

<b>Clinical Policy Title:</b>	dornase alfa
<b>Policy Number:</b>	RxA.451
<b>Drug(s) Applied:</b>	Pulmozyme®
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of Business (except Medicare)

## Criteria

### I. Initial Approval Criteria

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

1. Diagnosis of cystic fibrosis;
2. The requested drug is used in conjunction with standard therapies for cystic fibrosis (e.g., antimicrobials, bronchodilators, mucolytics, chest physiotherapy).

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

### II. Continued Therapy Approval

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

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.
2. The requested drug is used in conjunction with standard therapies for cystic fibrosis (e.g., antimicrobials, bronchodilators, mucolytics, chest physiotherapy).

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

## References

1. 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. 2013;187(7):680-689. Available at: <https://pubmed.ncbi.nlm.nih.gov/23540878/>. Accessed on March 24, 2025.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Policy title table was updated.</li> <li>2. Line of Business Policy Applies to was update to all lines of business.</li> <li>3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..."</li> </ol>	07/03/2020	09/14/2021

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<ul style="list-style-type: none"> <li>4. Initial and Continued Approval Duration was updated to specify Commercial and Medicaid.</li> <li>5. References were updated.</li> <li>6. Added “the requested drug is used in conjunction with standard therapies for CF” to the initial criteria and continued therapy criteria.</li> </ul>		
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.2 was updated to include prescriber criteria, “Prescribed by or in consultation with pulmonologist and gastroenterologist...”.</li> <li>2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".</li> <li>3. References were reviewed and updated.</li> </ul>	07/08/2021	09/14/2021
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.2: Updated to add an expert in treatment of cystic fibrosis.</li> <li>2. Initial Approval Criteria I.A.3: Updated to add examples of other standard therapies for CF e.g. antimicrobials, bronchodilators, mucolytics, chest physiotherapy.</li> <li>3. References were reviewed and updated.</li> </ul>	03/28/2022	07/18/2022
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> <li>1. Removed prior dosing criteria.</li> <li>2. Removed reauthorization requirement for positive response to therapy.</li> <li>3. Added examples of standard therapies for cystic fibrosis.</li> <li>4. Updated approval duration.</li> <li>5. References were reviewed and updated.</li> </ul>	11/22/2023	01/01/2024
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> <li>1. Removed prescriber criteria.</li> <li>2. Updated continuation of therapy language.</li> <li>3. References were reviewed and updated.</li> </ul>	03/24/2025	04/10/2025
<p>Policy was reviewed.</p>	12/11/2025	12/11/2025