

**BRONCHITOL
(mannitol)****RATIONALE FOR INCLUSION IN PA PROGRAM****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 practitioner 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).

Summary

Bronchitol (mannitol) is a sugar alcohol. Its mechanism of action in improving pulmonary function in



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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.