CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
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 (Non-Preferred Product) Alternative preferred products include generic tobramycin inhalation solution QUANTITY LIMIT — 224 mL per 56 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 diagnosis of cystic fibrosis and 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 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; AND
2. Evidence of disease stability or disease improvement
   a) Note: Disease improvement is evidenced by chart notes with any of the following:
      i) Improved FEV1 and/or other lung function tests;
      ii) Improvement in sweat chloride;
      iii) Decrease in pulmonary exacerbations;
      iv) Decrease in pulmonary infections;
      v) Increase in weight-gain;
      vi) Decrease in hospitalizations.

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 diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
06/12/2017	New policy for Bethkis created. Not covered diagnosis added.
12/29/2020	Quantity limit changed to 56 days from 28 days. Reauthorization criteria updated to ask for evidence of disease stability or improvement. Diagnosis of cystic fibrosis added to initial criteria. Kitabis removed as preferred option. Exclusion criteria updated to a simplified statement.
11/17/2021	Annual review, no changes

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..
2. Bethkis [package insert]. Woodstock, IL: Cornerstone Therapeutics, Inc.; 2012.
3. Bethkis. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com.

Effective date: 01/01/2022
Revised date: 11/17/2021