

## TOBI Podhaler in Cystic Fibrosis patients Prior Authorization Criteria

### Background:

Patients with Cystic Fibrosis (CF) are susceptible to lung infections with *Pseudomonas aeruginosa*. These infections may occur in childhood and become chronic as the patient reaches early adulthood. These chronic *Pseudomonas* infections are associated with an increased risk of morbidity and mortality. The use of tobramycin inhalation solution improves lung function and reduces hospitalizations in patients with CF with chronic *Pseudomonas* infection. Current guidelines recommend the use of tobramycin inhalation solution for treatment of these chronic lung infections in patients with CF who are  $\geq 6$  years of age.

TOBI Podhaler is a dry powder formulation of tobramycin that is available as an alternative to the nebulized solution. Currently only 1 trial has compared the safety and efficacy of TOBI Podhaler with TOBI nebulizer solution. That study was powered as a non-inferiority trial. TOBI Podhaler was shown to be non-inferior to TOBI nebulizer, however there was a higher incidence of drop-outs in the TOBI Podhaler arm compared to the nebulizer arm (26.9% vs 18.2% respectively). Discontinuation was mainly due to adverse effects (cough and lung disorders).

### Approval Criteria:

#### Initial Requests and Renewals

1. Provide clinical reason that patient cannot use TOBI nebulizer solution
2. Patient has a diagnosis of Cystic Fibrosis
3. Patient is not pregnant (Pregnancy Category D)
4. Patient is  $\geq 6$  years of age

### References:

1. Máiz L, Giron RM, Oliveira C et al. Inhaled antibiotics for the treatment of chronic bronchopulmonary *Pseudomonas aeruginosa* infection in cystic fibrosis: systemic review of randomised controlled trials. *Expert Opin Pharmacother* 2013; 14(9):1135-1149.
2. Tobramycin inhalation powder (TOBI podhalers) for Cystic Fibrosis. *Med Lett Drugs Ther* 2013; 55:1419;51-52.
3. Konstan MW, Geller DE, Minić P, Brockhaus F, Zhang J, Angyalosi G.. Tobramycin inhalation powder for *P. aeruginosa* infection in cystic fibrosis: The EVOLVE trial. *Pediatr Pulmonol* 2011; 46(3):230-238.
4. Konstan MW, Flume PA, Kappler M, et al. Safety, efficacy and convenience of tobramycin inhalation powder in cystic fibrosis patients: The EAGER trial. *J Cyst Fibros* 2011;10(1):54-61.

