CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Bethkis (tobramycin inhalation solution)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Bethkis, approved in 2012, is an inhaled aminoglycoside antibacterial indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*.
Cystic fibrosis is an autosomal recessive disease in which patients can have abnormal airways secretions, chronic endobronchial infection, and progressive airway obstruction.

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

Cystic Fibrosis

For **initial** authorization:
1. Member is at least 6 years of age; AND
2. Medication is prescribed by a pulmonologist or an infectious disease specialist; AND
3. Member has a diagnosis of cystic fibrosis with a positive culture for *Pseudomonas aeruginosa* documented in chart notes; AND
4. Member has documented forced expiratory volume in 1 second (FEV_1) of 40% to 80% predicted; AND
5. Member is not colonized with *Burkholderia cepacia*; AND
6. Member has tried and failed generic tobramycin inhalation solution and ineffectiveness, intolerance or contraindication is documented in chart notes.
7. **Dosage allowed/Quantity limit:** 300 mg twice daily by oral inhalation in repeated cycles of 28 days on drug, followed by 28 days off drug. Quantity limit: 224 mL 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 defined as 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 Bethkis (tobramycin 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 Bethkis created. Not covered diagnosis added.
12/29/2020	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. Kitabis removed as preferred option. Exclusion criteria updated to a simplified statement.
4/26/2022	Policy transferred to new template. Added references. Amended renewal criteria to reflect expected treatment response; removed sweat chloride and weight gain.
02/03/2025	Updated references.

References:

1. Bethkis [package insert]. Woodstock, IL: Cornerstone Therapeutics, Inc.; 2023.
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. Inhaled anti-pseudomonal antibiotics for long-term therapy in cystic fibrosis. Cochrane Database Syst Rev. 2022;11(11):CD001021. Published 2022 Nov 14. doi:10.1002/14651858.CD001021.pub4

Effective date: 07/01/2025
Revised date: 02/03/2025