Original Effective Date: 11/01/2016
Current Effective Date: 11/23/2023
Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C9796-A

Pulmozyme (dornase alfa)

PRODUCTS AFFECTED

Pulmozyme (dornase alfa)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Cystic fibrosis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case- by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CYSTIC FIBROSIS:
1. Documentation of a diagnosis of cystic fibrosis
   AND

2. Prescriber attests Pulmozyme will be used in conjunction with standard therapies for cystic fibrosis [e.g., chest physiotherapy, bronchodilators, antibiotics, anti-inflammatory therapy (e.g., ibuprofen, oral/inhaled corticosteroids)]

B. BRONCHIECTASIS (NON-COVERAGE):

1. Pulmozyme (dornase alfa) is considered not medically necessary for bronchiectasis due to insufficient evidence of therapeutic or clinical value. Initial study result in non-CF bronchiectasis showed no significant change in any outcome variables including spirometry and subjective measures of quality of life and dyspnea. In this study, aerosolized recombinant human DNase was well tolerated by the study population. In a randomized, double-blind, placebo-controlled study of 349 adult outpatients with idiopathic bronchiectasis, the aerosolized dornase alfa group had more frequent pulmonary exacerbations and FEV1 decline was greater compared to the placebo group. This led the authors to conclude that rhDNase was ineffective and potentially harmful in this group. The 2017 European Respiratory Society guidelines for the management of adult bronchiectasis recommends NOT offering recombinant human DNase to adult patients with bronchiectasis [strong recommendation, moderate quality of evidence].

CONTINUATION OF THERAPY:

A. CYSTIC FIBROSIS:

1. Documented beneficial and clinically significant response to treatment

DURATION OF APPROVAL:

Initial authorization:12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a pulmonologist, cystic fibrosis specialist or physician from a CF center accredited by the Cystic Fibrosis Foundation. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

None

QUANTITY:

2.5 mg inhaled once daily (30 ampules per month)

PLACE OF ADMINISTRATION:

The recommendation is that inhalation medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Inhalation

DRUG CLASS:

Hydrolytic enzymes

FDA-APPROVED USES:

Indicated in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function

COMPENDIAL APPROVED OFF-LABELED USES:

None- see exclusions

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
In cystic fibrosis (CF) members, retention of viscous purulent secretions in the airways contribute both to reduced pulmonary function and to exacerbations of infection. Purulent pulmonary secretions contain very high concentrations of extracellular DNA released by degenerating leukocytes that accumulate in response to infection. Pulmozyme (dornase alfa) is a recombinant human deoxy ribonuclease I (rhDNase) enzyme indicated. In conjunction with standard therapies, for the management of cystic fibrosis members to improve pulmonary function1,2 In members with an FVC ≥ 40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Pulmozyme (dornase alfa) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Pulmozyme (dornase alfa) include: patients with known hypersensitivity to dornase alfa, Chinese Hamster Ovary cell products, or any component of the product.
Aerosolized Dornase alfa is not effective in non-CF-related bronchiectasis and is potentially harmful.

OTHER SPECIAL CONSIDERATIONS:
Pulmozyme (dornase alfa) is administered through selected jet nebulizers in conjunction with an air compressor system (Durable Sidestream, Hudson T Up-draft II, Marquest Acorn II, PARIBABY, or PARI LC Plus) or eRapid Nebulizer System. Patients unable to inhale or exhale orally throughout the entire treatment period may use Pari-Baby nebulizer. Some patients may benefit from twice daily administration.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	N/A

AVAILABLE DOSAGE FORMS:
Pulmozyme SOLN 2.5MG/2.5ML

REFERENCES

1. Pulmozyme (dornase alfa) [prescribing information]. South San Francisco, CA: Genentech, Inc.; July 2021.
2. Fuchs HJ, Borowitz DS, et al. Effect of aerosolized recombinant human DNase on exacerbations of respiratory symptoms and on pulmonary function in members with cystic fibrosis. N Engl J Med

1994;331:637–42.
3. O'Donnell, A., Barker, A., Ilowite, J., & Fick, R. (1998). Treatment of Idiopathic Bronchiectasis With Aerosolized Recombinant Human Dnase I. Chest, 113(5), 1329-1334. Doi: 10.1378/chest.113.5.1329
4. O'Donnell, A. E., Barker, A. F., Ilowite, J. S., & Fick, R. B. (1998). Treatment of idiopathic bronchiectasis with aerosolized recombinant human Dnase I. rhDNase Study Group. Chest, 113(5), 1329–1334. https://doi.org/10.1378/chest.113.5.1329
5. Polverino, E., Goeminne, P., McDonnell, M., Aliberti, S., Marshall, S., & Loebinger, M. et al. (2017). European Respiratory Society guidelines for the management of adult bronchiectasis. European Respiratory Journal, 50(3), 1700629. Doi: 10.1183/13993003.00629-2017

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information	Q4 2023
REVISION- Notable revisions: Diagnosis Required Medical Information Prescriber Requirements Quantity Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file