

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 Indications

Management of cystic fibrosis in patients with *Pseudomonas aeruginosa*

B. Compendial Uses

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 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]. Sellersville, PA: Teva Pharmaceuticals USA; January 2019.
2. TOBI [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2015.
3. TOBI Podhaler [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2015.
4. Bethkis [package insert]. Woodstock, IL: Chiesi USA, Inc.; July 2017.
5. Kitabis Pak [package insert]. Midlothian, VA: PARI Respiratory Equipment, Inc.; May 2016.

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6. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado. Available at <https://www.micromedexsolutions.com> Accessed December 24, 2018.
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. Rosen, MJ. Chronic cough due to bronchiectasis: ACCP Evidence-Based Clinical Practice Guidelines. *Chest*. 2006;129:122S-131S.
9. Caremark Clinical Programs Review: Focus on Pulmonology; January 2008.