CARE VALUE POLICY

POLICY: Antibiotics (Inhaled) – Tobramycin Products Care Value Policy
- Bethkis® (tobramycin inhalation solution – Chiesa USA/Catalent Pharma Solutions)
- TOBI® (tobramycin inhalation solution – Novartis Pharmaceuticals, generic)
- TOBI® Podhaler (tobramycin inhalation powder – Novartis Pharmaceuticals)

REVIEW DATE: 05/12/2021

OVERVIEW

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

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 [generic] and TOBI Podhaler) do not require Prior Authorization. Requests for coverage of the Non-Preferred Products will be determined by exception criteria (below). Kitabis 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, TOBI Podhaler
Non-Preferred Product: Bethkis, TOBI

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Bethkis	**1. Cystic Fibrosis – Initial Therapy.** Approve for 1 year if the patient meets the following criteria (A and B): **A)** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)* criteria; AND **B)** Patient has tried tobramycin inhalation solution (generic) or TOBI Podhaler. **2. Cystic Fibrosis – Patient Currently Taking Bethkis.** Approve for 1 year if the patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria. **3. Bronchiectasis, Non-Cystic Fibrosis – Initial Therapy.** Approve for 1 year if the patient meets the following criteria (A and B): **A)** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria; AND **B)** Patient has tried tobramycin inhalation solution (generic). **4. Bronchiectasis, Non-Cystic Fibrosis – Patient Currently Taking Bethkis.** Approve for 1 year if the patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria. **5. Other Conditions – Patient Currently Taking Bethkis.** Approve for 1 month if the patient is continuing a course of therapy and meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria.
TOBI inhalation solution	**1. Cystic Fibrosis.** Approve for 1 year if the patient meets the following criteria (A and B): **A)** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)* criteria; AND **B)** Patient has tried tobramycin inhalation solution (generic) or TOBI Podhaler. **2. Bronchiectasis, Non-Cystic Fibrosis.** Approve for 1 year if the patient meets the following criteria (A and B): **A)** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria; AND **B)** Patient has tried tobramycin inhalation solution (generic). **3. Other Conditions.** Approve for 1 month if the patient is continuing a course of therapy and meets the following criteria (A and B): **A)** Patient meets the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria; AND **B)** Patient has tried tobramycin inhalation solution (generic).

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. Bethkis® inhalation solution [prescribing information]. Woodstock, IL: Chiesi USA/Catalent Pharma Solutions; December 2019.
4. TOBI® Podhaler inhalation powder [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2021.