Effective Date: 11/01/2016
Last P&T Approval/Version: 10/27/2021
Next Review Due By: 11/2022
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:
Adjunct treatment of cystic fibrosis, Parapneumonic pleural effusions and empyemas (off-label use): Intrapleural[provided as an inpatient hospital stay only]

REQUIRED MEDICALINFORMATION:
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 federalrequirements, 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

A. CYSTIC FIBROSIS:
1. Documentation of a diagnosis of cystic fibrosis confirmed by chart notes and appropriate testing
   AND
2. 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)]

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 or cystic fibrosis specialist.

AGE RESTRICTIONS:
None

QUANTITY:
30 ampules per month

PLACE OF ADMINISTRATION:
The recommendation is that inhalation medications in this policy will be for pharmacybenefit 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 Pulmozymehas 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.
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 dailyadministration.

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 SOL 1MG/ML (2.5ml vials)

REFERENCES

1. Pulmozyme [package insert]. 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. Simon RH. Cystic fibrosis: Overview of the treatment of lung disease. Topic 6372, Version 32.0. Mallory GB and Hoppin AG, Eds. UpToDate, 2014.
4. Treatment of idiopathic bronchiectasis with aerosolized recombinant human DNase I.rhDNase Study Group.AUO'Donnell AE, Barker AF, Ilowite JS, Fick RB SOChest. 1998;113(5):1329