



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1353-4
Program	Prior Authorization/Notification
Medications	Bronchitol [®] (mannitol)
P&T Approval Date	3/2021, 3/2022, 3/2023, 3/2024
Effective Date	6/1/2024

1. Background:

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.

2. Coverage Criteria^a:

A. Initial Authorization

1. **Bronchitol** will be approved based on **all** of the following criteria:

a. Diagnosis of cystic fibrosis (CF)

-AND-

b. Used in conjunction with standard CF therapies [e.g., chest physiotherapy, bronchodilators, antibiotics, anti-inflammatory therapy (e.g., ibuprofen, oral/inhaled corticosteroids)]

-AND-

c. Patient has passed the Bronchitol Tolerance Test

Authorization will be issued for 12 months.

B. Reauthorization

1. **Bronchitol** will be approved based on the following criteria:

a. Documentation of positive clinical response to Bronchitol therapy

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program.
- Supply limitations may be in place.

4. References:

1. Bronchitol [package insert]. Cary, NC: Chiesi USA, Inc.; November 2020.

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Change Control	
3/2021	New program.
3/2022	Annual review with no change to coverage criteria.
3/2023	Annual review. Clarified that “CF” refers to cystic fibrosis without change to clinical intent. Added state mandate.
3/2024	Annual review. No change to coverage criteria. Updated reference.