

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Kitabis Pak (tobramycin inhalation solution)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Kitabis Pak is an aminoglycoside antibacterial drug indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with *Pseudomonas aeruginosa* initially approved by the FDA in 2014. Cystic fibrosis is an autosomal recessive disease in which patients can have abnormal airways secretions, chronic endobronchial infection, and progressive airway obstruction.

Kitabis Pak (tobramycin inhalation solution) will be considered for coverage when the following criteria are met:

Cystic Fibrosis

For initial authorization:

1. Member is at least 6 years of age; AND
2. Medication must be prescribed by or in consultation with a pulmonologist or an infectious disease specialist; AND
3. Member has a diagnosis of cystic fibrosis with a positive culture for *Pseudomonas aeruginosa* documented in chart notes; AND
4. Member has documented forced expiratory volume in 1 second (FEV₁) 25% to 75% predicted; AND
5. Member is not colonized with *Burkholderia cepacia*; AND
6. Member has tried and failed generic tobramycin inhalation solution, and ineffectiveness, intolerance or contraindication is documented in chart notes.
7. Dosage allowed/Quantity limit: 300 mg every 12 hours; administer in repeated cycles of 28 days on drug followed by 28 days off drug (280 mL per 56 days).

If all the above requirements are met , the medication will be approved for 12 months.

For reauthorization :

1. Chart notes must show improvement or stabilized signs and symptoms of disease demonstrated by any of the following:
 - a) Improved FEV₁ and/or other lung function tests
 - b) Decrease in pulmonary exacerbations or hospitalization
 - c) Decrease in pulmonary infections

If all the above requirements are met , the medication will be approved for an additional 12 months .

CareSource considers Kitabis Pak (tobramycin inhalation solution) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off- Label policy.

