

Prior Authorization Criteria  
**Pulmozyme (recombinant dornase alfa)**

All requests for Pulmozyme (recombinant dornase alfa) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of Cystic Fibrosis and the following criteria is met:

- Evidence of cystic fibrosis transmembrane conductance regulator (CFTR) dysfunction by ONE of the following:
  - Elevated sweat chloride  $\geq 60$  mmol/L (on two occasions)
  - Presence of two disease-causing mutations in CFTR, one from each parental allele
  - Abnormal nasal potential difference measurements
- Member must be 3 months of age or older
- Medication must be prescribed by or in association with a pulmonologist
- Will be used in conjunction with standard cystic fibrosis therapies [e.g. oral, inhaled, and/or parenteral antibiotics; inhaled hypertonic saline; chest physiotherapy; bronchodilators; enzyme supplements/vitamins; oral or inhaled corticosteroids; other anti-inflammatory therapy (e.g. ibuprofen)]
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Member is receiving clinical benefit based on the prescriber's assessment
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

**PULMOZYME (DORNASE ALFA)  
PRIOR AUTHORIZATION FORM**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health<sup>SM</sup> Pharmacy Services. **FAX:** (888) 245-2049  
If needed, you may call to speak to a Pharmacy Services Representative.  
**PHONE:** (800) 392-1147 Monday through Friday 8:30am to 5:00pm

**PROVIDER INFORMATION**

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

**MEMBER INFORMATION**

Member Name:	DOB:
Gateway ID:	Member weight: _____ pounds or _____ kg

**REQUESTED DRUG INFORMATION**

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Date Medication Initiated:	

**Billing Information**

This medication will be billed:  at a pharmacy **OR**  
 medically (if medically please provide a JCODE: \_\_\_\_\_)

Place of Service:  Hospital  Provider's office  Member's home  Other

**Place of Service Information**

Name:	NPI:
Address:	Phone:

**MEDICAL HISTORY (Complete for ALL requests)**

**Diagnosis:**

- Cystic Fibrosis
- Is sweat chloride level  $\geq 60$  mmol/L on 2 occasions?  Yes  No
  - Are two disease-causing mutations in CFTR present (one from each parental allele)?  Yes  No
  - Is nasal potential difference (PD) abnormal?  Yes  No
- Other: \_\_\_\_\_ ICD-10: \_\_\_\_\_

Will Pulmozyme be used in conjunction with standard cystic fibrosis therapies (e.g., inhaled saline, physiotherapy, bronchodilators, antibiotics, corticosteroids, anti-inflammatory agents)?  Yes  No

**CURRENT or PREVIOUS THERAPY**

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

**REAUTHORIZATION**

Has the member experienced a clinical benefit with treatment?  Yes  No

**SUPPORTING INFORMATION or CLINICAL RATIONALE**


**Prescribing Provider Signature**

**Date**

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