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:


