HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Bronchitol (mannitol)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Bronchitol (mannitol) 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, initially approved by the FDA in 2020. 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. Documentation showing member has passed the Bronchitol tolerance test (BTT).
6. **Dosage allowed/Quantity limit:** 400 mg (10 capsules) twice daily, inhaled (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 defined as any of the following:
   a) Improved FEV1 and/or other lung function tests
   b) Decrease in pulmonary exacerbations
   c) Decrease in pulmonary infections
   d) Increase in weight-gain
   e) Decrease in hospitalizations

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

HAP 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.

References:

1. Bronchitol (mannitol) [prescribing information]. Cary, NC: Chiesi USA Inc; October 2020.
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3. Castellani C, Duff AJA, Bell SC, et al. ECFS best practice guidelines: the 2018 revision. *J Cyst Fibros*. 2018;17(2):153-178. doi:10.1016/j.jcf.2018.02.006
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. Patrick J. Moore & Robert Tarran (2018) The epithelial sodium channel (ENaC) as a therapeutic target for cystic fibrosis lung disease, Expert Opinion on Therapeutic Targets, 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):117-32.
8. Aitken ML, Bellon G, De Boeck K, Flume PA, Fox HG, Geller DE, Haarman EG, Hebestreit HU, Lapey A, Schou IM, Zuckerman JB, Charlton B; CF302 Investigators. Long-term inhaled dry powder mannitol in cystic fibrosis: an international randomized study. Am J Respir Crit Care Med. 2012 Mar 15;185(6):645-52. doi: 10.1164/rccm.201109-1666OC. Epub 2011 Dec 28. PMID: 22198974.
9. Agent P, Parrott H. Inhaled therapy in cystic fibrosis: agents, devices and regimens. Breathe. 2015 Jun 1;11(2):110-8.

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