Clinical Policy: Dornase Alfa (Pulmozyme)

Reference Number: PA.CP.PHAR.212
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for dornase alfa (Pulmozyme®).

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
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/day (2 ampules/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 (e.g.: stable or improved pulmonary function and quality of life, reduced hospitalization);
3. If request is for a dose increase, new dose does not exceed 5 mg/day (2 ampules/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

Background
Description/Mechanism of Action:
Pulmozyme is a recombinant human deoxyribonuclease I (rhDNase), an enzyme which selectively cleaves DNA (deoxyribonucleic acid). The protein is produced by genetically engineered Chinese Hamster Ovary cells containing DNA encoding for the native human protein, deoxyribonuclease I (DNase). Fermentation is carried out in a nutrient medium containing the antibiotic gentamicin, 100–200 mg/L. However, the presence of the antibiotic is not detectable in the final product. The primary amino acid sequence is identical to that of the native human enzyme. In preclinical *in vitro* studies, Pulmozyme hydrolyzes the DNA in sputum of CF patients and reduces sputum viscoelasticity. In CF patients, retention of viscous purulent secretions in the airways contributes both to reduced pulmonary function and to exacerbations of infection. Purulent pulmonary secretions contain very high concentrations of extracellular DNA released by crenated leukocytes which accumulate in response to infection.

Formulations:
Pulmozyme: Inhalation solution (preservative free)
- 1 mg/mL (2.5 mL)

Appendices
Appendix A: Abbreviation Key
CF: cystic fibrosis

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	

References
1. Pulmozyme Prescribing Information. South San Francisco, CA: Genentech, Inc.; December 2014. Available at https://www.pulmozyme.com. Accessed October 27, 2017.

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.