Clinical Policy Title:	dornase alfa
Policy Number:	RxA.451
Drug(s) Applied:	Pulmozyme®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of Business

Background

Dornase alfa (Pulmozyme®) is a recombinant DNase enzyme. It is indicated in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function.

In CF patients with a forced vital capacity ≥ 40% of predicted, daily administration of Pulmozyme® has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
dornase alfa (Pulmozyme®)	Cystic fibrosis	One 2.5 mg ampule inhaled once daily; some patients may benefit from twice daily administration	5 mg/day

Dosage Forms

- Inhalation solution in single-use ampules: 2.5 mg/2.5 mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Cystic Fibrosis (must meet all)**:**

1. Diagnosis of cystic fibrosis;
2. Prescribed by or in consultation with pulmonologist and gastroenterologist;
3. The requested drug is used in conjunction with standard therapies for cystic fibrosis;
4. Dose does not exceed 5 mg per day (2 ampules per day).

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Cystic Fibrosis (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. The requested drug is used in conjunction with standard therapies for cystic fibrosis;
4. If request is for a dose increase, new dose does not exceed 5 mg per day (2 ampules per day).

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. APPENDICES

APPENDIX A: Abbreviation/Acronym Key
CF: cystic fibrosis

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to dornase alfa, Chinese Hamster Ovary cell products, or any component of the product.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Dornase alfa is recommended for chronic use in both mild and moderate-to-severe disease per the American Thoracic Society 2013 CF guidelines.
- Severity of lung disease is defined by FEV_1 predicted as follows: normal, > 90% predicted; mildly impaired, 70-89% predicted; moderately impaired, 40-69% predicted; and severely impaired, < 40% predicted.

References

1. Pulmozyme® Prescribing Information. South San Francisco, CA: Genentech, Inc.; August 2020 . Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d8c78a7e-ff99-48f3-8952-643ec2ea0f86 . Accessed July 8, 2021.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013;187(7):680-689. Available at: https://pubmed.ncbi.nlm.nih.gov/23540878/ . Accessed on July 8, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was update to all lines of business.	07/03/2020	09/14/2021

3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Initial and Continued Approval Duration was updated to specify Commercial and Medicaid. 5. References were updated. 6. Added “the requested drug is used in conjunction with standard therapies for CF” to the initial criteria and continued therapy criteria.		
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Initial Approval Criteria I.A.2 was updated to include prescriber criteria, “Prescribed by or in consultation with pulmonologist and gastroenterologist…”. 3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. Appendix A was updated to remove abbreviation FDA. 5. References were reviewed and updated. 6.	07/08/2021	09/14/2021