MEDICATION POLICY:
Inhaled Tobramycin Products

Generic Name: Tobramycin inhalation

Therapeutic Class or Brand Name: N/A

Applicable Drugs (if Therapeutic Class): 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: 12/23/2022

Prior Authorization Criteria

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

I. Documented diagnosis of cystic fibrosis.

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, an infectious disease specialist, or a 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; 2021. Accessed December 20, 2022. https://resources.chiesiusa.com/Bethkis/BETHKIS_PI.pdf
2. Kitabis. Prescribing information. Pari Respiratory Equipment Inc; 2021. Accessed December 20, 2022. https://kitabis.com/prescribing-information
3. Tobi. Prescribing information. Mylan Pharmaceuticals Inc; 2018. Accessed December 20, 2022. 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; 2020. Accessed December 20, 2022. 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