

PRIOR AUTHORIZATION POLICY

POLICY: Antibiotics (Inhaled) – TOBI Podhaler Prior Authorization Policy

- TOBI® Podhaler (tobramycin inhalation powder – Novartis)

REVIEW DATE: 03/27/2024

OVERVIEW

TOBI Podhaler, an aminoglycoside antibiotic, is indicated for the management of **cystic fibrosis** (CF) patients with *Pseudomonas aeruginosa*.¹ 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*.

Guidelines

The Cystic Fibrosis Foundation (CFF) Pulmonary Therapeutics Committee (2013) provides recommendations for the use of chronic medications in the management of CF lung disease.² In patients ≥ 6 years of age with CF and moderate-to-severe lung disease with *P. aeruginosa* persistently present in cultures of the airways, the chronic use of inhaled tobramycin is strongly recommended to improve lung function, quality of life, and reduce exacerbations. For mild disease, the Committee recommends chronic use of inhaled tobramycin for patients ≥ 6 years of age with CF and *P. aeruginosa* persistently present in cultures of the airways, to reduce exacerbations.

The CFF published a systematic review of the literature regarding eradication of initial *P. aeruginosa* infections to develop guidelines for effective prevention (2014).³ The recommendations pertaining to inhaled antibiotics are as follows: 1) Inhaled antibiotic therapy is recommended for the treatment of initial or new growth of *P. aeruginosa* (the favored antibiotic regimen is tobramycin [300 mg twice daily] for 28 days); and 2) Prophylactic antipseudomonal antibiotics to prevent the acquisition of *P. aeruginosa* are not recommended.

The American Thoracic Society (ATS) published a clinical review (2013) of non-cystic fibrosis bronchiectasis on their webpage.⁴ The review lists nebulized antibiotics (e.g., colistin, gentamicin, tobramycin) as treatment options for the eradication or suppression of *P. aeruginosa*. The European Respiratory Society (ERS) have published guidelines (2017) for the management of adult bronchiectasis and recommends patients with a new isolate of *P. aeruginosa* be offered eradication antibiotic treatment which includes nebulized antibiotics (e.g., colistin, gentamicin, tobramycin).⁵ Neither the ATS nor the ERS guidelines include Tobi Podhaler® (tobramycin inhalation powder) as a treatment option for bronchiectasis and no clinical trials have been published with Tobi Podhaler for treatment of non-cystic fibrosis bronchiectasis.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of TOBI Podhaler. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with TOBI Podhaler as well as the monitoring required for adverse events and long-term efficacy, approval requires TOBI Podhaler to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

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RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Cystic Fibrosis.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 6 years of age; AND
 - B) Patient has *Pseudomonas aeruginosa* in culture of the airway; AND
Note: Examples of culture of the airway include sputum culture, oropharyngeal culture, bronchoalveolar lavage culture.
 - C) The medication is prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

Other Uses with Supportive Evidence

2. **Continuation of TOBI Podhaler.** Approve for 1 month if the patient was started on TOBI Podhaler and is continuing a course of therapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of TOBI Podhaler is not recommended in the following situations:

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

REFERENCES

1. TOBI® Podhaler inhalation powder [prescribing information]. East Hanover, NJ: Novartis; February 2023.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic Fibrosis Pulmonary Guidelines. Chronic Medications for Maintenance of Lung Health. *Am J Respir Crit Care Med.* 2013;187:680-689.
3. Mogayzel PJ, Naureckas ET, Robinson KA, et al; and the Cystic Fibrosis Foundation Pulmonary Clinical Practice Guidelines Committee. Pharmacologic approaches to prevention and eradication of initial *Pseudomonas aeruginosa* infection. *Ann Am Thorac Soc.* 2014;11(10):1640-1650.
4. McShane PJ, Naureckas ET, Tino G, Strek ME. Non-cystic fibrosis bronchiectasis. *Am J Respir Crit Care Med.* 2013;188:647-656.
5. Polverino E, Goeminne PC, McDonnell, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. *Eur Respir J.* 2017;50:1700629.