Clinical Policy: Dornase Alfa (Pulmozyme)

Reference Number: PA.CP.PHAR.212
Effective Date: 01/2018
Last Review Date: 07/2024

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 management of pediatric and adult patients with cystic fibrosis (CF) 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.

It is the policy of PA Health & Wellness that Pulmozyme is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of cystic fibrosis (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 both of the following (a or b):
   a. 5 mg per day;
   b. 2 ampules per day.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed both of the following (a or b):
   a. 5 mg per day;

b. 2 ampules per day.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently, receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. 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.

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.; February 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103532s5194lbl.pdf. Accessed May 9, 2024.
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.

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.
4. Cystic Fibrosis Foundation: Clinical Care Guidelines. Available at: https://www.cff.org/medical-professionals/clinical-care-guidelines. Accessed May 17, 2024.

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.

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
Removed initial requirement that therapeutic plan includes concomitant use of standard CF therapies as this is non-specific. References review and updated	02/2018
1Q 2019 annual review: references reviewed and updated.	01/2019
1Q 2020 annual review: references reviewed and updated.	01/2020
Added pulmonologist prescriber requirement; added requirement of therapeutic plan including concomitant use of standard CF therapies as indicated in PI.	07/2020
1Q 2021 annual review: added age restriction of 5 years and older; references reviewed and updated.	01/2021
Allowed an option for prescriber specialty of an expert in treatment of cystic fibrosis	07/2021
1Q 2022 annual review: references reviewed and updated.	01/2022
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023
3Q 2023 annual review: no significant changes; updated FDA approved indication section to align with language in prescriber information; references reviewed and updated.	07/2023
3Q 2024 annual review: no significant changes; references reviewed and updated.	07/2024