

## 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 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 a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

###### A. Cystic Fibrosis

Authorization of 24 months may be granted for members with cystic fibrosis when all of the following criteria are met:

1. *Pseudomonas aeruginosa* is present in airway cultures OR the member has a history of *Pseudomonas aeruginosa* infection or colonization in the airways.
2. The diagnosis of cystic fibrosis was confirmed by appropriate diagnostic or genetic testing.

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

Authorization of 12 months may be granted for members with non-cystic fibrosis bronchiectasis when the following criteria are met:

1. *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

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

##### IV. REFERENCES

1. Tobramycin inhalation solution [package insert]. Sellersville, PA: Teva Pharmaceuticals USA; December 2015.
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.; May 2014.
5. Kitabis Pak [package insert]. Midlothian, VA: PARI Respiratory Equipment, Inc.; November 2014.
6. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at <http://www.micromedexsolutions.com>. Accessed November 28, 2016.
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.