PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Tobi (tobramycin inhalation solution)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>Must use valid NDC code</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Pharmacy</td>
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<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Home</td>
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<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Preferred Product) Alternative preferred products include generic tobramycin solution and Kitabis Pak QUANTITY LIMIT — 280 mL per 30 days</td>
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<tr>
<td>LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY</td>
<td>Click Here</td>
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Tobi (tobramycin inhalation solution) is a 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) > 25% or < 75% 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 every 12 hours; 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.

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

CareSource considers Tobi (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

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<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>05/25/2017</td>
<td>New policy for Tobi created. Not covered diagnosis added.</td>
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References:


Effective date: 08/09/2017
Revised date: 05/25/2017