

Applicable Drugs: Bethkis (tobramycin inhalation solution), Kitabis Pak (tobramycin inhalation solution), TOBI (tobramycin inhalation solution), TOBI Podhaler (tobramycin inhalation powder), tobramycin inhalation solution (generic)

Preferred: Tobramycin inhalation solution (generic)

Non-preferred: Bethkis (tobramycin inhalation solution), Kitabis Pak (tobramycin inhalation solution), TOBI (tobramycin inhalation solution), TOBI Podhaler (tobramycin inhalation powder)

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 5/19/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

- I. Documented diagnosis of Cystic Fibrosis (CF).
- II. Positive culture demonstrating *Pseudomonas aeruginosa* in the respiratory tract.
- III. Minimum age requirement: 6 years old.
- IV. Treatment must be prescribed by or in consultation with a pulmonologist, infectious disease specialist, or physician who specializes in the treatment of cystic fibrosis.
- V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- VI. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Patients colonized with *Burkholderia cepacia*.
- Routine use for prophylaxis of *P. aeruginosa* infection.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Bethkis, Generic tobramycin inhalation solution, Kitabis Pak, TOBI: One 56 ampule carton per 56 days.
- TOBI Podhaler: One unit dose (blister pack), box of 224 capsules per 56 days.

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing positive clinical response (must have improved FEV1 AND a decrease in the sputum density of *P. aeruginosa*).

APPENDIX

N/A

REFERENCES

1. Bethkis. Prescribing information. Chiesi USA, Inc; 2023. Accessed May 19, 2026.
https://resources.chiesiusa.com/Bethkis/BETHKIS_PI.pdf
2. Kitabis. Prescribing information. Pari Respiratory Equipment Inc; 2023. Accessed May 19, 2026.
<https://kitabis.com/prescribing-information>
3. Tobi. Prescribing information. Mylan Pharmaceuticals Inc; 2023. Accessed May 19, 2026.
<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=6a3c3871-1d3a-44d6-8be3-526b30123ef7&type=display>
4. Tobi Podhaler. Prescribing information. Mylan Pharmaceuticals Inc; 2023. Accessed May 19, 2026.
<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?type=display&setid=c4b5bb1f-e158-4ac1-9c35-e98a416c743a>
5. Mogayzel PJ Jr, Naureckas ET, Robinson KA, et al. Cystic Fibrosis Foundation pulmonary guideline. Pharmacologic approaches to prevention and eradication of initial *Pseudomonas aeruginosa* infection. *Ann Am Thorac Soc*. 2014;11(10):1640-1650.
doi:10.1513/AnnalsATS.201404-166OC

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.