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Tobramycin Inhalation Powder

Table of Contents

Overview 1
Medical Necessity Criteria 1
Reauthorization Criteria 2
Authorization Duration 2
Conditions Not Covered 2
Background 2
References 3

Related Coverage Resources

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.

Overview

This policy supports medical necessity review for tobramycin inhalation powder (**TOBI® Podhaler**).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Tobramycin inhalation powder (TOBI Podhaler) is considered medically necessary when ONE of the following is met (1 or 2):

1. **Cystic Fibrosis.** Individual meets **ALL** of the following criteria (A, B, and C):
   A. Individual is 6 years of age or older
   B. Documentation of Pseudomonas aeruginosa in airway cultures (for example, 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.

2. **Continuation of Tobramycin Inhalation Powder Therapy.** Individual meets **BOTH** of the following criteria (A and B):
    A. Individual was started on tobramycin inhalation powder (TOBI Podhaler) and is continuing the course of therapy
    B. The medication is prescribed by, or in consultation with, a pulmonologist

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Tobramycin inhalation powder (TOBI Podhaler) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

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 (FEV_1) < 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 {BID}] 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 recommend 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.

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.