

BRONCHITOL (mannitol inhalation powder)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Bronchitol is indicated as add-on maintenance therapy to improve pulmonary function in adult patients 18 years and older with Cystic Fibrosis. Use Bronchitol only for adults who have passed the Bronchitol Tolerance Test.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Cystic Fibrosis

Authorization of 12 months may be granted for treatment of cystic fibrosis when all of the following criteria are met:

- A. Bronchitol will be used as add-on maintenance therapy for cystic fibrosis with an inhaled short acting bronchodilator.
- B. The member is at least 18 years of age.
- C. The medication is prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.
- D. The member has passed the Bronchitol Tolerance Test (documentation included with the request) and did not experience any of the following during the test:
 - 1. Bronchospasm
 - 2. Decrease in FEV1
 - 3. Decrease in oxygen saturation
- E. The member has tried and failed or has a contraindication to hypertonic saline and Pulmozyme.
- F. Documentation of baseline FEV1 and/or other lung function tests.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II who are experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., improvement in FEV1 from baseline and/or other lung function tests).

IV. QUANTITY LIMIT

- A. Bronchitol 40mg capsules, 20 capsules per day or 560 capsules per 28 days

V. REFERENCES

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