

# AETNA BETTER HEALTH®

Coverage Policy/Guideline

Name:TobramycinPage:1 of 2Effective Date:6/9/2025Last Review Date:5/27/2025

Applies to: ⊠Florida Kids ⊠New Jersey ⊠Maryland ⊠Pennsylvania Kids

#### 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:

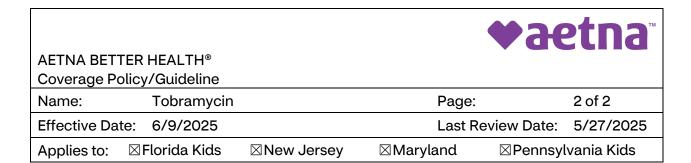
#### I. Criteria for Initial Approval:

# 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 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:**

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- 4. Bethkis [package insert]. Woodstock, IL: Chiesi USA, Inc.; February 2023.
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- 6. Lexicomp Online. Waltham, MA: UpToDate, Inc.. Available at: http://online.lexi.com. Accessed December 18, 2024.
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- 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