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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Respiratory Agents	**Original Policy Date:**	September 8, 2011
Subject:	Pulmozyme	**Page:**	1 of 4

Last Review Date: December 8, 2023

Pulmozyme

Description

Pulmozyme (dornase alfa)

Background
Cystic fibrosis is caused by defects in the cystic fibrosis gene, which codes for a protein transmembrane conductance regulator (*CFTR*) that functions as a chloride channel and is regulated by cyclic adenosine monophosphate (cAMP). Mutations in the *CFTR* gene result in abnormalities of cAMP-regulated chloride transport across epithelial cells on mucosal surfaces (1).

Six classes of defects resulting from *CFTR* mutations have been described with an autosomal recessive inheritance pattern. Most mutation carriers are asymptomatic and there is some variability in clinical phenotype in persons homozygous for the different mutations (1).

Dornase alfa is a highly purified solution of recombinant human deoxyribonuclease I (rhDNase), an enzyme which selectively cleaves DNA. The enzyme hydrolyzes the DNA present in sputum/mucus of patients with cystic fibrosis and reduces viscosity, thereby improving clearance of secretions (2).

Regulatory Status
FDA-approved indication: Pulmozyme is a recombinant DNase enzyme indicated in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function (2).

Off-Label Uses:
The use of Pulmozyme should be considered for all CF patients who may experience potential benefit in pulmonary function or who may be at risk of respiratory tract infection (2-4).

Related policies
Kalydeco, Orkambi, Symdeko, Trikafta

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Pulmozyme may be considered **medically necessary** if the conditions indicated below are met.

Pulmozyme may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

1. Cystic Fibrosis (CF)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Daily administration of Pulmozyme (dornase alfa) Inhalation Solution in conjunction with standard therapies is indicated in the management of cystic fibrosis patients to improve pulmonary function (2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Pulmozyme (dornase alfa) while maintaining optimal therapeutic outcomes.

References

1. Cohen-Cymberknoh M, Shoseyov D, Kerem E. Managing cystic fibrosis. Strategies that increase life expectancy and improve quality of life. Am J Respir Crit Care Med 2011;183: 1463-1471.
2. Pulmozyme [package insert]. South San Francisco, CA: Genentech, Inc.; July 2021.
3. Infant Care Guidelines: Cystic Fibrosis F, Borowitz D, Robinson KA, et al. Cystic Fibrosis Foundation evidence-based guidelines for management of infants with cystic fibrosis. The Journal of pediatrics. 2009;155(6 Suppl):S73-93.
4. Preschool Guidelines: Lahiri T, Hempstead SE, Brady C, et al. Clinical Practice Guidelines from the Cystic Fibrosis Foundation for Preschoolers with Cystic Fibrosis. Pediatrics. 2016;137(4).

Policy History

Date	Action
September 2011	Criteria modified to delete requirement for FVC >40%, based on manufacturer's package labeling: "Pulmozyme (dornase alfa) Inhalation Solution has also been evaluated in a second randomized, placebo-controlled study in clinically stable patients with baseline FVC <40% of predicted. Pulmozyme did not significantly reduce the risk of developing a respiratory tract infection requiring parenteral antibiotics.
September 2012	Annual editorial and reference update
March 2013	Annual editorial review
March 2014	Annual review
March 2015	Annual criteria review and reference update
December 2015	Annual editorial review
September 2016	Annual editorial review, addition of age, update to FDA indication to match package insert. Policy number change from 5.13.01 to 5.45.01

March 2017	Annual review
March 2018	Annual review Addition of criteria per Cystic Fibrosis guidelines for the use in all patients
June 2018	Annual editorial review and reference update
March 2019	Annual review
March 2020	Annual review
March 2021	Annual review
September 2022	Annual review and reference update
December 2022	Annual review
September 2023	Annual review
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.