

Reference number(s)
1887-A

SPECIALTY GUIDELINE MANAGEMENT

tobramycin inhalation solution/TOBI TOBI Podhaler (tobramycin inhalation powder) Bethkis (tobramycin inhalation solution) Kitabis Pak (tobramycin inhalation solution)

POLICY

I. 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.

A. FDA-Approved Indication

Management of cystic fibrosis in patients with *Pseudomonas aeruginosa*

B. 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.

II. 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.

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 member has a history of *Pseudomonas aeruginosa* infection or colonization in the airways.

III. 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.

IV. 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.

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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.
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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
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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