VENTURA COUNTY
HEALTH CARE PLAN

CARE VALUE POLICY

POLICY: Antibiotics (Inhaled) – Tobramycin Products Care Value Policy
- Bethkis® (tobramycin inhalation solution – Chiesi, generic)
- TOBI® (tobramycin inhalation solution – Mylan, generic)
- TOBI® Podhaler (tobramycin inhalation powder – Novartis)

REVIEW DATE: 03/27/2024

OVERVIEW

Tobramycin products are indicated for the management of cystic fibrosis in patients with *Pseudomonas aeruginosa.* TOBI (generic) is specifically indicated in patients ≥ 6 years of age.[1,3,5] Kitabis Pak (tobramycin inhalation solution, authorized generic) is another inhaled tobramycin product; the branded product is not included in this policy. Tobramycin inhalation solution products are given by nebulization.[1-3] Tobramycin inhalation solution (TOBI [generic] and Kitabis Pak [authorized generic]) is inhaled using the PARI LC PLUS nebulizer, a reusable "jet nebulizer", with DeVilbiss Pulmo-Aide compressor, administered over a period of approximately 15 minutes.[1,2,5] Bethkis (generic) is inhaled using the PARI LC PLUS nebulizer and the PARI Vios® Air compressor, administered over a period of approximately 15 minutes.[3] TOBI Podhaler consists of a dry powder formulation of tobramycin for oral inhalation only with the Podhaler device.[4]

POLICY STATEMENT

This Care Value program has been developed to encourage the use of Preferred Products. For all Non-Preferred products, the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try at least one Preferred Product prior to the approval of a Non-Preferred Product. Patients meeting the Prior Authorization criteria for a Non-Preferred Product who have not tried the Preferred Product will be directed to the Preferred Products. The Preferred Products (tobramycin inhalation solution [generics for Bethkis, Kitabis Pak, and TOBI] and TOBI Podhaler) do not require Prior Authorization. Requests for coverage of the Non-Preferred Products will be determined by exception criteria (below). Kitabis Pak (brand only) is not address in this Care Value 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 Product:	Tobramycin inhalation solution (generics to Bethkis, TOBI, and Kitabis Pak), TOBI Podhaler
Non-Preferred Product:	Bethkis, TOBI

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Bethkis	**1. Cystic Fibrosis.** **A)** Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic) or TOBI Podhaler. **B)** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)* criteria (1Ai), but has not met the exception criteria (1Aii) above, Bethkis is not approved. Approve tobramycin inhalation solution (generic) or TOBI Podhaler. **2. Bronchiectasis, Non-Cystic Fibrosis.** **A)** Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic). **B)** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria (2Ai), but has not met the exception criteria (2Aii) above, Bethkis is not approved. Approve tobramycin inhalation solution (generic). **3. Continuation of Therapy.** **A)** Approve for 1 month if the patient is continuing a course of therapy and meets BOTH of the following (i and ii): **i.** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhaled Solution PA* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic). **B)** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria (3Ai), but has not met the exception criteria (3Aii) above, TOBI inhalation solution is not approved. Approve tobramycin inhalation solution (generic).

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
TOBI inhalation solution	**1. Cystic Fibrosis.** **A)** Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic) or TOBI Podhaler. **B)** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)* criteria (1Ai), but has not met the exception criteria (1Aii) above, TOBI inhalation solution is not approved. Approve tobramycin inhalation solution (generic) or TOBI Podhaler. **2. Bronchiectasis, Non-Cystic Fibrosis.** **A)** Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic). **B)** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria (2Ai), but has not met the exception criteria (2Aii) above, TOBI inhalation solution is not approved. Approve tobramycin inhalation solution (generic). **3. Continuation of Therapy.** **A)** Approve for 1 month if the patient is continuing a course of therapy and meets BOTH of the following (A and B): **i.** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic). **B)** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria (3Ai), but has not met the exception criteria (3Aii) above, TOBI inhalation solution is not approved. Approve tobramycin inhalation solution (generic).

REFERENCES

1. Tobramycin Inhalation Solution [prescribing information]. Princeton, NJ: Dr. Reddy; February 2023.
2. TOBI® inhalation solution [prescribing information]. Morgantown, WV: Mylan; February 2023.
3. Bethkis® inhalation solution [prescribing information]. Woodstock, IL: Chiesi; February 2023.
4. TOBI® Podhaler inhalation powder [prescribing information]. East Hanover, NJ: Novartis; February 2023.
5. Tobramycin Inhalation Solution Pak [prescribing information]. Glen Allen, VA: Genericus; January 2024.