Commercial/Healthcare Exchange PA Criteria
Effective: 6/9/2021

Prior Authorization: BRONCHITOL® (mannitol)

Products Affected: Bronchitol (mannitol) inhalation powder - for oral inhalation use

Medication Description:
Mannitol is an osmotic diuretic that is metabolically inert in humans and occurs naturally, as a sugar, in fruits and vegetables. It promotes diuresis by increasing the osmolarity of the glomerular filtrate and thereby blocking the tubular reabsorption of water and enhancing excretion of sodium and chloride. The increase in extracellular osmolarity by IV administration leads to movement of intracellular water to the extracellular and vascular spaces thereby reducing intracranial pressure, intracranial edema, and intraocular pressure. The exact mechanisms through which inhaled mannitol causes bronchoconstriction are unknown. Because mannitol is free of electrolytes, it is useful in urology procedures as a nonhemolytic irrigant.

Covered Uses: Bronchitol is indicated as add-on maintenance therapy to improve pulmonary function in adult patients 18 years and older with Cystic Fibrosis.

Exclusion Criteria:
1. Hypersensitivity to mannitol or to any of the capsule components
2. Failure to pass the BRONCHITOL Tolerance Test (BTT)

Required Medical Information:
1. Diagnosis
2. Previous therapies tried and failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions:
Prescribed by, or in consultation with, a pulmonologist.

Coverage Duration:
BTT: 4 weeks
Initial approval and reauthorization:12 months.
If request is for BTT renewal, re-authorization is not permitted.

Other Criteria:

I. Initial Approval Criteria
~~A.~~ Cystic Fibrosis (must meet all):

1. Diagnosis of CF; AND
2. Age ≥ 18 years; AND
3. Medication is being used as an add-on maintenance therapy; AND
4. Documentation of inadequate response to hypertonic saline, unless contraindicated, or clinically significant adverse effects are experienced; AND
5. If request is for the 7-day or 4-week treatment pack, member meets both of the following (a and b):
   a. Documentation that member has successfully completed the BTT;
   b. Bronchitol is prescribed concurrently with a short-acting bronchodilator, such as: albuterol (Accuneb®, Proventil®, Ventolin®, ProAir®, ProAir RespiClick®), levalbuterol (Xopenex®, Xopenex® nebulizer solution), ipratropium bromide/albuterol (Combivent®, Duoneb®); AND
6. Dose does not exceed one of the following (a or b):
   a. For BTT: 400 mg (10 capsules) once;
   b. For 7-day or 4-week treatment pack: 800 mg (20 capsules) per day.

II. Continued Therapy

Cystic Fibrosis (must meet all):

1. Member is responding positively to therapy, and has significant improvement in FEV1; AND
2. Member has not experienced unacceptable toxicity from the drug. Some examples are severe bronchospasm, hypersensitivity reaction, kidney injury, etc; AND
3. If request is for a dose increase, new dose does not exceed 800 mg (20 capsules) per day.

***References*:**

1.BRONCHITOL® (mannitol) capsule for oral inhalation [Package Insert]. Cary, NC. Chiesi USA, Inc. Updated November 10, 2020. Accessed March 22, 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=454f092e-dcd0-47bd-a521-b07400403dad
2. BRONCHITOL® (mannitol) capsule for oral inhalation. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated March 3, 2021. Accessed March 24, 2021.
3. 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.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date

1	New Policy	New Policy	All	6/9/2021