

## Clinical Policy: Dornase Alfa (Pulmozyme)

Reference Number: IN.CP.PHAR.212

Effective Date: 01.01.2022

Last Review Date: 12.21

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Dornase alfa (Pulmozyme®) is a recombinant DNase enzyme.

### FDA Approved Indication(s)

Pulmozyme is indicated in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function.

In CF patients with a forced vital capacity  $\geq 40\%$  of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

## I. Initial Approval Criteria

### A. Cystic Fibrosis (must meet all):

1. Diagnosis of CF;
2. Prescribed by or in consultation with a pulmonologist, infectious disease or an expert in treatment of cystic fibrosis;
3. Dose does not exceed 5 mg (2 ampules) per day.

**Approval duration: 12 months**

### B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

## II. Continued Therapy

### A. Cystic Fibrosis (must meet all):

1. History of the requested agent within the past 365 days;
2. If request is for a dose increase, new dose does not exceed 5 mg (2 ampules) per day.

**Approval duration: 12 months**

### B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less); or**

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2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

### III. Appendices/General Information

#### *Appendix A: Abbreviation/Acronym Key*

CF: cystic fibrosis

FDA: Food and Drug Administration

#### *Appendix B: Contraindications/Boxed Warnings*

- Contraindication(s): known hypersensitivity to dornase alfa, Chinese Hamster Ovary cell products, or any component of the product
- Boxed warning(s): none reported

#### *Appendix C: General Information*

- Dornase alfa is recommended for chronic use in both mild and moderate-to-severe disease per the American Thoracic Society 2013 CF guidelines.
- Severity of lung disease is defined by FEV<sub>1</sub> predicted as follows: normal, > 90% predicted; mildly impaired, 70-89% predicted; moderately impaired, 40-69% predicted; and severely impaired, < 40% predicted.

### IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CF	One 2.5 mg ampule inhaled QD; some patients may benefit from BID administration	5 mg/day

### V. Product Availability

Inhalation solution in single-use ampules: 2.5 mg/2.5 mL

### VI. References

1. Pulmozyme Prescribing Information. South San Francisco, CA: Genentech, Inc.; January 2018. Available at <https://www.pulmozyme.com>. Accessed November 9, 2020.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines: Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. April 1, 2013; 187(7): 680-689.

### Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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HCPCS Codes	Description
J7639	Dornase alfa, inhalation solution, FDA-approved final product, noncompounded, administered through DME, unit dose form, per mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created for IN Medicaid Moratorium.	12.2021	01.2022