

Tobramycin Inhalation Products: Tobî®, Bethkis®, Kitabis™ Pak (tobramycin inhalation solution)

When requesting Tobî®, Bethkis®, or Kitabis™ Pak (tobramycin inhalation solution), the individual requiring treatment must be diagnosed with the FDA-approved indication or approved compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved Indication

Management of cystic fibrosis in individuals with *Pseudomonas aeruginosa*.

Approved Off-label Compendial Use

Treatment of bronchiectasis in individuals with *Pseudomonas aeruginosa*.

Coverage Guidelines

Cystic fibrosis

The individual must meet **all** of the following criteria for approval:

- Presence of *Pseudomonas aeruginosa* in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture); AND
- Tobramycin inhalation product is prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

Bronchiectasis, non-cystic fibrosis, with *Pseudomonas aeruginosa*

The individual must meet **all** of the following criteria for approval:

- Presence of *Pseudomonas aeruginosa* in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture);
- Is 18 years of age or older; AND
- Tobramycin inhalation product is prescribed by or in consultation with a pulmonologist.

Approval duration: 12 months

Dosing Recommendation

Tobramycin inhalation solution

Approve up to 300mg inhaled via nebulizer no more frequently than twice daily, no less than 6 hours apart, for 28 days alternating with 28 days off.

References

1. TOBI® inhalation solution [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2018.
2. Kitabis™ inhalation solution [prescribing information]. Woodstock, IL: Catalent Pharma Solutions; November 2014.
3. Bethkis® inhalation solution [prescribing information]. Woodstock, IL: Chiesi USA/Catalent Pharma Solutions; July 2017.
4. Flume PK, O'Sullivan BP, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. *Am J Respir Crit Care Med*. 2007;176:957-969.
5. Le J, Ashley ED, Neuhauser MM, et al and the Society of Infectious Diseases Pharmacists Aerosolized Antimicrobials Task Force. Consensus summary of aerosolized antimicrobial agents: application of guideline criteria. Insights from the Society of Infectious Diseases Pharmacists. *Pharmacotherapy*. 2010;30(6):562-584.
6. Geller DE. Aerosol antibiotics in cystic fibrosis. *Respir Care*. 2009;54(5):658-669.
7. 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;187:680-689.
8. Mogayzel PJ, Naureckas ET, Robinson KA, et al; and the Cystic Fibrosis Foundation Pulmonary Clinical Practice Guidelines Committee. Pharmacologic approaches to prevention and eradication of initial *Pseudomonas aeruginosa* infection. *Ann Am Thorac Soc*. 2014;11(10):1640-1650.
9. Barker AF, Couch L, Fiel SB, et al. Tobramycin solution for inhalation reduces sputum *Pseudomonas aeruginosa* density in bronchiectasis. *Am J Respir Crit Care Med*. 2000;162:481-485.
10. Orriols R, Hernando R, Ferrer A, et al. Eradication therapy against *Pseudomonas aeruginosa* in non-cystic fibrosis bronchiectasis. *Respiration*. 2015;90:299-305.
11. Drobnic ME, Sune P, Montoro JB, et al. Inhaled tobramycin in non-cystic fibrosis patients with bronchiectasis and chronic bronchial infection with *Pseudomonas aeruginosa*. *Ann Pharmacother*. 2005;39:39-44.
12. Scheinberg P, Shore E. A pilot study of the safety and efficacy of tobramycin solution for inhalation in patients with severe bronchiectasis. *Chest*. 2005;127:1420-1426.
13. McShane PJ, Naureckas ET, Tino G, Strek ME. Non-cystic fibrosis bronchiectasis. *Am J Respir Crit Care Med*. 2013;188:647-656.
14. Polverino E, Goeminne PC, McDonnell, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. *Eur Respir J*. 2017;50:1700629.
15. Orriols R, Roig J, Ferrer J, et al. Inhaled antibiotic therapy in non-cystic fibrosis patients with bronchiectasis and chronic bronchial infection by *Pseudomonas aeruginosa*. *Respir Med*. 1999;93:476-480.
16. Bilton D, Henig N, Morrissey B, Gotfried M. Addition of inhaled tobramycin to ciprofloxacin for acute exacerbations of *Pseudomonas aeruginosa* infection in adult bronchiectasis. *Chest*. 2006;130:1503-1510.