
Prior Authorization DRUG Guidelines

PULMOZYME® (dornase alpha)

Effective Date: 10/27/05

Date Developed: 9/1/05 by C. Wilhelmy MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19
(Archived 1/22/19)

The hallmark of cystic fibrosis lung disease is the presence of abundant, purulent airway secretions composed primarily of highly polymerized DNA. The principal source of this DNA is the nuclei of degenerating neutrophils, which is present in large concentrations in infected lung secretions. The presence of this DNA produces a viscous mucous that may contribute to the decreased mucociliary transport and persistent infections that are commonly seen in this population. Dornase alfa is a deoxyribonuclease (DNA) enzyme produced by recombinant gene technology. Dornase selectively cleaves DNA, thus reducing mucous viscosity and as a result, airflow in the lung is improved and the risk of bacterial infection may be decreased.

Pre-Authorization Criteria:

PULMOZYME® is used for the management of cystic fibrosis patients to reduce the frequency of respiratory infections that require parenteral antibiotics and to improve pulmonary function.

VCHCP requires that Pulmozyme be prescribed by a pulmonologist or physician with expertise in the care of patients with cystic fibrosis.

DOSING: ADULTS — Mucolytic: Inhalation: 2.5 mg once daily through selected nebulizers.

DOSING: PEDIATRIC— Children >3 months to Adults: 2.5 mg once daily through selected nebulizers; experience in children <5 years is limited.

Note: Patients unable to inhale or exhale orally throughout the entire treatment period may use Pari-Baby™ nebulizer. Some patients may benefit from twice daily administration.

USE — Management of cystic fibrosis patients to reduce the frequency of respiratory infections that require parenteral antibiotics, and to improve pulmonary function.

CONTRAINDICATIONS — Hypersensitivity to dornase alfa, Chinese hamster ovary cell products (eg, epoetin alfa), or any component of the formulation.

PREGNANCY RISK FACTOR — B

REFERENCES

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4. Mueller, GA, Rubins, G, Wessel, D, et al. Effects of Dornase Alfa on Pulmonary Function Tests in Infants with Cystic Fibrosis. *Am J Respir Crit Care Med* 1996; 153:A70.
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