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
References:


Effective date: 08/09/2017
Revised date: 06/12/2017