

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

DRUG NAME	Bethkis (tobramycin inhalation solution)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include generic tobramycin inhalation solution, Tobi and Kitabis Pak QUANTITY LIMIT – 224 mL per 28 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Bethkis (tobramycin inhalation solution) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

#### CYSTIC FIBROSIS

For **initial** authorization:

1. Member must be 6 years of age or older; AND
2. Member has a positive culture for Pseudomonas aeruginosa documented in chart notes; AND
3. Member is not colonized with Burkholderia cepacia; AND
4. Medication is prescribed by a pulmonologist or an infectious disease specialist; AND
5. Member has documented forced expiratory volume in 1 second (FEV1) > 40% or < 80% predicted; AND
6. Member has tried and failed generic tobramycin inhalation solution, Tobi inhalation solution and Kitabis Pak, and ineffectiveness, intolerance or contraindication is documented in chart notes.
7. **Dosage allowed:** 300 mg twice daily by oral inhalation in repeated cycles of 28 days on drug, followed by 28 days off drug.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be in compliance with all other initial criteria.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

CareSource considers Bethkis (tobramycin inhalation solution) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Non-cystic fibrosis bronchiectasis

DATE	ACTION/DESCRIPTION
06/12/2017	New policy for Bethkis created. Not covered diagnosis added.



References:

1. National Guideline Clearinghouse (NGC). Guideline summary: Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. In: National Guideline Clearinghouse (NGC) [Web site]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2013 Apr 01. [cited 2016 Dec 19]. Available: <https://www.guideline.gov>. Accessed February 9, 2017.
2. Bethkis [package insert]. Foster City, CA: Gilead Sciences Inc; 2014. Accessed March 10, 2017.
3. Bethkis. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed March 10, 2017.

Effective date: 08/09/2017

Revised date: 06/12/2017