

Clinical Policy: Tobramycin (Bethkis Inhalation Solution, Kitabis Pak, TOBI Inhalation Solution, TOBI Podhaler)

Reference Number: PA.CP.PHAR.211

Effective Date: 01/18

Last Review Date: 07/18

[Coding Implications](#)
[Revision Log](#)

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for tobramycin inhalation solution with nebulizer (Kitabis™ Pak/authorized generic Tobramycin Inhalation Solution Pak), tobramycin inhalation solution (Bethkis®, TOBI®/generic), and tobramycin inhalation powder (TOBI® Podhaler™).

FDA Approved Indication(s)

Bethkis, Kitabis Pak, TOBI, and TOBI Podhaler are indicated for the management of cystic fibrosis (CF) in patients with *Pseudomonas aeruginosa*. Kitabis Pak is specifically indicated for patients 6 years of age and older.

Limitation(s) of use: Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with forced expiratory volume in one second (FEV₁) < 25% or > 75% predicted (< 40% or > 80% predicted for Bethkis), or patients colonized with *Burkholderia cepacia*.

Policy/Criteria

It is the policy of Pennsylvania Health and Wellness that tobramycin inhalation solution and TOBI Podhaler are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cystic Fibrosis (must meet all):

1. Diagnosis of CF;
2. Age ≥ 6 years;
3. *Pseudomonas aeruginosa* is present in at least one airway culture;
4. Member meets one of the following (a or b):
 - a. Tobramycin is not prescribed concurrently (or for alternating use) with inhaled aztreonam (Cayston®);
 - b. If member is currently receiving inhaled aztreonam (Cayston), documentation supports inadequate response to aztreonam alone (e.g., deteriorating pulmonary status, recurrent pulmonary exacerbations);
5. Dose does not exceed (a or b):
 - a. Inhalation solution (Bethkis, Kitabis Pak, TOBI): 600 mg/day administered on a 28 days on/28 days off cycle;
 - b. Inhalation powder (TOBI Podhaler): 224 mg/day administered on a 28 days on/28 days off cycle.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Cystic Fibrosis (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (e.g.: stable or improved pulmonary function, improved quality of life, reduced hospitalization);
3. If tobramycin is prescribed concurrently (or for alternating use) with inhaled aztreonam (Cayston), documentation supports inadequate response to either agent alone (e.g., deteriorating pulmonary status, recurrent pulmonary exacerbations);
4. If request is for a dose increase, new dose does not exceed (a or b):
 - a. Inhalation solution (Bethkis, Kitabis Pak, TOBI): 600 mg/day administered on a 28 days on/28 days off cycle;
 - b. Inhalation powder (TOBI Podhaler): 224 mg/day administered on a 28 days on/28 days off cycle.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2):

1. Currently, receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:

Tobramycin is an aminoglycoside antimicrobial produced by *Streptomyces tenebrarius*. It acts primarily by disrupting protein synthesis leading to altered cell membrane permeability, progressive disruption of the cell envelope, and eventual cell death. When inhaled, tobramycin is concentrated in the airways.

Formulations:

Nebulization solution for inhalation

- Tobramycin (preservative free)
 - Bethkis: 300 mg tobramycin/4 mL (4 mL) (limited distribution)
 - Kitabis Pak: 300 mg tobramycin/5 mL (5 mL) (with reusable PARI LC Plus nebulizer)
 - Authorized generic available: Tobramycin Inhalation Solution Pak (with reusable PARI LC Plus nebulizer)
 - TOBI: 300 mg tobramycin/5mL (5 mL)
 - Generic available

Powder for inhalation (capsules and device)

- TOBI Podhaler: 28 mg tobramycin per capsule

Appendices

Appendix A: Abbreviation Key

CF: cystic fibrosis

FEV₁: forced expiratory volume in one second

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPSC Codes	Description
J7682	Tobramycin, inhalation solution, FDA-approved final product, noncompounded, unit dose form, administered through DME, per 300 mg
J7685	Tobramycin, inhalation solution, compounded product, administered through DME, unit dose form, per 300 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Removed baseline FEV requirement. Added allowance for concurrent/alternating use with aztreonam pending supportive documentation of inadequate response to either agent alone. References reviewed and updated		

References

1. Bethkis Prescribing Information. Woodstock, IL: Catalent Pharm Solutions, LLC; July 2017. Available at <http://www.bethkis.com>. Distribution network available at https://bethkis.com/wp-content/uploads/2015/10/BETHKIS-SpecialtyPharmacyInsert_R1-PRB.pdf. Accessed October 27, 2017.
2. Kitabis Pak Prescribing Information. Woodstock, IL: Catalent Pharm Solutions, LLC; November 2014. Available at <http://kitabis.com>. Accessed October 27, 2017.
3. TOBI Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2015. Available at <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tobi.pdf>. Accessed October 27, 2017.
4. TOBI Podhaler Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2015. Available at <https://www.tobipodhaler.com>. Accessed October 27, 2017.
5. Flume PA, Mogayzel PJ, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Treatment of pulmonary exacerbations. Am J Respir Crit Care Med. 2009; 180: 802-808.

6. 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*. April 1, 2013; 187 (7): 680-689.
7. Flume PA, Clancy JP, Retsch-Bogart GZ, et al. Continuous alternating inhaled antibiotics for chronic pseudomonal infection in cystic fibrosis. *J Cyst Fibrosis*. 2016; 15(6): 809-815.