PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Antibiotics (Inhaled) – Tobramycin Products

DATE REVIEWED: 05/06/2020

DRUGS AFFECTED:

- Bethkis® (tobramycin inhalation solution – Chiesa USA/Catalent Pharma Solutions)
- TOBI® (tobramycin inhalation solution – Novartis Pharmaceuticals, generics)
- TOBI® Podhaler (tobramycin inhalation powder – Novartis Pharmaceuticals)

OVERVIEW

Tobramycin inhalation solution (generic), TOBI, and Kitabis Pak are indicated for the management of cystic fibrosis (CF) in adults and pediatric patients ≥ 6 years of age with *P. aeruginosa*.[1-3] Bethkis is indicated for the management of CF patients with *P. aeruginosa*.[4] Generic tobramycin inhalation solution, Bethkis, Kitabis, and TOBI are given by nebulization.[1-4] TOBI, Kitabis, and the generic tobramycin inhalation solution are inhaled using the PARI LC PLUS nebulizer, a reusable "jet nebulizer", with DeVilbiss Pulmo-Aide compressor, administered over a period of approximately 15 minutes.[1-3] Kitabis Pak is co-packaged with the PARI LC PLUS nebulizer.[3] Bethkis is also inhaled using the PARI LC PLUS nebulizer and is used with the PARI Vios® Air compressor; it is administered over a period of approximately 15 minutes.[4] TOBI Podhaler is indicated for the management of CF in patients with *P. aeruginosa*.[5] TOBI Podhaler consists of a dry powder formulation of tobramycin for oral inhalation only with the Podhaler device.[5]

POLICY STATEMENT

This Preferred Specialty Management (PSM) program requires the patient to meet the ESI Standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA) Policy* criteria or the *Antibiotics (Inhaled) – TOBI Podhaler PA Policy* criteria for the Preferred and Non-Preferred Products, and requires the patient to try the Preferred Product, when clinically appropriate, prior to the approval of the Non-Preferred Product. Patients meeting the PA criteria for a Non-Preferred Product who have not tried the Preferred Product will receive authorization for the Preferred Product. Requests for coverage of the Non-Preferred Products will be determined by exception criteria (below). Kitabis is not address in this PSM program.

All approvals for Preferred and Non-Preferred Products are provided for 1 year unless otherwise noted below. In cases where approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

Preferred Products: Tobramycin inhalation solution
Non-Preferred Products: Bethkis, TOBI, TOBI Podhaler

RECOMMENDED EXCEPTION CRITERIA

Trade Name	Exception

Bethkis	**1. <u>Cystic Fibrosis – Initial Therapy</u>.** **A)** Approve for 1 year if the patient meets the following criteria (i <u>and</u> ii): **i.** Patient meets the ESI Standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic). **B)** For patients who met criteria 1Ai but NOT 1Aii, approve tobramycin inhalation solution. **2. <u>Cystic Fibrosis – Patient Currently Taking Bethkis</u>.** Approve for 1 year if the patient meets the ESI Standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria. **3. <u>Bronchiectasis, Non-Cystic Fibrosis – Initial Therapy</u>.** **A)** Approve for 1 year if the patient meets the following criteria (i <u>and</u> ii): **i.** Patient meets the ESI Standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic). **B)** For patients who met criteria 3Ai but NOT 3Aii, approve tobramycin inhalation solution. **4. <u>Bronchiectasis, Non-Cystic Fibrosis – Patient Currently Taking Bethkis</u>.** Approve for 1 year if the patient meets the ESI Standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria. **5. <u>Other Conditions – Patient Currently Taking Bethkis</u>.** Approve for 1 month if the patient is continuing a course of therapy and meets the ESI Standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria.
TOBI inhalation solution	**1. <u>Cystic Fibrosis</u>.** **A)** Approve for 1 year if the patient meets the following criteria (i <u>and</u> ii): **i.** Patient meets the ESI Standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic). **B)** For patients who met criteria 1Ai but NOT 1Aii, approve tobramycin inhalation solution. **2. <u>Bronchiectasis, Non-Cystic Fibrosis</u>.** **A)** Approve for 1 year if the patient meets the following criteria (i <u>and</u> ii): **i.** Patient meets the ESI Standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic). **B)** For patients who met criteria 2Ai but NOT 2Aii, approve tobramycin inhalation solution. **3. <u>Other Conditions</u>.** **A)** Approve for 1 month if the patient is continuing a course of therapy and meets the following criteria (i <u>and</u> ii): **i.** Patient meets the ESI Standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic). **B)** For patients who meet criteria 3Ai but NOT 3Aii, approve tobramycin inhalation solution
TOBI Podhaler	**1. <u>Cystic Fibrosis – Initial Therapy</u>.** **A)** Approve for 1 year if the patient meets the following criteria (i <u>and</u> ii): **i.** Patient meets the ESI Standard *Antibiotics (Inhaled) – TOBI Podhaler Prior Authorization (PA)* criteria; AND

	ii. Patient has tried or used, at any time in the past, tobramycin inhalation solution (generic). Note: Prior use of one other inhaled tobramycin product (i.e., Bethkis, TOBI, and Kitabis) would count toward this requirement. **B)** For patients who met criteria 1Ai but NOT 1Aii, offer to review for tobramycin inhalation solution using the ESI Standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria. **2. Cystic Fibrosis – Patient Currently Taking TOBI Podhaler.** Approve for 1 year if the patient meets the ESI Standard *Antibiotics (Inhaled) – TOBI Podhaler PA* criteria. **3. Other Conditions – Patient Currently Taking TOBI Podhaler.** Approve for 1 month if the patient is continuing a course of therapy and meets the ESI Standard *Antibiotics (Inhaled) – TOBI Podhaler PA* criteria.

REFERENCES

1. Generic Tobramycin Inhalation Solution [prescribing information]. Sellersville, PA: Teva Pharmaceuticals; October, 2013.
2. TOBI® inhalation solution [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2018.
3. Kitabis™ inhalation solution [prescribing information]. Woodstock, IL: Catalent Pharma Solutions; December 2019.
4. Bethkis® inhalation solution [prescribing information]. Woodstock, IL: Chiesi USA/Catalent Pharma Solutions; December 2019.
5. TOBI® Podhaler inhalation powder [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2015.