PRIOR AUTHORIZATION POLICY

POLICY: Cystic Fibrosis – Bronchitol Prior Authorization Policy
- Bronchitol® (mannitol oral inhalation powder – Pharmaxis/Chiesi)

REVIEW DATE: 02/07/2024

OVERVIEW

Bronchitol, a sugar alcohol, is indicated as add-on maintenance therapy to improve pulmonary function in patients ≥ 18 years of age with **cystic fibrosis** (CF).[1]

Safety

Bronchitol can cause bronchospasm, which can be severe in susceptible patients.[1] Therefore, Bronchitol is contraindicated in individuals who fail to pass the Bronchitol Tolerance Test. Prior to prescribing Bronchitol, the Bronchitol Tolerance Test must be administered and performed under the supervision of a healthcare practitioner who is able to manage acute bronchospasm, to identify patients who are suitable candidates for Bronchitol maintenance therapy. For patients who have passed the Bronchitol Tolerance Test, the recommended dosage of Bronchitol is 400 mg twice a day by oral inhalation (the contents of 10 capsules administered individually) via the inhaler. A short-acting bronchodilator should be administered by oral inhalation, 5 to 15 minutes before every dose of Bronchitol. Bronchitol should be taken once in the morning and once in the evening, with the later dose taken at least 2 to 3 hours before bedtime.

Guidelines

Bronchitol is not addressed in US guidelines for CF. Guidelines from the CF Foundation (2013) in the US strongly recommend chronic use of Pulmozyme® (dornase alfa inhalation solution) in patients ≥ 6 years of age with moderate to severe disease to improve lung function and quality of life, and reduce exacerbations. Pulmozyme is also recommended for chronic use in patients ≥ 6 years of age with asymptomatic or mild disease to improve lung function and reduce exacerbations. Chronic use of hypertonic saline is also recommended in individuals with CF who are ≥ 6 years of age to improve lung function and quality of life and reduce exacerbations.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Bronchitol. All approvals are provided for the duration noted below. 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, approval requires Bronchitol to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Cystic Fibrosis.** Approve for 1 year if the patient meets the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried hypertonic saline; AND
   - **C)** 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Bronchitol is not recommended in the following situations:

1. **Concomitant Use with Hypertonic Saline.** Bronchitol has not been studied in combination with hypertonic saline.[3-5]

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

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.