

PREFERRED SPECIALTY MANAGEMENT POLICY

- POLICY:** Antibiotics (Inhaled) – Tobramycin Products Preferred Specialty Management Policy
- Bethkis® (tobramycin inhalation solution – Chiesa USA/Catalent)
 - TOBI® (tobramycin inhalation solution – Novartis, generic)
 - TOBI® Podhaler (tobramycin inhalation powder – Novartis)

REVIEW DATE: 05/11/2022

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 Preferred Specialty Management (PSM) program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), 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 receive authorization for the Preferred Products. 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, TOBI Podhaler
Non-Preferred Products: Bethkis, TOBI

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Bethkis	<ol style="list-style-type: none"> 1. <u>Cystic Fibrosis – Initial Therapy.</u> <ol style="list-style-type: none"> A) Approve for 1 year if the patient meets the following criteria (i <u>and</u> ii): <ol style="list-style-type: none"> i. Patient meets the standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)</i> criteria; AND ii. Patient has tried tobramycin inhalation solution (generic) or TOBI Podhaler. B) If the patient has met the standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)</i> criteria (1Ai), but has <u>not</u> met the exception criteria (1Aii) above for brand Bethkis: approve tobramycin inhalation solution (generic) or TOBI Podhaler. 2. <u>Cystic Fibrosis – Patient Currently Taking Bethkis.</u> Approve for 1 year if the patient meets the standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA</i> criteria. 3. <u>Bronchiectasis, Non-Cystic Fibrosis – Initial Therapy.</u> <ol style="list-style-type: none"> A) Approve for 1 year if the patient meets the following criteria (i <u>and</u> ii): <ol style="list-style-type: none"> i. Patient meets the standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA</i> criteria; AND ii. Patient has tried tobramycin inhalation solution (generic). B) If the patient has met the standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA</i> criteria (3Ai), but has <u>not</u> met the exception criteria (3Aii) above for brand Bethkis, approve tobramycin inhalation solution (generic). 4. <u>Bronchiectasis, Non-Cystic Fibrosis – Patient Currently Taking Bethkis.</u> Approve for 1 year if the patient meets the standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA</i> 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 standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA</i> criteria.
TOBI inhalation solution	<ol style="list-style-type: none"> 1. <u>Cystic Fibrosis.</u> <ol style="list-style-type: none"> A) Approve for 1 year if the patient meets the following criteria (i <u>and</u> ii): <ol style="list-style-type: none"> i. Patient meets the standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)</i> criteria; AND ii. Patient has tried tobramycin inhalation solution (generic) or TOBI Podhaler. B) If the patient has met the standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)</i> criteria (1Ai), but has <u>not</u> met the exception criteria (1Aii), above for TOBI inhalation solution: approve tobramycin inhalation solution (generic) or TOBI Podhaler. 2. <u>Bronchiectasis, Non-Cystic Fibrosis.</u> <ol style="list-style-type: none"> A) Approve for 1 year if the patient meets the following criteria (i <u>and</u> ii): <ol style="list-style-type: none"> i. Patient meets the standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA</i> criteria; AND ii. Patient has tried tobramycin inhalation solution (generic). B) If the patient has met the standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA</i> criteria (2Ai), but has <u>not</u> met the exception criteria (2Aii), above for TOBI inhalation solution: approve tobramycin inhalation solution (generic).

	<p>3. <u>Other Conditions.</u></p> <p>A) Approve for 1 month if the patient is continuing a course of therapy and meets the following criteria (i and ii):</p> <ul style="list-style-type: none">i. Patient meets the standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA</i> criteria; ANDii. Patient has tried tobramycin inhalation solution (generic). <p>B) If the patient has met the standard <i>Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA</i> criteria (3Ai), but has <u>not</u> met the exception criteria (3Aii), above for TOBI inhalation solution: approve tobramycin inhalation solution (generic).</p>
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REFERENCES

1. Tobramycin Inhalation Solution [prescribing information]. Sellersville, PA: Teva; October, 2013.
2. TOBI® inhalation solution [prescribing information]. East Hanover, NJ: Novartis; October 2018.
3. Kitabis™ inhalation solution [prescribing information]. Woodstock, IL: Catalent; December 2019.
4. Bethkis® inhalation solution [prescribing information]. Woodstock, IL: Chiesi USA/Catalent; December 2019.
5. TOBI® Podhaler inhalation powder [prescribing information]. East Hanover, NJ: Novartis; July 2020.