BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

PULMOZYME® (dornase alfa) inhalation solution Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
  - **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for PULMOZYME (dornase alfa)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Pulmonologist or in consultation with a Pulmonologist

Indication
- Management of Cystic Fibrosis (CF) in conjunction with standard therapies to improve pulmonary function

Baseline Clinical Evaluation
- Completed baseline pulmonary function tests before starting treatment

- Continues other standard therapies for cystic fibrosis (e.g., albuterol inhaler, hypertonic saline inhalation, chest physiotherapy, exercise, CFTR modulator) when indicated

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (when available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Documentation Requirements

- A completed request form must be submitted, including:
  - Chart notes
  - Lab results (baseline pulmonary function tests)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy)

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualifications

- Continues to be seen by a Pulmonologist or is in consultation with a Pulmonologist

Clinical Response

- Positive clinical response defined as **ONE** of the following:
  - Stable or improved FEV1 or FVC from baseline
  - Fewer pulmonary exacerbations
  - Improvement of dyspnea and sputum clearance
  - Fewer respiratory tract infections requiring parenteral antibiotics

Adherence

- Adherence to the prescribed therapy regimen and additional standard therapies for cystic fibrosis (e.g., albuterol inhaler, hypertonic saline inhalation, chest physiotherapy, exercise, CFTR modulator) has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (when available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Documentation Requirements

- Chart notes

- Supporting clinical documentation with evidence of improvement in Cystic Fibrosis
- Lab values confirming safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

2. Off-Label Use of Cancer Medications

Description:

Cystic fibrosis (CF) is a life-threatening genetic disease caused by pathogenic mutations of the CF transmembrane conductance regulator (CFTR) gene. Complications of CF include decreased lung function, frequent infections of lung and sinus tract, poor weight gain and growth, diabetes, pancreatic insufficiency and liver disease. However, pulmonary disease remains the leading cause of morbidity and mortality in individuals with CF.

Treatment to improve pulmonary outcomes is multi-modal and may include CFTR modulators, airway clearance therapies, chest physiotherapy, exercise, infection prevention, bronchodilators and anti-inflammatories. CFTR modulators are a newer class of medications that work to improve function, production or intracellular processing of the defective CFTR protein. Pulmozyme, hypertonic saline, and mannitol are inhaled airway clearance agents to help clear purulent secretions from the airway.

Pulmozyme is a recombinant human deoxyribonuclease I (rhDNase), an enzyme which selectively cleaves DNA. In individuals with CF, retention of viscous purulent secretions in the airways contributes to reduced pulmonary function and to exacerbations of infection. These purulent secretions contain high concentrations of extracellular DNA. In *in vitro* studies, Pulmozyme hydrolyzed the DNA in the sputum and reduced sputum viscoelasticity. Clinical trials supported that Pulmozyme increased FEV1 from baseline and in patients with baseline FVC greater than or equal to 40%, Pulmozyme decreased the incidence of occurrence of first respiratory tract infection requiring parenteral antibiotics. Pulmozyme should be used in combination with other standard CF treatment. Pulmozyme is administered via nebulizer but should not be combined with other nebulized therapies.

Pulmozyme has not been found effective in other pulmonary conditions including chronic obstructive pulmonary disease (COPD), bronchiectasis, and atelectasis in children.

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Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Nebulization Devices to be used with Pulmozyme:

- Vibrating Mesh Nebulizers
  - AireHealth Nebulizer
  - eRapid Nebulizer System
  - Innospire Go
  - Intelligent Mesh Nebulizer
  - Pulmogine Vibrating Mesh Nebulizer
- Jet nebulizer connected to an approved air compressor
  - Durable Sidestream
  - Hudson T Up-draft II
  - Marquest Acorn II
  - PARIBABY
  - PARI LC Plus

Resources:

Pulmozyme (dornase alpha) product information, revised by Genentech, Inc. 02-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 13, 2025.

Simon RH. Cystic Fibrosis: Overview of the treatment of lung disease. In: UpToDate, Chmiel JF, Hoppin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through May 2025. Topic last updated March 22, 2024. Accessed June 24, 2025.

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