# PRIOR AUTHORIZATION POLICY

**POLICY:** Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization Policy
- Bethkis® (tobramycin inhalation solution – Chiesi, generic)
- Kitabis® (tobramycin inhalation solution – Pari, authorized generic)
- TOBI® (tobramycin inhalation solution – Mylan, generic)

**REVIEW DATE:** 03/18/2026

***INSTRUCTIONS FOR USE***

*THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.*

## CIGNA NATIONAL FORMULARY COVERAGE:

### OVERVIEW

The tobramycin inhalation solutions are aminoglycoside antibiotics indicated for the management of **cystic fibrosis (CF)** in patients with *Pseudomonas aeruginosa.*[1-3] TOBI (generic) and Kitabis (authorized generic) are indicated for the management of CF in patients ≥ 6 years of age.[1,2] Safety and efficacy have not been demonstrated in patients < 6 years of age, patients with forced expiratory volume in 1 second ($FEV_1$) < 25% or > 75% predicted, or patients colonized with *Burkholderia cepacia.* Bethkis (generic) is indicated for the management of CF patients with *P. aeruginosa*.[3] Safety and efficacy have not been demonstrated in patients < 6 years of age, patients with $FEV_1$ < 40% or > 80% predicted, or patients colonized with *B. cepacia*.

### Guidelines

The Cystic Fibrosis Foundation (CFF) Pulmonary Therapeutics Committee published recommendations for the use of chronic medications in the management of CF lung disease (2013).[4] In patients ≥ 6 years of age with CF and moderate-to-severe lung disease with *P. aeruginosa* persistently present in cultures of the airways, chronic use of inhaled tobramycin is strongly recommended to improve lung function and quality of life, and reduce exacerbations. For mild disease, the Committee recommends chronic use of inhaled tobramycin for patients ≥ 6 years of age with CF and *P. aeruginosa* persistently present in cultures of the airways, to reduce exacerbations.

The CFF published a systematic review of the literature regarding eradication of initial *P. aeruginosa* infections to develop guidelines for effective prevention (2014).[5] The recommendations pertaining to inhaled antibiotics are as follows: 1) Inhaled antibiotic therapy is recommended for the treatment of initial or new growth of *P. aeruginosa* (the favored antibiotic regimen is tobramycin [300 mg twice daily] for 28 days); and 2). Prophylactic antipseudomonal antibiotics to prevent the acquisition of *P. aeruginosa* are not recommended.

**Non-CF Bronchiectasis**

A few trials in adults support the efficacy of tobramycin inhalation solution (TIS) for the treatment of bronchiectasis with *P. aeruginosa* infection.[6-9,12,13] A literature review concluded that in patients with non-CF bronchiectasis and chronic *P. aeruginosa* infection, TIS is effective in reducing the density of bacteria in sputum, which may be associated with additional clinical benefit.[10,12]

There are no US guidelines focused on the pharmacologic treatment of Bronchiectasis. The European Respiratory Society (ERS) clinical practice guidelines for the management of adult bronchiectasis (2025) provide a strong recommendation in favor of long-term inhaled antibiotics in patients with chronic *P. aeruginosa* infection at high risk of exacerbation.[14] In patients with new isolation of *P. aeruginosa*, eradication treatment should be offered in accordance with the ERS 2017 guidelines for the management of adult bronchiectasis which recommend eradication antibiotic treatment including nebulized antibiotics (e.g., colistin, gentamicin, tobramycin).[11]

ERS guidelines for the management of children and adolescents with bronchiectasis suggest eradication therapy following an initial or new detection of *P. aeruginosa*.[12] It is acknowledged that there is currently no evidence for early eradication from well-conducted trials in children or adolescents with bronchiectasis. However, the recommendation places a higher value on the theoretical benefits of eradication and a lower value on possible treatment-related adverse effects.

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of tobramycin inhalation solution. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with tobramycin inhalation solution as well as the monitoring required for adverse events and long-term efficacy, approval requires tobramycin inhalation solution to be

prescribed by or in consultation with a physician who specializes in the condition being treated.

