



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

DORNASE ALFA

Generic	Brand	HICL	GCN	Exception/Other
DORNASE ALFA	PULMOZYME	08832		

This drug requires a written request for prior authorization.

**GUIDELINES FOR USE**

1. Does the patient have a diagnosis of cystic fibrosis?

If yes, continue to #2.

If no, do not approve.

**DENIAL TEXT:** Approval requires a diagnosis of cystic fibrosis and requests for twice daily dosing require a trial of once daily dosing.

2. Is the request for once daily dosing (30 ampules per month)?

If yes, **approve for 12 months with a quantity limit of #30 ampules per month.**

If no, continue to #3.

3. Has the patient tried once daily dosing (30 ampules per month per MRF or claims history)?

If yes, **approve for 12 months with a quantity limit of #60 ampules per month.**

If no, do not approve. **Enter a proactive authorization for 12 months with a quantity limit of #30 ampules per month.**

**DENIAL TEXT:** Approval requires a diagnosis of cystic fibrosis and requests for twice daily dosing require a trial of once daily dosing.

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**RATIONALE**

Promote appropriate utilization of Pulmozyme based on FDA approved indication.

**Dosage:** The recommended dose for use in most cystic fibrosis patients is one 2.5mg single-use ampule inhaled once daily using a recommended nebulizer. Some patients may benefit from twice daily administration.

**FDA APPROVED INDICATION**

Pulmozyme is indicated in conjunction with standard therapies in the management of cystic fibrosis patients to improve pulmonary function.

**REFERENCE**

- Genentech, Inc. Pulmozyme package insert. South San Francisco, CA. October 2010.

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Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/07/13

Created: 05/12

Client Approval: 01/13

P&T Approval: 05/12