

Antibiotics – Inhaled Aminoglycosides

Medical policy no. 07.00.00-1

Effective Date: July 1, 2018

Related medical policies:

- Antibiotics – Inhaled aztreonam (CAYSTON®)

Background:

Cystic fibrosis (CF) is a progressive, genetic disease that causes persistent lung infections and limits the ability to breathe over time. In people with CF, a defective gene causes a thick, sticky buildup of mucus in the lungs, pancreas, and other organs. In the lungs, the mucus clogs the airways and traps bacteria leading to infections, extensive lung damage, and eventually, respiratory failure.

Medical necessity

Drug	Medical Necessity
Tobramycin Nebulizer Solution <ul style="list-style-type: none"> • BETHKIS® • KITABIS™ Pak • TOBI™ • Generic tobramycin Tobramycin Inhalation Capsule <ul style="list-style-type: none"> • TOBI® Podhaler™ 	Inhaled tobramycin may be considered medically necessary when: Used to treat patients with cystic fibrosis (CF) known to have <i>Pseudomonas aeruginosa</i> in the lungs <ul style="list-style-type: none"> • Non-preferred product requires trial of a preferred product with same indication

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Tobramycin Nebulizer Solution <ul style="list-style-type: none"> • BETHKIS® • KITABIS™ Pak • TOBI™ • Generic tobramycin Tobramycin Inhalation Capsule <ul style="list-style-type: none"> • TOBI® Podhaler™ 	1. ONE of the following: <ol style="list-style-type: none"> BOTH of the following: <ol style="list-style-type: none"> Diagnosis of cystic fibrosis (CF) Positive culture for <i>Pseudomonas aeruginosa</i> infection in the lungs Severe hospital acquired pneumonia, or systemic inflammatory response syndrome (SIRS) as recommended or prescribed by Infectious Disease specialist 2. FEV ₁ between 25% and 80% predicted 3. NONE of the following: <ol style="list-style-type: none"> Less than (<) 6 years of age Positive colonization with <i>Burkholderia cepacia</i>
	Approve for 12 months
	Criteria (Reauthorization)
	Documentation of positive clinical response

	Approve for 12 months
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Dosage and quantity limits

Drug Name	Dose and Quantity Limits
BETHKIS®	224mL (56 ampules) per 28-days
KITABIS™ Pak	280mL (56 ampules) per 28-days
TOBI® Podhaler	224 capsules per 28-days
TOBI® nebulizer solution	280mL (56 ampules) per 28-days
Tobramycin nebulizer solution	280mL (56 ampules) per 28-days

References

1. TOBI Inhalation Solution [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; October 2015.
2. TOBI Podhaler [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; October 2015.
3. Bethkis [package insert]. Woodstock, Illinois: Cornerstone Therapeutics Inc.; May 2014.
4. Kitabis Pak [package insert]. Woodstock, Illinois: Catalent Pharma Solutions, LLC; November 2014.
5. Tobramycin Inhalation Solution [package insert]. Sellersville, PA.: Teva Pharmaceuticals USA; October 2015.