Clinical Policy: Dornase Alfa (Pulmozyme)

Reference Number: ERX.SPMN.76
Effective Date: 07/16
Last Review Date: 06/16

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

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that dornase alfa (Pulmozyme®) is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Cystic Fibrosis (CF) (must meet all):
      1. Diagnosis of CF;
      2. Prescribed dose of Pulmozyme does not exceed 2.5 mg administered up to twice daily;
      3. Therapeutic plan includes concomitant use of standard therapies for CF (e.g., antimicrobials, bronchodilators, supplemental oxygen, mucolytics).

   Approval duration: 6 months

   B. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy.

II. Continued Approval
   A. Cystic Fibrosis (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
      2. Member continues to respond positively to Pulmozyme therapy in one or more of the following areas: pulmonary function, quality of life, pulmonary exacerbations.

   Approval duration: 12 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
      2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

Background
Description/Mechanism of Action:
Pulmozyme is a recombinant human deoxyribonuclease I (rhDNase), an enzyme which selectively cleaves DNA. The protein is produced by genetically engineered Chinese Hamster Ovary (CHO) 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 \textit{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 degenerating leukocytes that accumulate in response to infection.

\textit{Formulations:}
Pulmozyme is administered by inhalation of an aerosol mist produced by a compressed air driven nebulizer or an approved nebulizer system. Pulmozyme is a sterile, clear, colorless, highly purified solution in single-use ampules. Each ampule delivers 2.5 mL of the solution to the nebulizer bowl. Each mL of aqueous solution contains 1 mg dornase alfa, calcium chloride dihydrate (0.15 mg) and sodium chloride (8.77 mg). The solution contains no preservative. The nominal pH of the solution is 6.3.

\textit{FDA Approved Indication:}
Pulmozyme (dornase alfa) is a recombinant DNase enzyme/inhalation solution indicated in conjunction with standard therapies for:

- Management of cystic fibrosis (CF) patients to improve pulmonary function.

\textit{In CF patients with an FVC \textgtr{}= 40\% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.}

\textbf{Appendices}

\textbf{Appendix A: Abbreviation Key}

- CF: cystic fibrosis
- FVC: forced vital capacity

\textbf{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.

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<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J7639</td>
<td>Dornase alfa, inhalation solution, FDA-approved final product, noncompounded, administered through DME, unit dose form, per mg</td>
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<th>Reviews, Revisions, and Approvals</th>
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<td>Policy created.</td>
<td>05/16</td>
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References

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.

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