

Antibiotics – Inhaled Aminoglycosides

WA.PHAR.79 Antibiotics- Inhaled Aminoglycosides

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 <input type="checkbox"/> 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: <ul style="list-style-type: none"> a. BOTH of the following: <ul style="list-style-type: none"> i. Diagnosis of cystic fibrosis (CF) ii. Positive culture for <i>Pseudomonas aeruginosa</i> infection in the lungs b. 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: <ul style="list-style-type: none"> a. Less than (<) 6 years of age b. Positive colonization with <i>Burkholderia cepacia</i> Approve for 12 months |
| Criteria (Reauthorization) | |



| | |
|--|------------------------------|
| | Approve for 12 months |
|--|------------------------------|

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.

