

Specialty Guideline Management

Tobramycin Inhalation

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
TOBI	tobramycin inhalation solution
TOBI Podhaler	tobramycin inhalation powder
Bethkis	tobramycin inhalation solution
Kitabis Pak	tobramycin inhalation solution

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication¹⁻⁵

Management of cystic fibrosis in adults and pediatric patients with *Pseudomonas aeruginosa*.

Compendial Use^{6,8,9}

Pseudomonas aeruginosa lower respiratory tract infection in patients with non-cystic fibrosis bronchiectasis.

All other indications are considered experimental/investigational and are not medically necessary.

Coverage Criteria

Cystic Fibrosis^{1-5,7,10}

Authorization of 12 months may be granted for members 2 years of age and older with cystic fibrosis when *Pseudomonas aeruginosa* is present in airway cultures OR the member has a history of *Pseudomonas aeruginosa* infection or colonization in the airways.

Bronchiectasis (Non-Cystic Fibrosis)^{6,8,9}

Authorization of 12 months may be granted for members with non-cystic fibrosis bronchiectasis when *Pseudomonas aeruginosa* is present in airway cultures OR the member has a history of *Pseudomonas aeruginosa* infection or colonization in the airways.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

References

1. Tobamycin inhalation solution pak [package insert]. Glen Allen, VA: Genericus, Inc.; January 2025.
2. Tobramycin inhalation solution [package insert]. Princeton, NJ: Dr. Reddy's Laboratories Inc.; February 2023.
3. TOBI [package insert]. Morgantown, WV: Mylan Specialty L.P.; February 2023.
4. TOBI Podhaler [package insert]. Morgantown, WV: Mylan Specialty L.P.; February 2023.
5. Bethkis [package insert]. Woodstock, IL: Chiesi USA, Inc.; February 2023.
6. Kitabis Pak [package insert]. Midlothian, VA: PARI Respiratory Equipment, Inc.; December 2024.
7. Lexicomp Online. Waltham, MA: UpToDate, Inc.. Available at: <http://online.lexi.com>. Accessed December 10, 2025.
8. Mogayzel PJ, 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
9. Rosen, MJ. Chronic cough due to bronchiectasis: ACCP evidence-based clinical practice guidelines. *Chest*. 2006;129(1 Suppl):122S-131S. doi:10.1378/chest.129.1_suppl.122S
10. Polverino E, Goeminne PC, McDonnell MJ, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. *Eur Respir J* 2017;50(3):1700629. doi:10.1183/13993003.00629-2017

Reference number(s)
1887-A

11. Lahiri T, Hempstead SE, Brady C, et al. Clinical practice guidelines from the Cystic Fibrosis Foundation for preschoolers with cystic fibrosis. *Pediatrics*. 2016;137(4):e20151784. doi:10.1542/peds.2015-1784