

**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).

**GPI Code:** 0700007000

**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:** 2/5/2019

**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](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. <http://kitabis.com/wp-content/uploads/2017/10/FULL-PRESCRIBING-INFO-DIGITAL-850D5601-Rev-C-05-16.pdf><http://kitabis.com/HealthcareProviders/prescribing-informationf> .
5. [https://resources.chiesiusa.com/Bethkis/BETHKIS\\_PI.pdf](https://resources.chiesiusa.com/Bethkis/BETHKIS_PI.pdf) .

## HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
2/6/2019	<ol style="list-style-type: none"> <li>1. <b>Changed</b> Kitabis® from listing under Preferred medications to under Non-Preferred.</li> <li>2. <b>Deleted</b> obsolete URL under References item #3 <a href="http://www.pharma.us.novartis.com/product/pi/pdf/tobi.pdf">http://www.pharma.us.novartis.com/product/pi/pdf/tobi.pdf</a></li> <li>3. <b>Changed</b> obsolete URL under References item #4 from <a href="http://kitabis.com/wp-content/uploads/2017/10/FULL-PRESCRIBING-INFO-DIGITAL-850D5601-Rev-C-05-16.pdf">http://kitabis.com/wp-content/uploads/2017/10/FULL-PRESCRIBING-INFO-DIGITAL-850D5601-Rev-C-05-16.pdf</a> to <a href="http://kitabis.com/HealthcareProviders/prescribing-information">http://kitabis.com/HealthcareProviders/prescribing-information</a> .</li> </ol>
12/7/2017	<ol style="list-style-type: none"> <li>1. <b>Changed</b> “Preferred: Tobramycin Inhalation Solution (generic); Non-preferred: TOBI® (tobramycin inhalation solution), TOBI® Podhaler™ (tobramycin inhalation powder)” to “Preferred: Kitabis® Pak (tobramycin inhalation solution), Tobramycin Inhalation Solution (generic); Non-preferred: Bethkis® (tobramycin inhalation solution), TOBI® (tobramycin inhalation solution), TOBI® Podhaler® (tobramycin inhalation powder)” under <b>Applicable Drugs</b>.</li> <li>2. <b>Changed</b> “VII. Non-preferred products (TOBI®, TOBI® Podhaler™) require a documented trial and failure of, intolerance to, or contraindication to the preferred product (generic Tobramycin Inhalation solution)” to “Non-preferred products (Bethkis®, TOBI®, TOBI® Podhaler®) require a documented trial and</li> </ol>

