medication must be prescribed by or in consultation with a pulmonologist or an infectious disease specialist; AND
3. Member has a diagnosis of cystic fibrosis and has a positive culture for *Pseudomonas aeruginosa* documented in chart notes; AND
4. Member has a documented trial and failure of or contraindication to generic tobramycin inhalation solution; AND
5. Member has documented forced expiratory volume in 1 second (FEV_1) 25% to 75% predicted (documented in chart notes and submitted with prior authorization request); AND
6. Member is not colonized with *Burkholderia cepacia.*
7. **Dosage allowed/Quantity limit:** 75 mg 3 times daily for 28 days in repeated cycles of 28 days on drug, followed by 28 days off drug (84 vials per 56 days).

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease demonstrated by any of the following:
   a) Improved FEV1 and/or other lung function tests
   b) Decrease in pulmonary exacerbations or hospitalization
   c) Decrease in pulmonary infections

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Cayston (aztreonam inhalation solution) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/12/2017	New policy for Cayston created. Not covered diagnosis added.
12/30/2020	Quantity limit changed to 56 days from 28 days. Reauthorization criteria updated to ask for evidence of disease stability or improvement. Diagnosis of cystic fibrosis added to initial criteria. Exclusion criteria updated to a simplified statement.
04/27/2022	Policy transferred to new template. Added references. Amended renewal criteria to reflect expected treatment response; removed sweat chloride and weight gain. Added preference for generic tobra soln.

References:

1. Cayston [package insert]. Foster City, CA: Gilead Sciences, Inc; 2019.
2. Mogayzel PJ Jr, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. *Am J Respir Crit Care Med*. 2013;187(7):680-689. doi:10.1164/rccm.201207-1160oe
3. Mogayzel PJ Jr, Naureckas ET, Robinson KA, et al. Cystic Fibrosis Foundation pulmonary guideline. pharmacologic approaches to prevention and eradication of initial Pseudomonas aeruginosa infection. *Ann Am Thorac Soc*. 2014;11(10):1640-1650. doi:10.1513/AnnalsATS.201404-166OC
4. Smith S, Rowbotham NJ, Regan KH. Inhaled anti-pseudomonal antibiotics for long-term therapy in cystic fibrosis [published online ahead of print, 2018 Mar 30]. *Cochrane Database Syst Rev*. 2018;3(3):CD001021. doi:10.1002/14651858.CD001021.pub3

Effective date: 10/01/2022
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