Pharmacy Policy Bulletin

Title:	Mannitol (Bronchitol®)
Policy #:	Rx.01.248

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Mannitol (Bronchitol®)** as provided under the member's prescription drug benefit.

Description:

Cystic fibrosis is a progressive genetic condition that affects many areas of the body, including the lungs, digestive system, sweat glands and the reproductive system. Cystic fibrosis is caused by mutations in the CTFR gene, resulting in the abnormal transport of chloride and sodium ions across cell epithelia. In the respiratory system, this means there is less transport of water into the airway secretions, resulting in thick and viscous mucus accumulating in airways. These viscous secretions can obstruct the airways and promote respiratory infections, which can cause tissue damage. Common symptoms associated with cystic fibrosis include difficulty breathing, persistent productive cough and recurrent respiratory infections. Over time, these symptoms can worsen, resulting in worsening respiratory function and eventually even respiratory failure.

The precise mechanism of action of Bronchitol® in improving pulmonary function in cystic fibrosis patients is unknown.

Bronchitol® is indicated as add-on maintenance therapy to improve pulmonary function in adult patients 18 years and older with Cystic Fibrosis. Use Bronchitol® only for adults who have passed the Bronchitol® Tolerance Test.

Policy:

INITIAL CRITERIA: Mannitol (Bronchitol®) is approved when all of the following are met:

1. Diagnosis of cystic fibrosis; and
2. Member is 18 years of age or older; and
3. Member has passed the Bronchitol Tolerance Test (BTT); and
4. Member has inadequate response or inability to tolerate ONE of the following:
    a. inhaled hypertonic saline; or
    b. Pulmozyme (dornase alfa); and
5. Prescribed by or in consultation with one of the following:
    a. Pulmonologist; or
    b. Specialist associated with a cystic fibrosis care center

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Mannitol (Bronchitol®) is re-approved when there is documentation of positive clinical response to therapy (e.g., improvement in lung function [forced expiratory volume in one second {FEV1}])

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Bronchitol® (mannitol) [Package insert]. Cary, NC: Chiesi USA, Inc. October 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=454f092e-dcd0-47bd-a521-b07400403dad. Accessed April 19, 2023.

Katikin JP. Cystic fibrosis: genetics and pathogenesis. UpToDate. February 2022. Available at: https://www.uptodate.com/contents/cystic-fibrosis-genetics-and-pathogenesis. Accessed April 19, 2023.

Katikin JP. Cystic fibrosis: clinical manifestations of pulmonary disease. UpToDate. February 2023. Available at: https://www.uptodate.com/contents/cystic-fibrosis-clinical-manifestations-of-pulmonary-disease. Accessed April 19, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Bronchitol®	Mannitol

Cross References:

Rx.01.33 Off Label Use

Policy Version Number:	3.00
P&T Approval Date:	March 16, 2023
Policy Effective Date:	July 01, 2023
Next Required Review Date:	March 16, 2024