PREFERRED SPECIALTY MANAGEMENT POLICY

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

REVIEW DATE: 03/29/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Tobramycin products are indicated for the management of cystic fibrosis in patients with *Pseudomonas aeruginosa.* Tobramycin inhalation solution (TOBI, generic) is specifically indicated in patients ≥ 6 years of age.[1,2] Kitabis® Pak (tobramycin inhalation solution authorized generic) is another inhaled tobramycin product, but is not included in this policy. Tobramycin inhalation solution and Bethkis are given by nebulization.[1-3] Tobramycin inhalation solution 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] 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.[3] TOBI Podhaler consists of a dry powder formulation of tobramycin for oral inhalation only with the Podhaler device.[4]

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.

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

Antibiotics (Inhaled) – Tobramycin non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
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 standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic) or TOBI Podhaler. **B)** If the patient has met the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution Prior Authorization (PA)* criteria (1Ai), but has <u>not</u> met the exception criteria (1Aii) above, Bethkis is not approved. 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 *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 standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria; AND **ii.** Patient has tried tobramycin inhalation solution (generic).

	B) If the patient has met the standard *Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA* criteria (3Ai), but has not met the exception criteria (3Aii) above, Bethkis is not approved. Approve 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.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
TOBI inhalation solution	**1. Cystic Fibrosis.** **A)** Approve for 1 year if the patient meets the following criteria (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)** If the patient has met 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 the following criteria (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)** If the patient has met 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. Other Conditions.** **A)** Approve for 1 month if the patient is continuing a course of therapy and meets the following criteria (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)** If the patient has met 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; April 2020.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/11/2022
Early Annual Revision	No criteria changes.	03/29/2023