HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Pulmozyme (dornase alfa inhalation solution)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Pulmozyme, approved in 1993, is a recombinant DNase enzyme indicated in conjunction with standard therapies for the management of cystic fibrosis patients to improve pulmonary function.
Cystic fibrosis is an autosomal recessive disease in which patients can have abnormal airways secretions, chronic endobronchial infection, and progressive airway obstruction.

Pulmozyme (dornase alfa inhalation solution) will be considered for coverage when the following criteria are met:

Cystic Fibrosis

For **initial** authorization:
1. Member is at least 3 months of age; AND
2. Medication must be prescribed by or in consultation with a pulmonologist or an infectious disease specialist; AND
3. Member has a diagnosis of cystic fibrosis.
4. **Dosage allowed/Quantity limit:** 2.5 mg (1 ampule) inhaled once daily using a recommended jet nebulizer per prescribing information. Quantity limit: 30 ampules per 30 days.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes must show improvement or stabilized signs and symptoms of disease demonstrated by any of the following:
   a) Improved FEV1 and/or other lung function tests;
   b) Decrease in pulmonary exacerbations;
   c) Decrease in pulmonary infections;
   d) Decrease in hospitalizations.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Pulmozyme (dornase alfa inhalation solution) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
04/28/2022	Policy transferred to new template. Changed age limit from 5 years to 3 months. Removed FVC requirement. Updated references.
01/30/2025	Simplified reauthorization criteria to align with expected response.

References:

1. Pulmozyme [package insert]. South San Francisco, CA: Genentech Inc; 2024.
2. Mogayzel PJ Jr, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. *Am J Respir Crit Care Med*. 2013;187(7):680-689. doi:10.1164/rccm.201207-1160oe.
3. Yang C, Montgomery M. Dornase alfa for cystic fibrosis. *Cochrane Database Syst Rev*. 2021;3(3):CD001127. Published 2021 Mar 18. doi:10.1002/14651858.CD001127.pub5

Effective date: 07/01/2025
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