MEDICAL MUTUAL®

Drug Policy

Policy:	Bronchitol (mannitol inhalation powder)	Annual Review Date: 02/20/2025 Last Revised Date: 02/20/2025

OVERVIEW

Bronchitol is a sugar alcohol indicated as add-on maintenance therapy to improve pulmonary function in patients ≥ 18 years of age with Cystic Fibrosis (CF). Use of Bronchitol in the United States is only indicated for adults who have passed the Bronchitol Tolerance Test (BTT).

POLICY STATEMENT

This policy involves the use of Bronchitol. Prior authorization is recommended for pharmacy benefit coverage of Bronchitol. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Bronchitol as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Bronchitol be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Bronchitol is recommended in those who meet the following criteria:

1. <u>Cystic Fibrosis; Initial Use</u>
Criteria. *Patient must meet the following criteria (A, B, C, D, E, and F):*

A. The patient is 18 years of age or older; AND
B. Patient has tried hypertonic saline; AND
C. The patient has passed the Bronchitol Tolerance Test*; AND
D. Patient will pre-medicate with a short-acting bronchodilator; AND
E. The medication is prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis; AND
F. The medication is used as add-on maintenance therapy to improve pulmonary function.

2. <u>Cystic Fibrosis; Continuation of Therapy</u>
Criteria. *Patient must meet the following criteria (A, B, C, D, E, F, and G):*

A. The patient is 18 years of age or older; AND
B. Patient has tried hypertonic saline; AND
C. The patient has passed the Bronchitol Tolerance Test; AND
D. Patient will pre-medicate with a short-acting bronchodilator; AND
E. The medication is prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis; AND
F. The medication is used as add-on maintenance therapy to improve pulmonary function
G. The patient has experienced an adequate response to therapy, as evidenced by improvement in FEV1 and/or other lung function tests per the prescribing physician.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Bronchitol has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concomitant Use with Hypertonic Saline.** Bronchitol has not been studied in combination with hypertonic saline.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

***Documentation Requirements:**
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Bronchitol® oral inhalation powder [prescribing information]. Frenchs Forest NSW, Australia/Cary, NC: Pharmaxis/Chiesi; October 2020.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Pulmonary clinical practice guidelines committee. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. *Am J Respir Crit Care Med.* 2013;187(7):680-689.
3. Flume P, Amelina E, Daines CL, et al. Efficacy and safety of inhaled dry-powder mannitol in adults with cystic fibrosis: An international, randomized controlled study. *J Cyst Fibr.* 2020;30(6):1003-1009.

4. Bilton D, Robinson P, cooper P, et al; for the CF301 Study Investigators. Inhaled dry powder mannitol in cystic fibrosis: an efficacy and safety study. *Eur Respir J*. 2011;38:1071-1080.
5. Aitken ML, Bellon G, De Boeck K, et al; for the CF302 Investigators. Long-term inhaled dry powder mannitol in cystic fibrosis. An international randomized study. *Am J Respir Crit Care*. 2012;185(6): 645-652.