UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1084-13
Program	Prior Authorization/Notification
Medication	Pulmozyme® (dornase alfa)
P&T Approval Date	8/2012, 5/2013, 2/2014, 2/2015, 2/2016, 2/2017, 2/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023, 2/2024, 2/2025
Effective Date	5/1/2025

1. Background:

Pulmozyme (dornase alfa) is a recombinant deoxyribonuclease (DNase) enzyme 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 (FVC) ≥ 40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.[1]

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Pulmozyme** will be approved based on **both** of the following criteria:

   a. Diagnosis of cystic fibrosis

   -AND-

   b. Used in conjunction with standard CF therapies [e.g., chest physiotherapy, bronchodilators, antibiotics, anti-inflammatory therapy (e.g., ibuprofen, oral/inhaled corticosteroids)]

Authorization of therapy will be issued for 12 months.

B. Reauthorization

1. **Pulmozyme** will be approved based on the following criterion:

   a. Documentation of positive clinical response to Pulmozyme therapy

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Pulmozyme [package insert]. South San Francisco, CA: Genentech, Inc.; July 2021.
2. Mogayzel P, Naureckas E, Robinson K, Mueller G, Hadjiliadis D, Hoag J, Lubsch L, Hazle L, Sabadosa K, Marshall B; Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. American Journal of Respiratory and Critical Care Medicine 2013;187:680-689.

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Change Control	
2/2014	Updated authorization to 60 months. Removed reauthorization criteria.
2/2015	Annual review with no change to coverage criteria. Updated references.
2/2016	Annual review with no changes to clinical content. Changed authorization period to 12 months and added re-authorization period for 12 months. Administrative changes only to background section. Updated reference.
2/2017	Annual review with no changes to coverage criteria.
2/2018	Annual review with no changes to coverage criteria.
2/2019	Annual review. Updated references. Updated background information.
2/2020	Annual review. Updated background. No changes to coverage criteria.
2/2021	Annual review. No changes to coverage criteria.
2/2022	Annual review with no changes to coverage criteria. Updated references.
2/2023	Annual review. No changes to coverage criteria. Added state mandate footnote.
2/2024	Annual review with no changes to coverage criteria.
2/2025	Annual review with no changes to coverage criteria.