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**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

**FDA-Approved Indication**

1. **Cystic Fibrosis.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   **A)** Patient has *Pseudomonas aeruginosa* in culture of the airway; AND
   Note: Examples of culture of the airway include sputum culture, oropharyngeal culture, bronchoalveolar lavage culture.
   **B)** The medication is prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

**Other Uses with Supportive Evidence**

2. **Bronchiectasis, Non-Cystic Fibrosis**. Approve for 1 year if the patient meets BOTH of the following (A and B):
   **A)** Patient has *Pseudomonas aeruginosa* in culture of the airway; AND
   Note: Examples of culture of the airway include sputum culture, oropharyngeal culture, bronchoalveolar lavage culture.
   **B)** The medication is prescribed by or in consultation with a pulmonologist.

3. **Continuation of Tobramycin Inhalation Solution Therapy**. Approve for 1 month if the patient was started on tobramycin inhalation solution and is continuing a course of therapy.

**CONDITIONS NOT COVERED**

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**is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

1. **Nasal Rinse**. Tobramycin inhalation solution is not approvable for compounding of tobramycin nasal rinse.

**REFERENCES**

1. TOBI® inhalation solution [prescribing information]. Morgantown, WV: Mylan; February 2023.
2. Kitabis® inhalation solution [prescribing information]. Midlothian, VA: Pari; April 2023.
3. Bethkis® inhalation solution [prescribing information]. Woodstock, IL: Chiesi; February 2023.

4. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic Fibrosis Pulmonary Guidelines. Chronic Medications for Maintenance of Lung Health. *Am J Respir Crit Care Med*. 2013;187:680-689.
5. Mogayzel PJ, Naureckas ET, Robinson KA, et al; and the Cystic Fibrosis Foundation Pulmonary Clinical Practice Guidelines Committee. Pharmacologic approaches to prevention and eradication of initial *Pseudomonas aeruginosa* infection. *Ann Am Thorac Soc*. 2014;11(10):1640-1650.
6. Barker AF, Couch L, Fiel SB, et al. Tobramycin solution for inhalation reduces sputum *Pseudomonas aeruginosa* density in bronchiectasis. *Am J Respir Crit Care Med*. 2000;162:481-485.
7. Orriols R, Hernando R, Ferrer A, et al. Eradication therapy against *Pseudomonas aeruginosa* in non-cystic fibrosis bronchiectasis. *Respiration*. 2015;90:299-305.
8. Drobnic ME, Sune P, Montoro JB, et al. Inhaled tobramycin in non-cystic fibrosis patients with bronchiectasis and chronic bronchial infection with *Pseudomonas aeruginosa*. *Ann Pharmacother*. 2005;39:39-44.
9. Scheinberg P, Shore E. A pilot study of the safety and efficacy of tobramycin solution for inhalation in patients with severe bronchiectasis. *Chest*. 2005;127:1420-1426.
10. Barker AF and Karamooz E. Non-cystic fibrosis bronchiectasis in adults a review. *JAMA*. 2025;334(3):253-264.
11. Polverino E, Goeminne PC, McDonnell, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. *Eur Respir J*. 2017;50:1700629.
12. Elborn JS, BLasi F, Haworth CS, et al. Bronchiectasis and inhaled tobramycin: A literature review. *Respir Med.* 2022:192:106728.
13. Guan WJ, Xu JF, Luo H, et al. A double-blind randomized placebo-controlled Phase III trial of tobramycin inhalation solution in adults with bronchiectasis with *Pseudomonas aeruginosa* infection. *Chest.* 2023;163(1):64-76.
14. Chalmers JD, Haworth CS, Flume P, et al. European Respiratory Society clinical practice guideline for the management of adult bronchiectasis. *Eur Respir J.* 2025;66: 2501126.
15. Chang AB, Fortescue R, Gromwood K, et al. European Respiratory Society guidelines for the management of children and adolescents with bronchiectasis. *Eur Respir J.* 2021;58:200990.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | Generic to Bethkis was added to the policy. No criteria changes. | 03/27/2024 |
| Annual Revision | No criteria changes. | 03/12/2025 |
| Annual Revision | **Bronchiectasis, Non-Cystic Fibrosis.** The requirement that the patient is ≥ 18 years of age was removed. | 03/18/2026 |