

PHARMACY POLICY STATEMENT Kentucky 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 NOT MEDICALLY NECESSARY	Click Here

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