

Pulmozyme® (dornase alfa) (Inhalation)

Document Number: IC-0101

Last Review Date: 10/24/2022

Date of Origin: 11/28/2011

Dates Reviewed: 12/2011, 12/2012, 03/2013, 02/2014, 12/2014, 10/2015, 10/2016, 10/2017, 10/2018, 11/2019, 11/2020, 11/2021, 11/2022

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Pulmozyme 1 mg/ml solution for inhalation: 2 ampules per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 5 billable units per day

III. Initial Approval Criteria ^{1-5,11}

Coverage is provided in the following conditions:

- Patient is at least 3 months of age; **AND**
- Patient has baseline forced vital capacity (FVC) \geq 40% predicted; **AND**

Cystic Fibrosis (CF) † Φ ¹⁻⁵

- Patient has a documented diagnosis of cystic fibrosis*; **AND**
- Patient will receive treatment in conjunction with standard cystic fibrosis therapies, such as: oral, inhaled and/or parenteral antibiotics (e.g., tobramycin, aztreonam, azithromycin); chest physiotherapy; cystic fibrosis transmembrane conductance regulator (CFTR) potentiators (e.g., lumacaftor/ivacaftor, ivacaftor); bronchodilators (e.g., albuterol solution/HFA, pirbuterol MDI, levalbuterol solution/HFA); enzyme supplements (e.g., pancrelipase); vitamins; analgesics or anti-inflammatory therapy (e.g., ibuprofen, oral or inhaled corticosteroids)

**Note: It is recommended that patients diagnosed with CF be managed at a Cystic Fibrosis Foundation-accredited CF Care Center, if resources are available.*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria ^{1,10}

Coverage may be renewed based on the following criteria:

- Patient continues to meet the indication-specific relevant criteria identified in section III; **AND**
- Disease response as indicated by a significant decrease in respiratory tract infections, improvement in pulmonary function, etc.; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity allergic reaction, etc.

V. Dosage/Administration ¹

Indication	Dose
Cystic Fibrosis	2.5 mg (1 single-dose ampule) inhaled 1-2 times daily, using a recommended jet nebulizer/compressor system or eRapid™ Nebulizer System

VI. Billing Code/Availability Information

HCPCS Code:

- J7639 – Dornase alfa, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose form, per milligram; 1 billable unit = 1 mg

NDC:

- Pulmozyme 1 mg/mL single-dose ampule, solution for inhalation (carton of 30 ampules): 50242-0100-xx

VII. References

1. Pulmozyme [package insert]. South San Francisco, CA; Genentech, Inc.; July 2021. Accessed October 2022.
2. Mogayzel PJ Jr, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013 Apr 1;187(7):680-9.
3. Farrell PM, White TB, Ren CL, et al. Diagnosis of Cystic Fibrosis: Consensus Guidelines from the Cystic Fibrosis Foundation. J Pediatr. 2017 Feb;181S:S4-S15.e1. doi: 10.1016/j.jpeds.2016.09.064.
4. Lahiri T, Hempstead SE, Brady C, et al. Clinical Practice Guidelines From the Cystic Fibrosis Foundation for Preschoolers With Cystic Fibrosis. Pediatrics Volume 137, number 4, April 2016: e2 0151784
5. Castellani C, Duff AJA, Bell SC, et al. ECFS best practice guidelines: the 2018 revision. J Cyst Fibros. 2018 Mar;17(2):153-178. doi: 10.1016/j.jcf.2018.02.006.

6. Fuchs HJ, Borowitz DS, Christiansen DH, Morris EM, Nash ML, Ramsey BW, Rosenstein BJ, Smith AL, Wohl ME. Effect of aerosolized recombinant human DNase on exacerbations of respiratory symptoms and on pulmonary function in patients with cystic fibrosis. The Pulmozyme Study Group. N Engl J Med. 1994 Sep 8;331(10):637-42. doi: 10.1056/NEJM199409083311003. PMID: 7503821.
7. McCoy K, Hamilton S, Johnson C. Effects of 12-week administration of dornase alfa in patients with advanced cystic fibrosis lung disease. Pulmozyme Study Group. Chest. 1996 Oct;110(4):889-95. doi: 10.1378/chest.110.4.889. PMID: 8874241.
8. Cystic Fibrosis Foundation, Borowitz D, Robinson KA, et al. Cystic Fibrosis Foundation evidence-based guidelines for management of infants with cystic fibrosis. J Pediatr. 2009;155(6 Suppl):S73-S93. doi:10.1016/j.jpeds.2009.09.001.
9. Kapnadak SG, Dimango E, Hadjiliadis D, et al. Cystic Fibrosis Foundation consensus guidelines for the care of individuals with advanced cystic fibrosis lung disease. JCF. May2020.19;3:344-354. <https://doi.org/10.1016/j.jcf.2020.02.015>
10. Mitchell RM, Jones AM, Barry PJ. CFTR modulator therapy in patients with cystic fibrosis and an organ transplant. Paediatr Respir Rev. 2018 Jun;27:6-8. doi: 10.1016/j.prrv.2018.04.003. Epub 2018 Apr 25.
11. Wagener JS, Rock MJ, McCubbin MM, et al. Aerosol delivery and safety of recombinant human deoxyribonuclease in young children with cystic fibrosis: a bronchoscopic study. Pulmozyme Pediatric Bronchoscopy Study Group. J Pediatr. 1998 Oct;133(4):486-91. doi: 10.1016/s0022-3476(98)70055-1. PMID: 9787685.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E84.0	Cystic fibrosis with pulmonary manifestations
E84.1	Cystic fibrosis with intestinal manifestations
E84.11	Meconium ileus in cystic fibrosis
E84.19	Cystic fibrosis with other intestinal manifestations
E84.8	Cystic fibrosis with other manifestations
E84.9	Cystic fibrosis, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

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XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaajiila qarqaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

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