# Clinical Policy: Dornase Alfa (Pulmozyme)

Reference Number: ERX.SPA.25
Effective Date: 07.01.16
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

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 ≥ 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.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Pulmozyme is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

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

1. Diagnosis of CF;
2. Prescribed by or in consultation with a pulmonologist or an expert in treatment of cystic fibrosis;
3. Therapeutic plan includes concomitant use of standard CF therapies (e.g., antimicrobials, bronchodilators, mucolytics, chest physiotherapy);
4. Dose does not exceed 5 mg (2 ampules) per day.

**Approval duration: 6 months**

**B. Other diagnoses/indications**

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*
CF: cystic fibrosis
FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*
Not applicable

*Appendix C: 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 D: 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 $FEV_1$ predicted as follows: normal, > 90% predicted; mildly impaired, 70-89% predicted; moderately impaired, 40-69% predicted; and severely impaired, < 40% predicted.

**V. 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 |

**VI. Product Availability**

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

**VII. References**

1. Pulmozyme Prescribing Information. South San Francisco, CA: Genentech, Inc.; January 2018. Available at www.pulmozyme.com. Accessed December 2, 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. 2013; 187(7): 680-689.
3. Kapnadak SG, Dimango E, Hadjiliadis D, et al. Cystic Fibrosis Foundation consensus guidelines for the care of individuals with advanced cystic fibrosis lung disease. *J Cyst Fibros* 2020 May;19(3):344-354. doi: 10.1016/j.jcf.2020.02.015.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 1Q18 annual review:<br>Initial: Removed requirement that therapeutic plan includes concomitant use of standard CF therapies as this is non-specific. | 10.26.17 | 02.18 |
| 1Q 2019 annual review: no significant changes; references reviewed and updated. | 10.17.18 | 02.19 |
| 1Q 2020 annual review: no significant changes; references reviewed and updated. | 10.28.19 | 02.20 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Added pulmonologist prescriber requirement; added requirement of therapeutic plan including concomitant use of standard CF therapies as indicated in PI. | 04.22.20 | 08.20 |
| 1Q 2021 annual review: allowed an option for prescriber specialty of an expert in treatment of cystic fibrosis; references reviewed and updated. | 11.09.20 | 02.21 |
| 1Q 2022 annual review: no significant changes; references reviewed and updated. | 10.29.21 | 02.22 |

**Important Reminder**
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.