CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Tobi, Tobi Podhaler (tobramycin inhalation solution)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Tobi and Tobi Podhaler are an aminoglycoside antibacterial indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa* initially approved by the FDA in 1997 and 2013 respectively. Cystic fibrosis is an autosomal recessive disease in which patients can have abnormal airways secretions, chronic endobronchial infection, and progressive airway obstruction.

Tobi and Tobi Podhaler (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 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 documented forced expiratory volume in 1 second (FEV_1) 25% to 80% predicted; AND
5. Member is not colonized with *Burkholderia cepacia*; AND
6. For Tobi Podhaler or brand name Tobi inhalation solution, member must have trial and failure of generic tobramycin inhalation solution with ineffectiveness, intolerance or contraindication documented in chart notes
7. **Dosage allowed/Quantity limit:** administer in repeated cycles of 28 days on drug followed by 28 days off drug.
   a) Tobi: 300 mg every 12 hours. Quantity limit: 280 mL per 56 days.
   b) Tobi Podhaler: 112 mg (4 x 28 mg capsules) every 12 hours. Quantity limit: 224 capsules 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 Tobi and Tobi Podhaler (tobramycin inhaled 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
05/25/2017	New policy for Tobi created. Not covered diagnosis added.
12/30/2020	Reauthorization criteria updated to simplified statement. Diagnosis of cystic fibrosis added to initial criteria. Kitabis removed as preferred option. Exclusion criteria updated. Generic tobramycin and Tobi Podhaler added to policy.
04/28/2022	Policy transferred to new template. Updated references. Corrected Podhaler QL from 228 to 224. Changed FEV1 from 25-75% to 25-80%. Amended renewal criteria to reflect expected treatment response; removed sweat chloride and weight gain.
01/31/2025	Updated references.

References:

1. Tobi [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; 2023.
2. Tobi Podhaler [prescribing information]. Mylan; 2023.
3. 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.
4. 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
5. 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
6. 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

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