PREFERRED SPECIALTY MANAGEMENT POLICY

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

REVIEW DATE: 03/19/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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*.** 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 Preferred Specialty Management (PSM) 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). 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. Note: Kitabis Pak (brand only) is not addressed in this PSM program.

Preferred Product: Tobramycin inhalation solution (generics to Bethkis, TOBI, and Kitabis Pak), TOBI Podhaler

Non-Preferred Product: Bethkis, TOBI

***Antibiotics (Inhaled) – Tobramycin Products Preferred Specialty Management Policy* 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. 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, Bethkis is not approved. Approve tobramycin inhalation solution (generic).

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 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 (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 (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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	No criteria changes. Criteria were updated to synch with the current intent and branching logic.	03/29/2023
Annual Revision	**Products**: Generic to Bethkis was added to the policy. **Policy Statement**: The policy statement was updated to clarify that Kitabis Pak *brand* is not targeted in the policy. Additionally, clarification was added that tobramycin inhalation solution includes the generics for Bethkis, Kitabis Pak, and TOBI. **Preferred Products**: Generic to Bethkis was added (this automatically rolled into the generic tobramycin inhalation solution product listed). Clarification was added that the tobramycin inhalation solution includes the generics for Bethkis, Kitabis Pak, and TOBI. Bethkis **Cystic Fibrosis – Initial Therapy.** Initial therapy was removed from this condition of coverage due to availability of the generic product. **Cystic Fibrosis – Patient Currently Taking Bethkis.** This condition of coverage was removed due to availability of the generic product. **Bronchiectasis, Non-Cystic Fibrosis – Initial Therapy.** Initial therapy was removed from this condition of coverage due to availability of the generic product.	03/27/2024

	Bronchiectasis, Non-Cystic Fibrosis – Patient Currently Taking Bethkis. This condition of coverage was removed due to availability of the generic product. **Other Conditions – Patient is Currently Taking Bethkis.** This condition of coverage was removed due to availability of the generic product. **Continuation of Therapy.** This condition of coverage was added. Bethkis is approved for 1 month if the patient is continuing a course of therapy and has met the standard Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA criteria AND has tried tobramycin inhalation solution (generic). If the patient has met the standard Antibiotics (Inhaled) – Tobramycin Inhalation Solution PA criteria, but has not tried tobramycin inhalation solution (generic) Bethkis is not approved; tobramycin inhalation solution (generic) is approved.	
Annual Revision	No criteria changes.	03/19/2025