Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Pulmozyme (Dornase Alfa)

This criteria was recommended for review by a MCO to ensure appropriate and safe utilization.

Clinical Criteria Information included in this Document

- Drugs requiring prior authorization: the list of drugs requiring prior authorization for this clinical criteria

- 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); provided when applicable

- References: clinical publications and sources relevant to this clinical criteria

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

Revision Notes

Annual review by staff

Updated references

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Drugs Requiring Prior Authorization

The listed GCNs may not be an indication of Texas Medicaid Formulary coverage. To learn the current formulary coverage, visit txvendordrug.com/searches/formulary-drug-search.

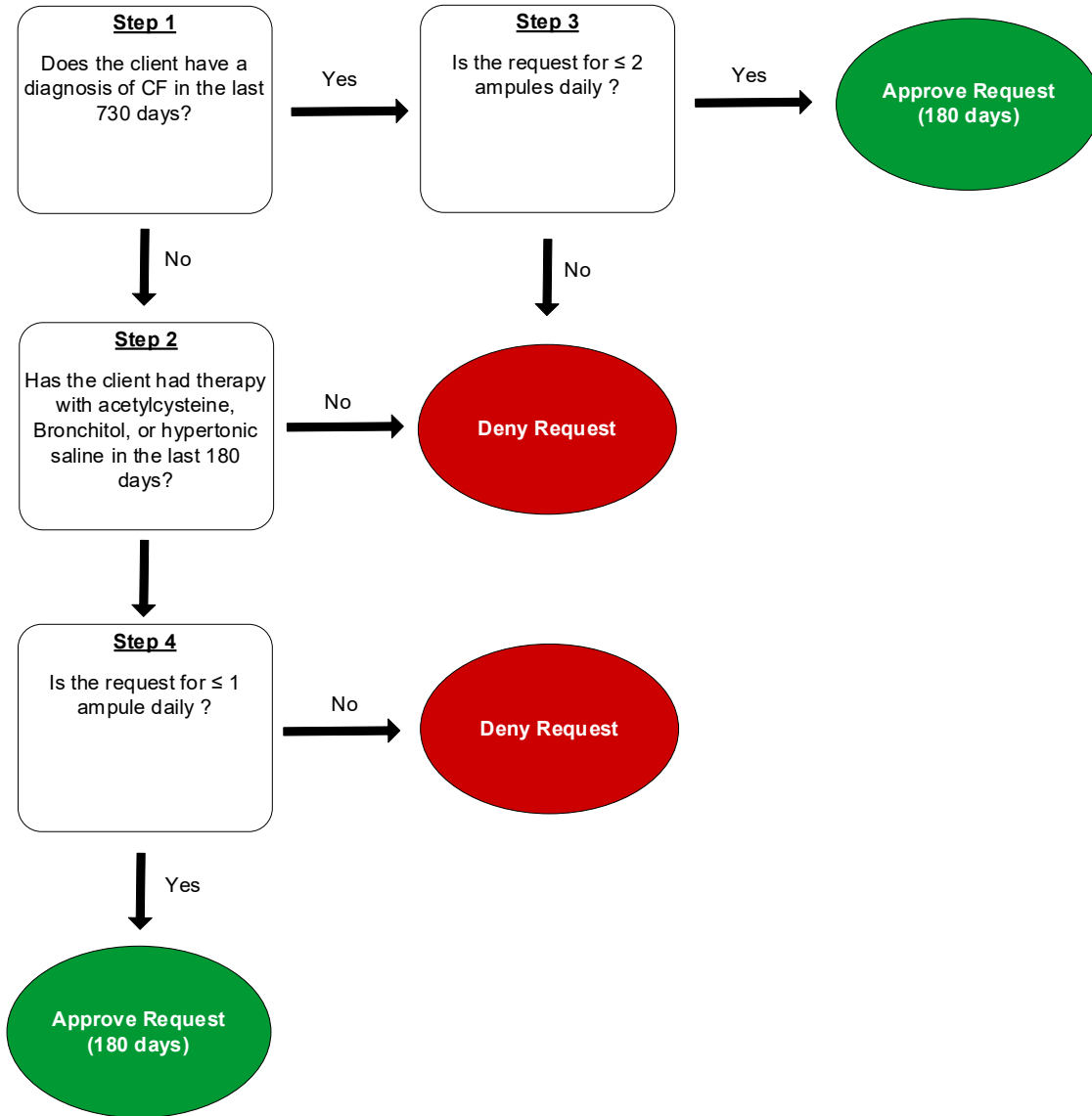| Drugs Requiring Prior Authorization	
Label Name	**GCN**
PULMOZYME 1 MG/ML AMPUL	27200

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Clinical Criteria Logic

1. Does the client have a diagnosis of cystic fibrosis (CF) 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 (≤) two ampules daily?

    [ ] Yes – Approve (180 days)

    [ ] No – Deny

4. Is the request for less than or equal to (≤) one ampule daily?

    [ ] Yes – Approve (180 days)

    [ ] No – Deny

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Clinical Criteria Logic Diagram

PAXPRESS™

Step 1

Does the client have a diagnosis of CF in the last 730 days?

— Yes →

Step 3

Is the request for ≤ 2 ampules daily ?

— Yes →

Approve Request (180 days)

No ↓ (from Step 1)

Step 2

Has the client had therapy with acetylcysteine, Bronchitol, or hypertonic saline in the last 180 days?

— No →

Deny Request

No ↓ (from Step 3)

Deny Request

↓ (from Step 2)

Step 4

Is the request for ≤ 1 ampule daily ?

— No →

Deny Request

Yes ↓

Approve Request (180 days)

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Clinical Criteria Supporting Tables

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

Table 2 (therapy with acetylcysteine, Bronchitol, or hypertonic saline) Required quantity: *1* Look back timeframe: *180* days	
GCN	**Label Name**
02400	ACETYLCYSTEINE 10% VIAL
02401	ACETYLCYSTEINE 20% VIAL
36299	BRONCHITOL 40 MG INHALE CAP
98520	PULMOSAL 7% VIAL
02373	SODIUM CHLORIDE 3% VIAL
98520	SODIUM CHLORIDE 7% VIAL

Pulmozyme (Dornase Alfa)

Clinical Criteria References

1. Pulmozyme Prescribing Information. South San Francisco, CA. Genentech, Inc. February 2024.

2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2025. Available at www.clinicalpharmacology.com. Accessed on August 14, 2025.

3. Drug Facts and Comparisons. eFacts [online]. 2025. Available at www.factsandcomparisons.com. Accessed on August 14, 2025.

4. 2025 ICD-10-CM Diagnosis Codes, Volume 1. 2025. Available at www.icd10data.com. Accessed on August 14, 2025.

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
02/16/2024	• Annual review by staff • Updated references
01/17/2025	• Annual review by staff • Updated references
08/29/2025	• Annual review by staff • Updated references