	<p>failure of, intolerance to, or contraindication to a preferred product (refer to plan document for the list of preferred products)" <b>under Prior Authorization Criteria.</b></p> <p>3. <b>Changed</b> "Generic Tobramycin Inhalation Solution, TOBI®: One 56 ampule carton per 56 days; TOBI® Podhaler™..." <b>to</b> "Bethkis®, Generic Tobramycin Inhalation Solution, Kitabis® Pak, TOBI®: One 56 ampule carton per 56 days; TOBI® Podhaler®..." <b>under Quantity/Days Supply Restrictions.</b></p> <p>4. <b>Added</b> "<a href="http://kitabis.com/wp-content/uploads/2017/10/FULL-PRESCRIBING-INFO-DIGITAL-850D5601-Rev-C-05-16.pdf">http://kitabis.com/wp-content/uploads/2017/10/FULL-PRESCRIBING-INFO-DIGITAL-850D5601-Rev-C-05-16.pdf</a>" <b>and</b> "<a href="https://resources.chiesiusa.com/Bethkis/BETHKIS_PI.pdf">https://resources.chiesiusa.com/Bethkis/BETHKIS_PI.pdf</a>" <b>under References.</b></p>
9/29/2016	<p>1. <b>Removed</b> <a href="http://www.avmed.org/pdf/unsecure/Providers/Tools/AvMed%20Pharmacy%20Guidelines/2/Tobi.pdf">http://www.avmed.org/pdf/unsecure/Providers/Tools/AvMed%20Pharmacy%20Guidelines/2/Tobi.pdf</a> <b>and</b> "<a href="http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/Tobi_Form.pdf">http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/Tobi_Form.pdf</a>" <b>from References</b> (links no longer valid).</p>
4/7/2015	<p>1. <b>Changed</b> "Documented diagnosis of Cystic Fibrosis with confirmed <i>Pseudomonas aeruginosa</i> (per sputum culture obtained within the previous 30 days)" <b>to</b> "I. Documented diagnosis of cystic fibrosis; II. Positive culture demonstrating <i>Pseudomonas aeruginosa</i> in the lungs; III. FEV<sub>1</sub> must be greater than 25% and less than 80% predicted" <b>under Prior Authorization Criteria.</b></p> <p>2. <b>Changed</b> "N/A" <b>to</b> "Patients colonized with <i>Burkholderia cepacia</i>" <b>under Exclusion Criteria.</b></p> <p>3. <b>Changed</b> "6 months (3 cycles: each cycle is 28 days on treatment then 28 days off treatment)" <b>to</b> "6 months" <b>following Authorization under Approval Length.</b></p> <p>4. <b>Changed</b> "An updated letter of medical necessity showing maintenance or improvement on medication" <b>to</b> "An updated letter of medical necessity or progress notes showing positive clinical response (must have improved FEV<sub>1</sub> AND a decrease in the sputum density of <i>P. aeruginosa</i>)" <b>following Re-Authorization under Approval Length.</b></p> <p>5. <b>Updated</b> "<a href="http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/tobi.pdf">http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/tobi.pdf</a>" <b>to</b> "<a href="http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/Tobi_Form.pdf">http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/Tobi_Form.pdf</a>" <b>and</b> "<a href="http://www.pharma.us.novartis.com/cs/www.pharma.us.novartis.com/product/pdf/tobi.pdf">http://www.pharma.us.novartis.com/cs/www.pharma.us.novartis.com/product/pdf/tobi.pdf</a>" <b>to</b> "<a href="http://www.pharma.us.novartis.com/product/pi/pdf/tobi.pdf">http://www.pharma.us.novartis.com/product/pi/pdf/tobi.pdf</a>" <b>under References.</b></p>
2/18/2014	<p>1. <b>Adapted policy to new format.</b></p> <p>2. <b>Changed Generic Name from</b> "Tobramycin" <b>to</b> "Tobramycin Inhalation".</p> <p>3. <b>Changed Applicable Drugs from</b> "N/A" <b>to</b> "Preferred: Tobramycin Inhalation Solution (generic); Non-preferred: TOBI® (tobramycin inhalation solution), TOBI® Podhaler™ (tobramycin inhalation powder)".</p> <p>4. <b>Added GPI Code.</b></p> <p>5. <b>Changed criterion II under Prior Authorization Criteria from</b> "Prescribed dose is 300mg BID (6-12 hours apart) to be administered in repeated cycles of 28 days on drug followed by 28 days off drug" <b>to</b> "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".</p>

	<ol style="list-style-type: none"><li>6. <b>Added</b> "Non-preferred products (TOBI®, TOBI® Podhaler™) require a documented trial and failure of, intolerance to, or contraindication to the preferred product (generic Tobramycin Inhalation solution)" <b>requirement to Prior Authorization Criteria.</b></li><li>7. <b>Changed Quantity/Days Supply Restrictions from</b> "One 56 ampule carton per month" to "Generic Tobramycin Inhalation Solution, TOBI®: One 56 ampule carton per 56 days; TOBI® Podhaler™: One unit dose (blister pack), box of 224 capsules per 56 days".</li><li>8. <b>Updated references</b> to include Medi-Span, updated website address for MDwise policy, and package insert for TOBI Podhaler.</li></ol>
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**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.