

**Texas Prior Authorization Program  
Clinical Criteria**

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**Drug/Drug Class****Pulmozyme (dornase alfa)**

*This criteria was recommended for review by an MCO to ensure appropriate and safe utilization*

**Clinical Criteria Information Included in this Document****Pulmozyme**

- **Drugs requiring clinical prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Clinical prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

**Note:** Click the hyperlink to navigate directly to that section.

**Revision Notes**

- Initial publication and presentation to the DUR Board



## Pulmozyme (dornase alfa)

### Drugs Requiring Clinical Prior Authorization

*The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit [TxVendorDrug.com/formulary/formulary-search](http://TxVendorDrug.com/formulary/formulary-search).*

Label Name	GCN
PULMOZYME 1 MG/ML AMPUL	27200



## Pulmozyme (dornase alfa)

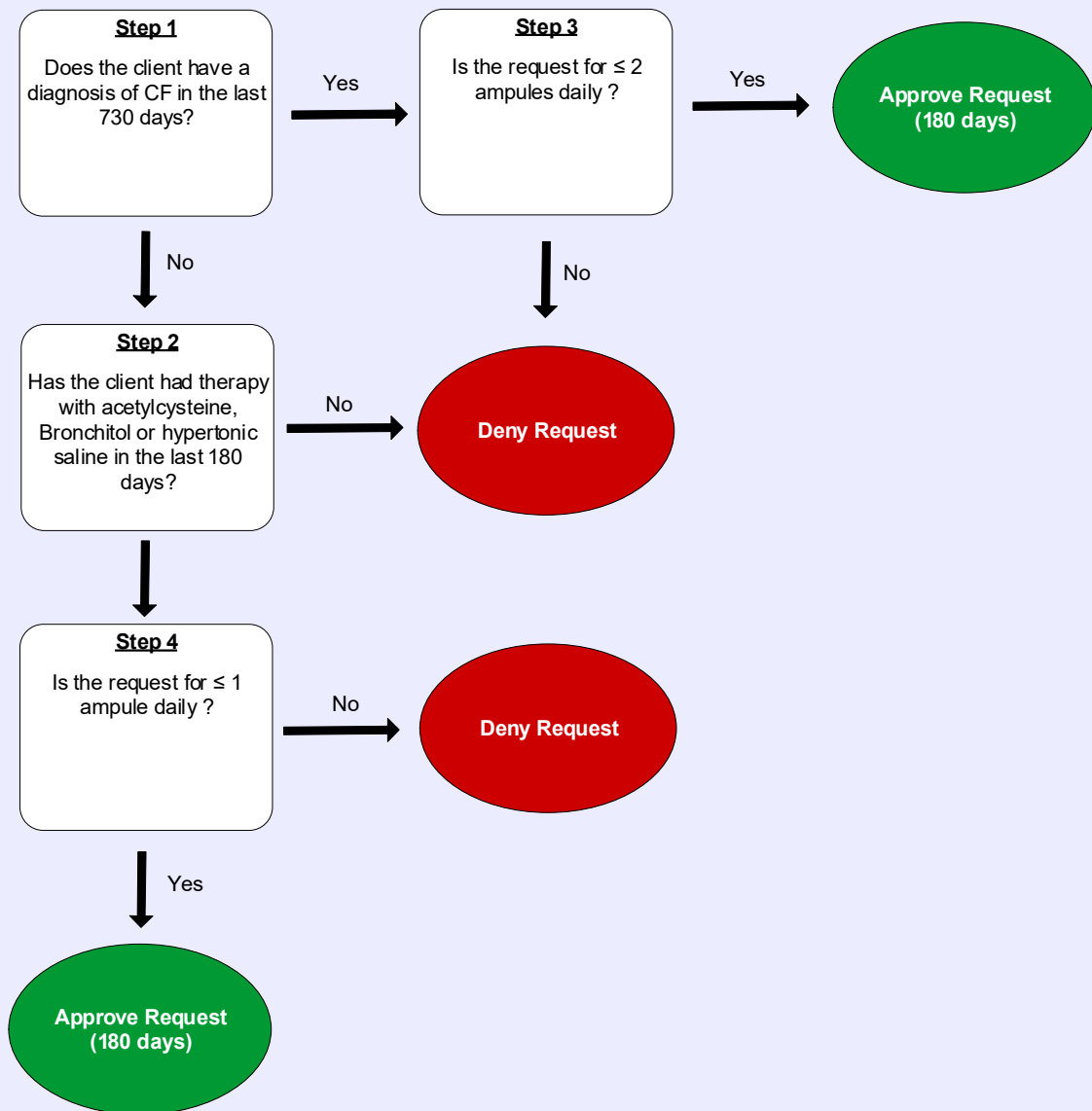
### Clinical Criteria Logic

1. Does the client have a **diagnosis of cystic fibrosis** in the last 730 days?  
 Yes – Go to #3  
 No – Go to #2
2. Has the client had therapy with **acetylcysteine, Bronchitol or hypertonic saline** in the last 180 days?  
 Yes – Go to #4  
 No – Deny
3. Is the request for less than or equal to ( $\leq$ ) two ampules daily?  
 Yes – Approve (180 days)  
 No – Deny
4. Is the request for less than or equal to ( $\leq$ ) one ampule daily?  
 Yes – Approve (180 days)  
 No – Deny



# Pulmozyme (dornase alfa)

## Clinical Criteria Logic Diagram





## Inhaled Antibiotics

### Clinical Criteria Supporting Tables

<b>Step 1 (diagnosis of cystic fibrosis)</b> <b>Required quantity: 1</b> <b>Look back timeframe: 730 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
E8411	CYSTIC FIBROSIS WITH INTESTINAL MANIFESTATIONS, MECONIUM ILEUS IN CF
E8419	CYSTIC FIBROSIS WITH OTHER INTESTINAL MANIFESTATIONS
E848	CYSTIC FIBROSIS WITH OTHER MANIFESTATIONS
E840	CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS
E849	CYSTIC FIBROSIS, UNSPECIFIED

<b>Step 2 (therapy with sodium chloride for oral inhalation or acetylcysteine)</b> <b>Required quantity: 1</b> <b>Look back timeframe: 180 days</b>	
<b>Label Name</b>	<b>GCN</b>
ACETYLCYSTEINE 10% VIAL	02400
ACETYLCYSTEINE 20% VIAL	02401
BRONCHITOL 40 MG INHALE CAP	36299
PULMOSAL 7% VIAL	98520
SODIUM CHLORIDE 3% VIAL	02373
SODIUM CHLORIDE 7% VIAL	98520



## **Pulmozyme (dornase alfa)**

### **Clinical Criteria References**

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2021. Available at [www.clinicalpharmacology.com](http://www.clinicalpharmacology.com). Accessed on January 21, 2022.
2. Drug Facts and Comparisons. eFacts [online]. 2021. Available from Wolters Kluwer Health, Inc. Accessed on January 21, 2022.
3. Pulmozyme Prescribing Information. South San Francisco, CA. Genentech, Inc. July 2021.

## Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
01/21/2022	Initial publication and presentation to the DUR Board