MEDICATION POLICY

Generic Name: Tobramycin Inhalation

Therapeutic Class or Brand Name: TOBI®

Applicable Drugs (if Therapeutic Class)**:**

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).

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 12/7/17

GPI Code: 0700007000

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. FEV_1 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 FEV_1 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/tobi.pdf.
4. http://www.pharma.us.novartis.com/product/pi/pdf/tobipodhaler.pdf.
5. http://kitabis.com/wp-content/uploads/2017/10/FULL-PRESCRIBING-INFO-DIGITAL-850D5601-Rev-C-05-16.pdf.
6. https://resources.chiesiusa.com/Bethkis/BETHKIS_PI.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
12/7/2017	1. **Changed** "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 Applicable Drugs**. 2. **Changed** "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 failure of, intolerance to, or contraindication to a preferred product (refer to plan document for the list of preferred products)" **under Prior Authorization Criteria**. 3. **Changed** "Generic Tobramycin Inhalation Solution, TOBI®: One 56 ampule carton per 56 days; TOBI® Podhaler™…" **to** "Bethkis®, Generic Tobramycin Inhalation Solution, Kitabis® Pak, TOBI®: One 56 ampule carton per 56 days; TOBI® Podhaler®…" **under Quantity/Days Supply Restrictions**. 4. **Added** "http://kitabis.com/wp-content/uploads/2017/10/FULL-PRESCRIBING-INFO-DIGITAL-850D5601-Rev-C-05-16.pdf" **and** "https://resources.chiesiusa.com/Bethkis/BETHKIS_PI.pdf" **under References**.
9/29/2016	1. **Removed** "http://www.avmed.org/pdf/unsecure/Providers/Tools/AvMed%20Pharmacy%20Guidelines/2/Tobi.pdf" **and** "http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/Tobi_Form.pdf" **from References** (links no longer valid).
4/7/2015	1. **Changed** "Documented diagnosis of Cystic Fibrosis with confirmed *Pseudomonas aeruginosa* (per sputum culture obtained within the previous 30 days)" **to** "I. Documented diagnosis of cystic fibrosis; II. Positive culture demonstrating *Pseudomonas aeruginosa* in the lungs; III. FEV_1 must be greater than 25% and less than 80% predicted" **under Prior Authorization Criteria**. 2. **Changed** "N/A" **to** "Patients colonized with *Burkholderia cepacia*" **under Exclusion Criteria**. 3. **Changed** "6 months (3 cycles: each cycle is 28 days on treatment then 28 days off treatment)" **to** "6 months" **following Authorization under Approval Length**. 4. **Changed** "An updated letter of medical necessity showing maintenance or improvement on medication" **to** "An updated letter of medical necessity or progress notes showing positive clinical response (must have improved FEV_1 AND a decrease in the sputum density of *P. aeruginosa*)" **following Re-Authorization under Approval Length**. 5. **Updated** "http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/tobi.pdf" **to** "http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/Tobi_Form.pdf"**and** "http://www.pharma.us.novartis.com/cs/www.pharma.us.novartis.com/product/pi/pdf/tobi.pdf" **to** "http://www.pharma.us.novartis.com/product/pi/pdf/tobi.pdf" **under References**.
2/18/2014	1. **Adapted policy to new format.** 2. **Changed Generic Name from** "Tobramycin" **to** "Tobramycin Inhalation". 3. **Changed Applicable Drugs from** "N/A" **to** "Preferred: Tobramycin Inhalation Solution (generic); Non-preferred: TOBI® (tobramycin inhalation solution), TOBI® Podhaler™ (tobramycin inhalation powder)". 4. **Added GPI Code**. 5. **Changed criterion II under Prior Authorization Criteria from** "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" **to** "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". 6. **Added** "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)" **requirement to Prior Authorization Criteria**.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
	7. **Changed Quantity/Days Supply Restrictions from** "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". 8. **Updated references** to include Medi-Span, updated website address for MDwise policy, and package insert for TOBI Podhaler.