



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Tobramycin

Page: 1 of 3

Effective Date: 7/15/2024

Last Review Date: 5/2024

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
	<input checked="" type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Texas

### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for tobramycin inhalation solution under the patient's prescription drug benefit.

### Description:

#### I. FDA-Approved Indication

Management of cystic fibrosis in patients with *Pseudomonas aeruginosa*

#### II. Compendial Use

*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.

### Applicable Drug List:

tobramycin 300 mg/5 mL inhalation solution  
tobramycin 300 mg/4 mL inhalation solution  
TOBI  
TOBI Podhaler (tobramycin inhalation powder)  
Bethkis (tobramycin inhalation solution)  
Kitabis Pak (tobramycin inhalation solution)

### Policy/Guideline:

#### I. **Criteria for Initial Approval:**

##### A. **Cystic Fibrosis**

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. Patient must also be unable to take tobramycin 300 mg/5 mL nebulizer solution (generic) for the given diagnosis, due to a trial and inadequate treatment response, or intolerance, or a contraindication.

##### B. **Bronchiectasis (Non-Cystic Fibrosis)**

Authorization of 12 months may be granted for members with non-cystic fibrosis bronchiectasis when *Pseudomonas aeruginosa* is present in airway cultures OR the



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Tobramycin

Page: 2 of 3

Effective Date: 7/15/2024

Last Review Date: 5/2024

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
	<input checked="" type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Texas

member has a history of *Pseudomonas aeruginosa* infection or colonization in the airways. Patient must also be unable to take tobramycin 300 mg/5 mL nebulizer solution (generic) for the given diagnosis, due to a trial and inadequate treatment response, or intolerance, or a contraindication.

## II. Criteria for Continuation of Therapy:

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

### Approval Duration and Quantity Restrictions:

**Approval:** 12 months

### Quantity Level Limit:

- Bethkis: 224 mL per 28 days (56 ampules per 28 days)
- Kitabis Pak: 280 mL per 28 days (56 ampules per 28 days)
- TOBI (tobramycin inhalation solution): 280 mL per 28 days (56 ampules per 28 days)
- TOBI Podhaler: 224 capsules per 28 days
- tobramycin inhalation solution: 56 ampules per 28 days

### References:

1. Tobramycin inhalation solution [package insert]. Princeton, NJ: Dr. Reddy's Laboratories Inc.; February 2023.
2. TOBI [package insert]. Morgantown, WV: Mylan Specialty L.P.; February 2023.
3. TOBI Podhaler [package insert]. Morgantown, WV: Mylan Specialty L.P.; February 2023.
4. Bethkis [package insert]. Woodstock, IL: Chiesi USA, Inc.; February 2023.
5. Kitabis Pak [package insert]. Midlothian, VA: PARI Respiratory Equipment, Inc.; August 2023.
6. Lexicomp Online. Waltham, MA: UpToDate, Inc. Available at: <https://online.lexi.com>. Accessed December 18, 2023.  
[http://online.lexi.com.proxy.lib.uwaterloo.ca/lco/action/doc/retrieve/docid/patch\\_f/533571?hl=231814](http://online.lexi.com.proxy.lib.uwaterloo.ca/lco/action/doc/retrieve/docid/patch_f/533571?hl=231814).
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(7):680-689. doi: 10.1164/rccm.201207-1160oe
8. 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
9. 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



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Tobramycin

Page: 3 of 3

Effective Date: 7/15/2024

Last Review Date: 5/2024

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
	<input checked="" type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Texas

10. 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