BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

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ARCHIVE DATE:

PULMOZYME® (dornase alfa) inhalation solution

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

PULMOZYME® (dornase alfa) inhalation solution

Criteria:

- **Criteria for initial therapy:** Pulmozyme (dornase alfa) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in Cystic Fibrosis or is in consultation with a Pulmonologist
  2. A confirmed diagnosis of **Cystic Fibrosis (CF)**
  3. Individual uses and continues other standard therapies for cystic fibrosis (e.g., albuterol inhaler, hypertonic saline inhalation, chest physiotherapy, exercise, CFTR modulator).
  4. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. FEV1

  Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Pulmozyme (dornase alfa) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in Cystic Fibrosis or is in consultation with a Pulmonologist
  2. Individual's condition has responded
     a. Response defined as ONE of the following:
        i. Stable or improved FEV1 from baseline
        ii. Fewer pulmonary exacerbations
        iii. Improvement of dyspnea and sputum clearance
  3. Individual continues other standard therapies for cystic fibrosis (e.g., albuterol inhaler, hypertonic saline inhalation, chest physiotherapy, exercise, CFTR modulator).
  4. Individual has been adherent with the medication

  Renewal duration: 12 months

- 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 a Non-Cancer Medications**
  2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

PULMOZYME® (dornase alfa) inhalation solution

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.

Definitions:

Nebulization Devices to be used with Pulmozyme:

- eRapid Nebulizer System
- Jet nebulizer connected to an approved air compressor
    - Durable Sidestream
    - Hudson T Up-draft II
    - Marquest Acorn II
    - PARIBABY
    - PARI LC Plus

Resources:

Pulmozyme product information, revised by Genentech, Inc. 12/2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on July 30, 2021.

Simon RH. Cystic Fibrosis: Overview of the treatment of lung disease. In: UpToDate, Mallory GB, Hoppin AG (Ed), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on August 9, 2021.