PHARMACY POLICY STATEMENT
Indiana Medicaid

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STATUS	Prior Authorization Required

Bronchitol (mannitol) is a sugar alcohol indicated as add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis, initially approved by the FDA in 2020. Cystic fibrosis is an autosomal recessive disease in which patients can have abnormal airways secretions, chronic endobronchial infection, and progressive airway obstruction.

Bronchitol (mannitol) will be considered for coverage when the following criteria are met:

Cystic Fibrosis

For initial authorization:

1. Member is at least 18 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; AND
4. Member had an inadequate response, intolerance, or contraindication to documented prior therapy with nebulized hypertonic saline (7%); AND
5. Documentation showing member has passed the Bronchitol tolerance test (BTT).
6. Dosage allowed/Quantity limit: 400 mg (10 capsules) twice daily, inhaled (560 capsules per 28 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 defined as any of the following:
   a) Improved FEV1 and/or other lung function tests
   b) Decrease in pulmonary exacerbations
   c) Decrease in pulmonary infections
   d) Increase in weight-gain
   e)