Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2020**
Policy Number: PA.CP.PHAR.212	**Effective Date: 01/01/2018** **Revision Date: 01/15/2020**
Policy Name: Dornase Alfa (Pulmozyme)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

References reviewed and updated.

Name of Authorized Individual (Please type or print):	**Signature of Authorized Individual:**
Francis G. Grillo, MD	Francis Gregory Grillo M.D

Clinical Policy: Dornase Alfa (Pulmozyme)

Reference Number: PA.CP.PHAR.212
Effective Date: 01/18
Last Review Date: 01/20

Coding Implications
Revision Log

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.

It is the policy of Pennsylvania Health and 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. Dose does not exceed 5 mg per day (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 Pennsylvania Health and 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 5 mg per day (2 ampules per day).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**
1. Currently, receiving medication via Pennsylvania Health and 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.; January 2018. Available at https://www.pulmozyme.com. Accessed October 28, 2019.
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.

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	Approval Date
Removed initial requirement that therapeutic plan includes concomitant use of standard CF therapies as this is non-specific. References review and updated	02/18	
1Q 2019 annual review: references reviewed and updated.	01/19	
1Q 2020 annual review: references reviewed and updated.	01/2020	