PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Bronchitol (mannitol)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Bronchitol, approved in 2020, 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.
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. Member has documentation showing they have passed the Bronchitol tolerance test (BTT).
6. **Dosage allowed/Quantity limit:** 400 mg (10 capsules) twice daily by oral inhalation. Quantity limit: 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 such as improved FEV_1 and/or other lung function tests.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Bronchitol (mannitol) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/13/2021	New policy for Bronchitol created.
04/26/2022	Policy transferred to new template. Annual review; no updates.
02/05/2025	Simplified reauthorization criteria to align with expected response.

References:

1. Bronchitol (mannitol) [prescribing information]. Cary, NC: Chiesi USA Inc; 2024.
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4. Smyth AR, Bell SC, Bojcin S, et al. European Cystic Fibrosis Society Standards of Care: Best Practice guidelines. *J Cyst Fibros*. 2014;13 Suppl 1:S23-S42. doi:10.1016/j.jcf.2014.03.010
5. Teper A, Jaques A, Charlton B. Inhaled mannitol in patients with cystic fibrosis: a randomised open label dose response trial. *Journal of Cystic Fibrosis*. 2011 Jan 1;10(1):1-8.
6. Moore PJ, Tarran R. The epithelial sodium channel (ENaC) as a therapeutic target for cystic fibrosis lung disease. *Expert Opin Ther Targets*. 2018;22(8):687-701. doi:10.1080/14728222.2018.1501361
7. Tildy BE, Rogers DF. Therapeutic options for hydrating airway mucus in cystic fibrosis. *Pharmacology*. 2015;95(3-4):117-132. doi:10.1159/000377638
8. Aitken ML, Bellon G, De Boeck K, et al. Long-term inhaled dry powder mannitol in cystic fibrosis: an international randomized study. *Am J Respir Crit Care Med*. 2012;185(6):645-652. doi:10.1164/rccm.201109-1666OC
9. Agent P, Parrott H. Inhaled therapy in cystic fibrosis: agents, devices and regimens. *Breathe (Sheff)*. 2015;11(2):110-118. doi:10.1183/20734735.021014

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