Drug Coverage Policy

Effective Date.....7/15/2026
Coverage Policy Number IP0483
Policy Title.....Pulmozyme

Cystic Fibrosis – Pulmozyme

- Pulmozyme® (dornase alfa inhalation solution – Genentech/Roche)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Pulmozyme, a recombinant human deoxyribonuclease I, is indicated in conjunction with standard therapies for the management of patients with **cystic fibrosis** to improve pulmonary function.[1]

Guidelines
Guidelines from the Cystic Fibrosis Foundation (2007, updated in 2013) address the chronic use of medications for management of lung health in cystic fibrosis patients ≥ 6 years of age.[2,3] These guidelines recommend Pulmozyme use for patients with cystic fibrosis regardless of disease severity to improve lung function and reduce exacerbations. Separate guidelines have addressed Pulmozyme use in younger patients.[4,5] Although efficacy data are lacking in patients < 5 years of age, safety and tolerability have been established in patients as young as 3 months.[1,5] Cystic Fibrosis Foundation guidelines for infants < 2 years of age (2009) and children between 2 and 5 years of age (2016) support Pulmozyme use in these populations based on individual circumstances.[4,5]

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Pulmozyme. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Pulmozyme as well as the monitoring required for adverse events and long-term efficacy, approval requires Pulmozyme to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Pulmozyme is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Cystic Fibrosis.** Approve for 1 year if the medication is prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

Conditions Not Covered
Pulmozyme for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Asthma.** Mucus hypersecretion may be mediated by a variety of causes, including inflammation, irritation, stimulation, or mucus-producing tumors.[6] However, efficacy of Pulmozyme is not established for conditions other than cystic fibrosis.[9] In a pilot study of patients with severe acute asthma (n = 50), there was no significant difference in forced expiratory volume in 1 second (FEV_1) with Pulmozyme use vs. placebo.[7,9]

2. **Bronchiectasis, Idiopathic.** A multicenter, double-blind, randomized, placebo-controlled 24-week trial (n = 349) examined the effect of Pulmozyme vs. placebo in patients with idiopathic bronchiectasis (i.e., bronchiectasis not related to cystic fibrosis).[8] Patients in the Pulmozyme arm experienced worsened lung function and more frequent pulmonary exacerbations vs. placebo. The authors concluded that Pulmozyme should not be used in this population. Another small double-blind, placebo-controlled, Phase II trial (n = 14) examined Pulmozyme in adults with non-cystic fibrosis bronchiectasis. Pulmozyme failed to show any significant change in any of the outcome variables or in sputum transportability.[9,10]

References

1. Pulmozyme® inhalation solution [prescribing information]. South San Francisco, CA: Genentech/Roche; February 2024.
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4. Borowitz D, Robinson KA, Rosenfeld M, et al, Cystic Fibrosis Foundation. Cystic Fibrosis Foundation evidence-based guidelines for management of infants with cystic fibrosis. *J Pediatr.* 2009;155(6 Suppl):S73-93.
5. Lahiri T, Hempstead SE, Brady C, et al. Clinical practice guidelines from the Cystic Fibrosis Foundation for preschoolers with cystic fibrosis. *Pediatrics.* 2016;137(4): e20151784.
6. Rubin BK. Aerosol medications for treatment of mucus clearance disorders. *Respiratory Care.* 2015;60(6):825-832.
7. Silverman RA, Foley F, Dalipi R, et al. The use of rhDNase in severely ill, non-intubated adult asthmatics refractory to bronchodilators: a pilot study. *Respir Med.* 2012; 106(8):1096-1102.
8. O'Donnell AE, Barker AF, Ilowite JS, Fick RB. Treatment of idiopathic bronchiectasis with aerosolized recombinant human DNase I. rhDNase Study Group. *Chest.* 1998;113(5):1329-1334.
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10. Wills PJ, Wodehouse T, Corkery K, Mallon K,Wilson R, and Cole PJ. Short-term recombinant human DNase in bronchiectasis. Effect on clinical state and in vitro sputum transportability. *Am J Respir Crit Care Med.* 1996;154:413-417.

Revision Details

Summary of Changes	Review Date	Effective Date
Updated coverage policy title from *Dornase Alfa* to *Cystic Fibrosis – Pulmozyme*. **Cystic Fibrosis.** **Removed** criterion, *"used to improve pulmonary function in cystic fibrosis (CF)."* **Treatment of Complicated Pleural Effusions.** **Removed** criteria for coverage of, *Treatment of Complicated Pleural Effusions*.	6/20/2024	9/1/2024
No criteria changes.	5/22/2025	7/1/2025
No criteria changes.	5/21/2026	7/15/2026

The policy effective date is in force until updated or retired.

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