

Tobi® (tobramycin), Tobi® Podhaler™ (tobramycin), Bethkis® (tobramycin), and Kitabis™ Pak (tobramycin inhaled products)



When requesting Tobi® (tobramycin), Tobi® Podhaler™ (tobramycin), Bethkis® (tobramycin), and Kitabis™ Pak (tobramycin), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indication

- Indicated for the management of cystic fibrosis in individuals with *Pseudomonas aeruginosa*¹⁻⁴

Approved Off-label Compendial uses⁵

- No off-label uses meet evidence standards

Coverage Guidelines

For the approved indication, the individual does **not** have the following contraindication or exclusion to therapy:

- A hypersensitivity to any aminoglycoside¹⁻⁴

Cystic Fibrosis¹⁻⁴

The individual must meet **all** of the following criteria for approval:

- Diagnosis of cystic fibrosis¹⁻⁴ confirmed by appropriate diagnostic or genetic testing⁶
- Lung infection with positive identification (either by culture or DNA testing) of *Pseudomonas aeruginosa* infection¹⁻⁴

Approval duration: 12 months

Additional Information for Prescribers

- Bronchospasm can occur with inhalation of tobramycin inhalation solution. Treat as medically appropriate, if it occurs.¹⁻⁴
- Tinnitus and hearing loss have been reported in individuals receiving tobramycin inhalation solution. If noted, manage as medically appropriate, including potentially discontinuing tobramycin inhalation solution.¹⁻⁴
- Nephrotoxicity has been associated with aminoglycosides as a class. If nephrotoxicity develops, manage the individual as medically appropriate, including potentially discontinuing tobramycin inhalation solution.¹⁻⁴
- Aminoglycosides may aggravate muscle weakness because of a potential curare-like effect on neuromuscular function. If neuromuscular blockade occurs, it

may be reversed by the administration of calcium salts but mechanical assistance may be necessary.¹⁻⁴

References

1. Tobi® prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corporation: October 2015. <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tobi.pdf>. Accessed February 6, 2017.
2. Tobi® Podhaler™ prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corporation: Revised December 2016. <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tobipodhaler.pdf>. Accessed February 6, 2017.
3. Bethkis® prescribing information. Woodstock, Illinois: Chiesi USA: Revised May 2014. http://chiesiusa.com/wp-content/uploads/Bethkis_PI.pdf. Accessed February 6, 2017.
4. Kitabis™ PAK prescribing information. Woodstock, Illinois: Catalent Pharma Solutions, LLC: Revised November 2014. <http://kitabis.com/wp-content/uploads/pdfs/Kitabis-Pak-Full-Prescribing-Information.pdf>. Accessed February 6, 2017.
5. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 6, 2017. <https://www.micromedexsolutions.com>.
6. Farrell PM, Rosenstein BJ, White TB, et al. Guidelines for diagnosis of cystic fibrosis in newborns through older adults: Cystic Fibrosis Foundation consensus report. *J Pediatr*. 2008;153(2):S4.