

Effective: June 13, 2023

<b>Guideline Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Non-Formulary <input type="checkbox"/> Step-Therapy <input type="checkbox"/> Administrative
<b>Applies to:</b>	
<b>Commercial Products</b>	
<input checked="" type="checkbox"/> Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988 <input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617-673-0988 CareLink <sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization	
<b>Public Plans Products</b>	
<input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988	

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

### Food and Drug Administration – Approved Indications

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.

Use Bronchitol (mannitol) only in adult patients who have passed the Bronchitol (mannitol) Tolerance Test.

## Clinical Guideline Coverage Criteria

The plan may authorization coverage of Bronchitol for Members when all of the following criteria are met:

1. Documented diagnosis of cystic fibrosis
- AND**
2. The patient is at least 18 years of age
- AND**
3. Documentation of **one (1)** of the following:
  - a. Trial and failure with hypertonic saline
  - b. Clinical inappropriateness of hypertonic saline

## Limitations

1. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

## Codes

None

## References

1. Bronchitol (mannitol) [prescribing information]. Cary, NC: Chiesi USA, Inc.; October 2020.

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## Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- June 13, 2023: No changes
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## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.