

Generic Name: Tobramycin Inhalation

Therapeutic Class or Brand Name: TOBI®

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: 7/15/2021

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 lungs.
- III. FEV1 must be greater than 25% and less than 80% predicted.
- IV. Prescribed dose is 300mg (or four 28 mg capsules if prescription is for TOBI® Podhaler™) BID to be administered in repeated cycles of 28 days on drug followed by 28 days off drug.
- V. Minimum age requirement: 6 years old.
- VI. The prescriber is a Pulmonologist or an Infectious Disease Specialist.
- VII. Non-preferred products (Bethkis®, TOBI®, TOBI® Podhaler®) require a documented trial and failure of, intolerance to, or contraindication to a preferred product (refer to plan document for the list of preferred products).

EXCLUSION CRITERIA

- Patients colonized with *Burkholderia cepacia*.

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. https://www.mdwise.org/MediaLibraries/MDwise/Files/For%20Providers/Tools%20and%20Resources/Pharmacy%20Resources/Pharmacy%20Drug/TOBI_PA_Criteria_Updated_10_2011.pdf .
2. Medi-Span®.
3. <http://www.pharma.us.novartis.com/product/pi/pdf/tobipodhaler.pdf> .
4. <https://kitabis.com/HealthcareProviders/prescribing-information> . .
5. https://resources.chiesiusa.com/Bethkis/BETHKIS_PI.pdf .

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.