UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tobramycin Inhalation

Program	Prior Authorization
Medication	Bethkis®, Kitabis™ Pak, TOBI™ Nebulizer Solution and TOBI® Podhaler™, tobramycin solution for inhalation
Markets in Scope	California, Colorado,, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

1. Background:

Bethkis (tobramycin) is an inhaled aminoglycoside antibacterial indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*. Safety and efficacy have not been demonstrated in patients under the age of six years, patients with a forced expiratory volume in one second (FEV1) less than 40% or greater than 80% predicted, or patients colonized with *Burkholderia cepacia*. Bethkis is administered by inhalation using a hand-held PARI LC Plus® Reusable Nebulizer with a PARI Vios Air compressor. After 28 days of therapy, patients should stop Bethkis therapy for the next 28 days, and then resume therapy for the next 28 day on and 28 day off cycle.[3]

TOBI (tobramycin) is an antibacterial aminoglycoside indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV1 < 25% or > 75% predicted, or patients colonized with *Burkholderia cepacia.*[1] TOBI Nebulizer Solution is specifically formulated for inhalation using the DeVilbiss® Pulmo-Aide® air compressor and PARI LC Plus® Reusable Nebulizer.[1] After 28 days of therapy, patients should stop TOBI therapy for the next 28 days, and then resume therapy for the next 28 day on and 28 day off cycle.[1]

TOBI Podhaler is an antibacterial aminoglycoside indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa.* Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV1 <25% or >80% predicted, or patients colonized with *Burkholderia cepacia.* After 28 days of therapy, patients should stop TOBI Podhaler therapy for the next 28 days, and then resume therapy for the next 28 day on and 28 day off cycle.[2]

Kitabis Pak (co-packaging of tobramycin inhalation solution and PARI LC Plus® Reusable Nebulizer) is indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with *Pseudomonas aeruginosa*. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV1 <25% or >75% predicted, or patients colonized with *Burkholderia cepacia*. After 28 days of therapy, patients should stop

Kitabis therapy for the next 28 days, and then resume therapy for the next 28 day on and 28 day off cycle.[4]

Members will be required to meet the coverage criteria below.

2. Coverage Criteria:

A. Bethkis

1. Authorization

a. **Bethkis** will be approved based on the following criteria:

(1) Diagnosis of cystic fibrosis (CF)

Authorization will be issued for 12 months

B. Non-Preferred Products

1. Initial Authorization

a. **Kitabis Pak, TOBI Nebulizer Solution, TOBI Podhaler, or tobramycin solution for inhalation** will be approved based on **all** of the following criteria:

(1) Diagnosis of cystic fibrosis (CF)

-AND-

(2) Lung infection with positive culture demonstrating *Pseudomonas aeruginosa* infection

-AND-

(3) History of failure, intolerance, or contraindication to Bethkis

Authorization will be issued for 12 months

2. Reauthorization

a. **Kitabis Pak, TOBI Nebulizer Solution, TOBI Podhaler, or tobramycin solution for inhalation** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Kitabis Pak, TOBI Nebulizer Solution, TOBI Podhaler, or tobramycin solution for inhalation therapy

Authorization will be issued for 12 months

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. TOBI Inhalation Solution [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; October 2015.
2. TOBI Podhaler [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; Ju;ly 2020.
3. Bethkis [package insert]. Woodstock, Illinois: Catalent Pharma Solutions, LLC; December 2019.
4. Kitabis Pak [package insert]. Woodstock, Illinois: Catalent Pharma Solutions, LLC; December 2019.
5. Tobramycin Inhalation Solution [package insert]. Sellersville, PA: Teva Pharmaceuticals USA; February 2019.

Program	Prior Authorization
Change Control	
9/19/2013	New guideline
6/19/2014	Bethkis added to the PDL with prior authorization. Tobi Nebulizer deleted from PDL.
12/17/2015	Annual review, no change
11/2016	Updated non-preferred products section and added reauthorization criteria. Updated policy template.
2/2017	Annual review with no changes to coverage criteria.
9/2017	Removed lung infection with positive culture requirement and reauthorization criteria for Bethkis to allow for Dx to Rx implementation.
2/2018	Annual review. Updated references.
2/2019	Annual review. Added separate TOBI Podhaler description in the background. Updated references.
2/2020	Annual review. Minor updates to the background. Updated references.
2/2021	Annual review. Updated reference. No changes to coverage

	criteria.