Pharmacy Medical Necessity Guidelines:
Tobi® Podhaler™ (tobramycin)

Effective: March 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Tobramycin inhalation medications are indicated for the management of cystic fibrosis in adults and pediatric patients 6 years and older with *Pseudomonas aeruginosa.*

Tobramycin nebulization solution and powder for inhalation should be administered in alternating periods of 28 days on drug and 28 days off drug.

Generic tobramycin 300 mg/ 5ml nebulization solution is the preferred product and is covered for Tufts RITogether members without restriction.

COVERAGE GUIDELINES

The plan may authorize coverage of **Tobi Podhaler** when the following criterion is met:

1. The Member meets one of the following:
    a. The Member has had an inadequate response or adverse reaction to tobramycin inhalation solution

    OR

    b. The provider indicates clinical inappropriateness of therapy with tobramycin nebulization solution.

LIMITATIONS

1. A quantity limit of one inhaler per 56 days applies.

CODES

None

REFERENCES

1. Bethkis (tobramycin) [prescribing information]. Woodstock, IL: Chiesi; February 2023.
2. Tobi (tobramycin) [prescribing information]. Morgantown, WV: Mylan Specialty, LP; February 2023.
3. Tobi Podhaler inhalation powder (tobramycin) [prescribing information]. Morgantown, WV: Mylan Specialty, LP; February 2023.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 13, 2023: No changes.
2. March 12, 2024: Effective April 1, 2024, updated RxUM fax number.
3. March 11, 2025: No changes
4. March 10, 2026: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined

population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services