Reference number(s)
4338-A

SPECIALTY GUIDELINE MANAGEMENT

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.
B. The member has passed the Bronchitol Tolerance Test and did not experience any of the following during the test:
    1. Bronchospasm
    2. Decrease in FEV1
    3. Decrease in oxygen saturation
C. The member is at least 18 years of age.

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).

IV. REFERENCES

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