CareSource

PHARMACY POLICY STATEMENT Georgia Medicaid	
DRUG NAME	**Pulmozyme (dornase alfa inhalation solution)**
BILLING CODE	**Must use valid NDC code**
BENEFIT TYPE	**Pharmacy**
SITE OF SERVICE ALLOWED	**Home**
COVERAGE REQUIREMENTS	**Prior Authorization Required (Preferred Product)** **QUANTITY LIMIT— 75 per 30 days**
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	**Click Here**

Pulmozyme (dornase alfa inhalation solution) is a preferred product and will only be considered for coverage under the pharmacy benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CYSTIC FIBROSIS

For initial authorization:

1. **Member must be 5 years of age or older; AND**
2. **Medication must be prescribed by a pulmonologist or an infectious disease specialist; AND**
3. **Member has a diagnosis of cystic fibrosis; AND**
4. **Member has forced vital capacity (FVC) predicted > 40% documented in chart note.**
5. **Dosage allowed: 2.5 mg daily using a recommended jet nebulizer/compressor system, or eRapid Nebulizer System. Some patients may benefit from twice daily administration.**

If member meets all the requirements listed above, the medication will be approved for 12 months.

For reauthorization:

1. **Member must be in compliance with all other initial criteria.**
2. **Evidence of disease stability or disease improvement**
   a) **Note: Disease improvement is evidenced by chart notes with any of the following:**
      i) **Improved FEV1 and/or other lung function tests;**
      ii) **Improvement in sweat chloride;**
      iii) **Decrease in pulmonary exacerbations;**
      iv) **Decrease in pulmonary infections;**
      v) **Increase in weight-gain;**
      vi) **Decrease in hospitalizations.**

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Pulmozyme (dornase alfa inhalation solution) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- **Atelectasis**

- Parapneumonic pleural effusions and empyemas (adults)

DATE	ACTION/DESCRIPTION
05/25/2017	New policy for Pulmozyme created. Not covered diagnosis added.
12/31/2020	Updated verbiage of approved nebulizers. Diagnosis of cystic fibrosis added to initial criteria.

References:

1. National Guideline Clearinghouse (NGC). Guideline summary: Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. In: National Guideline Clearinghouse (NGC) [Web site]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2013 Apr 01. [cited 2016 Dec 19]. Available: https://www.guideline.gov.
2. Pulmozyme [package insert]. South San Francisco, CA: Genentech Inc; 2014.
3. Pulmozyme. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com.
4. Pulmozyme. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com.

Effective date: 07/01/2021
Revised date: 12/31/2020