

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 3157-6
Program	Step Therapy
Medication	Bronchitol® (mannitol)
P&T Approval Date	6/2021, 3/2022, 3/2023, 3/2024, 3/2025, 3/2026
Effective Date	6/1/2026

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try hypertonic saline before providing coverage for Bronchitol.

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:

<p>A. Bronchitol will be approved based on the following criterion:</p> <ol style="list-style-type: none"> History of failure, contraindication, or intolerance to inhaled hypertonic saline (e.g., HyperSal) (document date of trial and list reason for therapeutic failure, contraindication, or intolerance) <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>^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.</p>

3. Additional Clinical Rules:

- 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 and/or therapeutic class.
- Medical Necessity, Supply Limits and/or Notification may be in place.

4. References:

1. Bronchitol [package insert]. Cary, NC: Chiesi USA, Inc.; October 2024.

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Change Control	
6/2021	New program.
3/2022	Annual review with no change to coverage criteria.
3/2023	Annual review with no change to coverage criteria.
3/2024	Annual review with no change to coverage criteria. Updated reference.
3/2025	Annual review with no change to coverage criteria. Updated reference.
3/2026	Annual review with no change to coverage criteria. Updated reference.