



Original Effective Date: 11/01/2016  
 Current Effective Date: 12/01/2025  
 Last P&T Approval/Version: 10/29/2025  
 Next Review Due By: 10/2026  
 Policy Number: C8665-A

## Tobramycin for Inhalation

### PRODUCTS AFFECTED

Bethkis (tobramycin neb solution), Kitabis (tobramycin neb solution), Tobi (tobramycin neb solution), Tobi Podhaler (tobramycin inhal caps), tobramycin nebulized solution

### COVERAGE POLICY

*Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.*

#### **Documentation Requirements:**

*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

#### **DIAGNOSIS:**

Cystic fibrosis, Bronchiectasis

#### **REQUIRED MEDICAL INFORMATION:**

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

#### **A. CYSTIC FIBROSIS:**

1. Documented diagnosis of cystic fibrosis  
AND
2. Documentation of pseudomonas aeruginosa in at least one airway [DOCUMENTATION]

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REQUIRED]

AND

3. FOR BETHKIS: Documentation that member has a forced expiratory volume in one second (FEV1) between 40% and 80% predicted [DOCUMENTATION REQUIRED]  
OR  
FOR KITABIS, TOBI INHALATION SOLUTION, TOBRAMYCIN INHALATION SOLUTION:  
Documentation that member has a forced expiratory volume in one second (FEV1) between 25% and 75% predicted [DOCUMENTATION REQUIRED]  
OR  
FOR TOBI PODHALER: Documentation that member has a forced expiratory volume in one second (FEV1) between 25% and 80% predicted [DOCUMENTATION REQUIRED]  
AND
4. Prescriber attests (or the clinical reviewer has found) that the member is not colonized with *Burkholderia cepacia*  
AND
5. (a) Documentation that therapeutic plan does NOT include concurrent or alternating use of Cayston with TOBI/TOBI Podhaler or tobramycin inhalation  
OR  
(b) If concurrent therapy is requested: Documentation member has tried and failed monotherapy with Cayston (aztreonam) AND tobramycin separately prior to using concurrent alternating therapy [DOCUMENTATION REQUIRED]  
AND
6. Documentation member has tried, failed or has medical necessity for using any product other than preferred formulary agent (tobramycin nebulized solution)  
AND
7. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to inhaled tobramycin include: patients with a known hypersensitivity to any aminoglycoside]

### B. NON-CYSTIC FIBROSIS BRONCHIECTASIS:

1. Documented diagnosis of non-cystic fibrosis bronchiectasis  
AND
2. Documentation member has had three or more exacerbations per year OR significant morbidity from fewer exacerbations  
AND
3. Documentation that member has tobramycin sensitive *pseudomonas aeruginosa* present in the respiratory secretions  
AND
4. Documentation of baseline forced expiratory volume in one second (FEV1), frequency and severity of exacerbations, or symptoms  
AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to inhaled tobramycin include: patients with a known hypersensitivity to any aminoglycoside]

### CONTINUATION OF THERAPY:

#### A. CYSTIC FIBROSIS:

1. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms  
AND
2. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history  
AND

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3. If inhaled tobramycin (Bethkis, Kitabis Pak, TOBI, TOBI Podhaler) is prescribed concurrently (or for alternating use) with Cayston, documentation supports inadequate response to both agents alone (e.g., deteriorating pulmonary status, recurrent pulmonary exacerbations) [DOCUMENTATION REQUIRED]  
AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

### B. NON-CYSTIC FIBROSIS BRONCHIECTASIS:

1. Documentation of positive clinical response as demonstrated by reduced sputum Pseudomonas density, improved forced expiratory volume in one second (FEV1), decreased hospitalizations and/or frequency or severity of exacerbations  
AND
2. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history  
AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

### DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

### PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a pulmonologist, infectious disease specialist, cystic fibrosis specialist or physician from a CF center accredited by the Cystic Fibrosis Foundation. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

### AGE RESTRICTIONS:

6 years of age and older

### QUANTITY:

CYSTIC FIBROSIS: 28 day supply every 56 days (28 days on, 28 days off)

NON-CYSTIC FIBROSIS BRONCHIECTASIS: 160 mg or 300 mg twice daily (28 days on, 28 days off)

### PLACE OF ADMINISTRATION:

The recommendation is that inhalation medications in this policy will be for pharmacy benefit coverage and patient self-administered.

## DRUG INFORMATION

### ROUTE OF ADMINISTRATION:

Inhalation

### DRUG CLASS:

Aminoglycoside

### FDA-APPROVED USES:

Indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with *Pseudomonas aeruginosa*

*Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with a forced expiratory volume in one second (FEV1) less than 40% or greater than 80% predicted [BETHKIS], FEV1 less than 25% or greater than 75% predicted [KITABIS, TOBI INHALATION SOLUTION, TOBRAMYCIN INHALATION SOLUTION], FEV1 less than 25% or greater than 80% predicted [TOBI PODHALER], or patients colonized with Burkholderia cepacia.*

**COMPENDIAL APPROVED OFF-LABELED USES:**

Pseudomonas aeruginosa lower respiratory tract infection in patients with non-cystic fibrosis bronchiectasis

**APPENDIX**

**APPENDIX:**

None

**BACKGROUND AND OTHER CONSIDERATIONS**

**BACKGROUND:**

None

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

All other uses of Tobramycin for inhalation are considered experimental/investigational and therefore, will follow Molina’s Off-Label policy. Contraindications to Tobramycin for inhalation include: patients with a known hypersensitivity to any aminoglycoside.

**OTHER SPECIAL CONSIDERATIONS:**

The use of continuous alternating therapy (i.e., alternating different inhaled antibiotics in order to provide continuous therapy) lacks sufficient evidence. The efficacy of this practice was evaluated in a randomized, double-blind, phase 3 trial. 90 patients received 28-days inhaled tobramycin alternating with either 28- days inhaled aztreonam or placebo. Although the study found reduced exacerbation and respiratory hospitalization rates with the alternating tobramycin/aztreonam regimen compared to tobramycin/placebo, it was underpowered, and these results were not statistically significant.

Administer Bethkis using a hand-held PARI LC PLUS Reusable Nebulizer with a PARI Vios Air compressor.

Administer Kitabis, TOBI, Tobramycin inhalation solution using the PARI LC PLUS Reusable Nebulizer and DeVilbiss Pulmo-Aide compressor.

**CODING/BILLING INFORMATION**

***CODING DISCLAIMER.*** Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
N/A	N/A

**AVAILABLE DOSAGE FORMS:**

- Bethkis NEBU 300MG/4ML
- Kitabis Pak NEBU 300MG/5ML
- Tobi NEBU 300MG/5ML
- Tobi Podhaler CAPS 28MG
- Tobramycin NEBU 300MG/4ML
- Tobramycin NEBU 300MG/5ML

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Duration of Approval FDA-Approved Uses	Q4 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Age Restrictions FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q4 2023

## Drug and Biologic Coverage Criteria

REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file