Clinical Policy: Dornase Alfa (Pulmozyme)

Reference Number: CP.PHAR.212
Effective Date: 05/16
Last Review Date: 05/17

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® 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 dose of Pulmozyme does not exceed 2.5 mg twice daily;
3. Therapeutic plan includes concomitant use of standard CF therapies (e.g., antimicrobials, bronchodilators, mucolytics, chest physiotherapy).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy (e.g.: stable or improved pulmonary function and quality of life, reduced hospitalization);
3. Prescribed dose of Pulmozyme does not exceed 2.5 mg twice daily.

Approval duration: 12 months

B. Other diagnoses/indications (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

2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

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)

FDA Approved Indications:
Pulmozyme is a recombinant DNase enzyme/inhalation solution indicated in conjunction with standard therapies for:

- Management of 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.

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
Policy split from CP.PHAR.54 CF Treatments. Examples of standard therapies are added for PI indication phrase “in conjunction with standard therapies”. Appendix C (clinical reasons to continue CF therapy) is replaced by “Member continues to respond	05/16	05/16

Reviews, Revisions, and Approvals	Date	Approval Date
positively to Pulmozyme therapy in one or more of the following areas: pulmonary function, quality of life, pulmonary exacerbations". "A measured decrease in FEV1 of greater than or equal to 10 percent" is removed as a discontinuation reason. Approval periods are extended from 3 to 6 and 6 to 12 months.		
Efficacy statement edited to indicate general positive response to therapy.	05/17	05/17

References

1. Pulmozyme Prescribing Information. South San Francisco, CA: Genentech, Inc.; December 2014. Available at https://www.gene.com/download/pdf/pulmozyme_prescribing.pdf. Accessed May 1, 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.

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for

members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.