

PHARMACY POLICY STATEMENT

Marketplace

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

Tobi and Tobi Podhaler are an aminoglycoside antibacterial indicated for the management of cystic fibrosis patients with _____ 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 _____ documented in chart notes; AND
4. Member has documented forced expiratory volume in 1 second (FEV₁) 25% to 80% predicted; AND
5. Member is not colonized with _____; 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:** 300 mg every 12 hours for the solution (280 mL per 56 days) or 112 mg (4 x 28 mg capsules) every 12 hours for Podhaler (224 capsules per 56 days); administer in repeated cycles of 28 days on drug followed by 28 days off drug

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.