BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.45.014

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Respiratory Agents	**Original Policy Date:**	February 26, 2021
Subject:	Bronchitol	**Page:**	1 of 4

Last Review Date: December 13, 2024

Bronchitol

Description

Bronchitol (mannitol) for oral inhalation

Background
Bronchitol (mannitol) is a sugar alcohol. Its mechanism of action in improving pulmonary function in cystic fibrosis patients is unknown (1).

Regulatory Status
FDA-approved indication: Bronchitol 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 only in adults who have passed the Bronchitol Tolerance Test (1).

Prior to prescribing Bronchitol for the treatment of cystic fibrosis, the Bronchitol Tolerance Test (BTT) must be administered and performed under the supervision of a healthcare practioner who is able to manage acute bronchospasm, to identify patients who are suitable candidates for Bronchitol maintenance therapy (1).

A short-acting bronchodilator should be administered by oral inhalation, 5-15 minutes before every dose of Bronchitol (1).

Clinical trials of Bronchitol did not include patients with hepatic or renal impairment. No specific dose recommendations for these patient populations are available. However, an increase in systemic exposure to mannitol can be expected in patients with renal impairment based on kidney being the primary route of elimination (1).

Hemoptysis may occur with Bronchitol use. Bronchitol has not been studied in patients with a history of episodes of significant hemoptysis (volume greater than 60 mL) in the previous 3 months. Bronchitol should be discontinued in the event of hemoptysis (1).

Safety and effectiveness of Bronchitol in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Bronchitol may be considered **medically necessary** if the conditions indicated below are met.

Bronchitol may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Cystic fibrosis (CF)

AND ALL of the following:

1. Used as add-on maintenance therapy to improve pulmonary function (standard CF therapies include: bronchodilators, inhaled antibiotics, dornase alfa)
2. Patient has passed the Bronchitol Tolerance Test (BTT)
3. A short-acting bronchodilator (albuterol or equivalent) will be administered 5-15 minutes before every dose of Bronchitol
4. No episode of hemoptysis (volume >60 mL) in the previous 3 months
5. Prescriber agrees to monitor for increased systemic exposure of Bronchitol in patients with renal impairment

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Cystic fibrosis (CF)

AND ALL of the following:

1. Patient has had an improvement in lung function (e.g. improvement in FEV_1)
2. Used as add-on maintenance therapy to improve pulmonary function (standard CF therapies include: bronchodilators, inhaled antibiotics, dornase alfa)
3. A short-acting bronchodilator (albuterol or equivalent) will be administered 5-15 minutes before every dose of Bronchitol
4. No episode of hemoptysis (volume >60 mL)
5. Prescriber agrees to monitor for increased systemic exposure of Bronchitol in patients with renal impairment

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 1680 capsules per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Bronchitol (mannitol) is a sugar alcohol. Its mechanism of action in improving pulmonary function in cystic fibrosis patients is unknown. Safety and effectiveness of Bronchitol in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Bronchitol while maintaining optimal therapeutic outcomes.

References

1. Bronchitol [package Insert]. Sandyford Dublin, Ireland: Pharmaxis Europe Limited; June 2024.

Policy History

Date	Action
March 2021	Addition to PA
April 2021	Addition of “Prescriber agrees to monitor for increased systemic exposure of Bronchitol in patients with renal impairment” per SME
June 2021	Annual review
March 2022	Annual review
March 2023	Annual review. Changed policy number to 5.45.014
December 2023	Annual review
March 2024	Annual review
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.