CareSource

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	**Tobi (tobramycin inhalation solution), Tobi Podhaler**
BILLING CODE	**Must use valid NDC**
BENEFIT TYPE	**Pharmacy**
SITE OF SERVICE ALLOWED	**Home**
COVERAGE REQUIREMENTS	**Prior Authorization Required** **QUANTITY LIMIT—280 mL per 56 days (solution)** **228 capsules per 56 days (podhaler)**
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	**Click Here**

Tobi (brand name) and Tobi Podhaler are non-preferred products and generic tobramycin inhaled solution is a preferred product. These 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) > 25% or < 75% predicted; AND**
6. **For Tobi Podhaler or brand name Tobi inhalation solution, member must have trial and failure of generic tobramycin inhalation solution with ineffectiveness, intolerance or contraindication documented in chart notes.**
7. **Dosage allowed: 300 mg every 12 hours for the solution or 112 mg (4 x 28 mg capsules) every 12 hours for podhaler; administer 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.**
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 Tobi, Tobi podhaler, and generic tobramycin inhaled solution not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/25/2017	New policy for Tobi created. Not covered diagnosis added.
12/30/2020	Reauthorization criteria updated to simplified statement. Diagnosis of cystic fibrosis added to initial criteria. Kitabis removed as preferred option. Exclusion criteria updated. Generic tobramycin and Tobi podhaler added to policy.

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. Tobi [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; 2015.
3. Tobi. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com.

Effective date: 07/01/2021
Revised date: 12/30/2020