

**Protocol for Bronchitol® (mannitol)
Approved October 2021**

Background:

Bronchitol, 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.

Criteria for approval:

Patient meets ALL the following:

1. The patient is 18 years of age or older
2. The patient has a diagnosis of cystic fibrosis (CF)
3. The patient has passed the Bronchitol Tolerance Test (documentation will be required)
4. The patient will use Bronchitol with standard CF therapies (e.g., bronchodilators, antibiotics, chest physiotherapy, etc.). A short-acting bronchodilator is used by oral inhalation 5-15 minutes before every dose of Bronchitol.
5. Medication is prescribed by or in consultation with a pulmonologist or a specialist in the treatment of CF
6. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Initial Approval: 6 months

Continuation of therapy:

1. Medication is prescribed by or in consultation with a pulmonologist or a specialist in the treatment of CF
2. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Renewal Approval: 12 months

References:

1. Bronchitol injection [prescribing information]. Chiesi USA, Inc. Cary, NC 27518. October 2020
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. P.A. Flume, E. Amelina, C.L. Daines et al., Efficacy and safety of inhaled dry-powder mannitol in adults with cystic fibrosis: An international, randomized controlled study, *Journal of Cystic Fibrosis*, <https://doi.org/10.1016/j.jcf.2021.02.011> Accessed August 5, 2021