MEDICAL MUTUAL®

Drug Policy

Policy:	TOBI Podhaler (tobramycin inhalation powder)	Annual Review Date: 02/20/2025 Last Revised Date: 02/20/2025

OVERVIEW

Tobramycin is an aminoglycoside antibiotic which disrupts protein synthesis ultimately leading to cell death. *In vitro*, tobramycin is bactericidal at concentration at or just above the minimum inhibitory concentration and has activity against gram-negative microorganisms including *Pseudomonas aeruginosa*.

TOBI Podhaler is indicated for the management of cystic fibrosis (CF) in patients with *P. aeruginosa*. Safety and efficacy have not been demonstrated in patients < 6 years of age, patients with forced expiratory volume in 1 second (FEV1) < 25% or > 80% predicted, or patients colonized with *Burkholderia cepacia.*

POLICY STATEMENT

This policy involves the use of TOBI Podhaler. Prior authorization is recommended for pharmacy benefit coverage of TOBI Podhaler. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below.

Automation: When available, patient age, and the ICD-10 codes for Cystic Fibrosis (ICD-10: E84.*) will be used for automation to allow approval of the requested medication.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of TOBI Podhaler is recommended in those who meet the following criteria:

1. **Cystic Fibrosis**
   Criteria. *Approve if the patient is 6 years of age or older.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* *365 days*
B) *Extended Approval:* *365 days*

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CONDITIONS NOT RECOMMENDED FOR APPROVAL

TOBI Podhaler has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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7. McShane PJ, Naureckas ET, Tino G, Strek ME. Non-cystic fibrosis bronchiectasis. *Am J Respir Crit Care Med*. 2013;188:647-656.
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