

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

| Program Number | 2025 P 1353-5 |
|-------------------|--|
| Program | Prior Authorization/Notification |
| Medications | Bronchitol® (mannitol) |
| P&T Approval Date | 3/2021, 3/2022, 3/2023, 3/2024, 3/2025 |
| Effective Date | 6/1/2025 |

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 <u>all</u> 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.; January 2024.

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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. |
| 3/2025 | Annual review. No change to coverage criteria. Updated reference. |