CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Bronchitol (mannitol)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 560 capsules per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Bronchitol (mannitol) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CYSTIC FIBROSIS

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Member must have a diagnosis of cystic fibrosis; AND
3. Medication must be prescribed by or in consultation with a pulmonologist or an infectious disease specialist; 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:** 400 mg (10 capsules) twice daily, inhaled.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Evidence of disease stability or disease improvement
   a) Note: Disease improvement is evidenced by chart notes with any of the following:
      i) Improved FEV1 and/or other lung function tests;
      ii) Decrease in pulmonary exacerbations;
      iii) Decrease in pulmonary infections;
      iv) Increase in weight-gain;
      v) Decrease in hospitalizations.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Bronchitol (mannitol) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
01/13/2021	New policy for Bronchitol created.

References:

1. Bronchitol (mannitol) [prescribing information]. Cary, NC: Chiesi USA Inc; October 2020.
2. Flume PA, Aitken ML, Bilton D, et al. Optimising inhaled mannitol for cystic fibrosis in an adult population. *Breathe Sheff Engl* 2015;11:39-48.
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.

Effective date: 07/01/2021
Revised date: 01/13/2021