UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1109-14
Program	Prior Authorization/Notification - tobramycin inhalation solution/powder
Medication*	Bethkis®, Kitabis® Pak¥, TOBI™ Nebulizer Solution and TOBI® Podhaler™, tobramycin solution for inhalation * This list is subject to change ¥ Kitabis Pak is excluded from coverage for the majority of our benefits.
P&T Approval Date	5/2013, 2/2014, 2/2015, 2/2016, 2/2017, 2/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023, 9/2023, 9/2024, 9/2025
Effective Date	11/16/2025

1. Background:

Bethkis (tobramycin) is an inhaled aminoglycoside antibacterial indicated for the management of cystic fibrosis (CF) patients with *Pseudomonas aeruginosa* (*P. aeruginosa*). Safety and efficacy have not been demonstrated in patients under the age of six years, patients with a forced expiratory volume in less than one second (FEV_1) <40% or >80% predicted, or patients colonized with *Burkholderia cepacia* (*B. cepacia*). Bethkis is administered by inhalation using a hand-held PARI LC Plus® Reusable Nebulizer with a PARI Vios Air compressor. After 28 days of therapy, patients should stop Bethkis therapy for the next 28 days, and then resume therapy for the next 28 day on and 28 day off cycle.[3]

TOBI (tobramycin) and tobramycin inhalation solution are aminoglycoside antibacterials indicated for the management of CF patients with *P. aeruginosa*. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV_1 <25% or >75% predicted, or patients colonized with *B. cepacia.* TOBI is specifically formulated for inhalation using the DeVilbiss® Pulmo-Aide® air compressor and PARI LC Plus® Reusable Nebulizer. After 28 days of therapy, patients should stop TOBI therapy for the next 28 days, and then resume therapy for the next 28 day on and 28 day off cycle.[1, 5]

TOBI Podhaler (tobramycin) is an antibacterial aminoglycoside indicated for the management of CF patients with *P. aeruginosa*. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV_1 <25% or >80%, or patients colonized with *B. cepacia*. The contents of TOBI Podhaler capsules are only for oral inhalation and should only be used with the Podhaler device. After 28 days of therapy, patients should stop TOBI therapy for the next 28 days, and then resume therapy for the next 28 day on and 28 day off cycle.[2]

Kitabis Pak (co-packaging of tobramycin inhalation solution and PARI LC Plus® Reusable Nebulizer) is an aminoglycoside antibacterial drug indicated for the management of CF in adults and pediatric patients 6 years of age and older with *P. aeruginosa*. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV_1 <25% or >75% predicted, or patients colonized with *B. cepacia*. After 28 days of therapy, patients should stop Kitabis therapy for the next 28 days, and then resume therapy for the next 28 day on and 28 day off cycle.[4]

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Bethkis, Kitabis Pak, TOBI Solution for Inhalation, TOBI Podhaler, or tobramycin solution for inhalation** will be approved based on **both** of the following criteria:

   a. **One** of the following:

      (1) Diagnosis of cystic fibrosis (CF)

      -OR-

      (2) **Both** of the following:

         (a) Diagnosis of noncystic fibrosis bronchiectasis

         -AND-

         (b) **One** of the following:

            i. Three or more exacerbations per year

            -OR-

            ii. Two or more exacerbations requiring hospitalization per year

   -AND-

   b. Lung infection with positive culture demonstrating *Pseudomonas aeruginosa* infection

2. **Authorization will be issued for 12 months**

   a. Reauthorization

      (1) **Bethkis, Kitabis Pak, TOBI Solution for Inhalation, TOBI Podhaler, or tobramycin solution for inhalation** will be approved based on the following criterion:

         (a) Documentation of positive clinical response to Bethkis, Kitabis Pak, TOBI Nebulizer Solution, TOBI Podhaler, or tobramycin solution for inhalation therapy

   Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- Not all tobramycin products are covered. Refer to the most current UHC prescription drug list to identify covered products.
- Exclusion: Kitabis Pak is excluded from coverage for the majority of our benefits.

4. References:

1. TOBI Inhalation Solution [package insert]. East Hanover, NJ: Mylan Pharmaceuticals; February 2023.
2. TOBI Podhaler [package insert]. San Carlos, CA: Mylan Pharmaceuticals Inc.; February 2023.
3. Bethkis [package insert]. Woodstock, Illinois: Chesi USA, Inc.; February 2023.
4. Kitabis Pak [package insert]. Woodstock, Illinois: Catalent Pharma Solutions, LLC; April 2023.
5. Tobramycin Inhalation Solution [package insert]. Sellersville, PA.: Teva Pharmaceuticals USA; December 2024.
6. Polverino E, Goeminne PC, McDonnell MJ, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. Eur Respir J. 2017;50(3):1700629. Published 2017 Sep 9. doi:10.1183/13993003.00629-2017
7. Spencer S, Felix LM, Milan SJ, et al. Oral versus inhaled antibiotics for bronchiectasis. Cochrane Database Syst Rev. 2018;3(3):CD012579. Published 2018 Mar 27. doi:10.1002/14651858.CD012579.pub2
8. Chang AB, Bell SC, Byrnes CA, et al. Thoracic Society of Australia and New Zealand (TSANZ) position statement on chronic suppurative lung disease and bronchiectasis in children, adolescents and adults in Australia and New Zealand. Respirology. 2023;28(4):339-349. doi:10.1111/resp.14479
9. Laska IF, Crichton ML, Shoemark A, Chalmers JD. The efficacy and safety of inhaled antibiotics for the treatment of bronchiectasis in adults: a systematic review and meta-analysis. Lancet Respir Med. 2019;7(10):855-869. doi:10.1016/S2213-2600(19)30185-7

Program	Prior Authorization/Notification – Bethkis (tobramycin inhalation solution), TOBI Nebulizer Solution (tobramycin inhalation solution) and TOBI Podhaler (tobramycin inhalation powder)
Change Control	
2/2014	Updated Background information and added criteria for Bethkis. Removed reauthorization criteria and increased authorization to 60 months.
2/2015	Annual review. Added coverage for Kitabis Pak and tobramycin inhalation solution. Updated background, clinical rules and references.
2/2016	Annual review with no changes to clinical content. Changed authorization period to 12 months and added re-authorization period for 12 months. Updated references.
2/2017	Annual review. No changes to coverage criteria.
2/2018	Annual review. No changes to coverage criteria. Updated reference.

2/2019	Annual review. No changes to coverage criteria. Updated background and references.
2/2020	Annual review. Updated background and references. No changes to coverage criteria.
2/2021	Annual review. Updated references. No changes to coverage criteria. Notation of exclusion for Kitabis Pak from the majority of our benefits.
2/2022	Annual review without changes to coverage criteria. Updated background and references.
2/2023	Annual review without changes to coverage criteria. Added state mandate footnote and updated references.
9/2023	Added coverage criteria for noncystic fibrosis bronchiectasis with recurrent exacerbations. Updated references.
9/2024	Annual review. No changes to coverage criteria. Updated references.
9/2025	Annual review. No changes to coverage criteria. Updated references.