Pharmacy Drug Policy & Procedure

Policy Name:	Bronchitol (mannitol)	Policy #:	2842P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Bronchitol (mannitol) for the treatment of Cystic Fibrosis.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Bronchitol (mannitol) under the Specialty Pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Cystic Fibrosis

1.1 Diagnosis of Cystic Fibrosis
1.2 Ordered by, or in consultation with a pulmonologist (lung doctor)
1.3 Age 18 or older
1.4 Documentation that the patient has passed the Bronchitol Tolerance Test (BTT)
1.5 Documented failure, intolerance, or contraindication to hypertonic saline
1.6 Bronchitol will be used concurrently with dornase alfa
1.7 Bronchitol will be prescribed concurrently with a short-acting bronchodilator (such as albuterol)

2. Exclusion Criteria

2.1 Patient has failed Bronchitol Tolerance Test

3. Quantity Limits

3.1 BTT: 10 capsules once
3.2 Maintenance therapy: 560 capsules per 28 days

4. Approval Period

4.1 Initial Approval: 12 months
4.2 Subsequent Approvals: 12 months with documented positive response to therapy indicated by an improvement in lung function as determined by the change from baseline in FEV_1

CPT Codes

HCPCS Codes

References

1. Bronchitol (mannitol) [prescribing information]. Cary, NC: Chiesi USA, Inc; October 2020.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines: chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013; 187(7): 680-689.
3. De Boeck K, Haarman E, Hull J, et al. Inhaled dry powder mannitol in children with cystic fibrosis: a

randomised efficacy and safety trial. J Cyst Fibros. 2017;16(3):380-387.
4. Kapnadak SG, Dimango E, Hempstead SE, et al. Cystic Fibrosis Foundation consensus guidelines for the care of individuals with advanced cystic fibrosis lung disease. J Cyst Fibros. 2020 May;19(3):344-354.

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