Genentech | ACCESS SOLUTIONS®
A Member of the Roche Group

for Pulmozyme®
(dornase alfa)

SAMPLE CODING

Cystic Fibrosis

TYPE	CODE		DESCRIPTION
Diagnosis: ICD-10-CM	E84.0		Cystic fibrosis with pulmonary manifestations
	E84.8		Cystic fibrosis with other manifestations
	E84.9		Cystic fibrosis, unspecified
Drug: HCPCS	J7639		Dornase alfa, inhalation solution, FDA-approved final product, noncompounded, administered through DME, unit dose form, per mg
Drug: NDC Note: Payer requirements regarding use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference.	10-digit	11-digit	
	50242-100-40	50242-0100-40	30 ampules containing 2.5 mg of dornase alfa in 2.5 mL of solution
Administration procedures: CPT	G0333		Pharmacy dispensing fee for initial inhalation drug(s); initial 30-day supply to a beneficiary
	Q0513		Pharmacy dispensing fee for inhalation drug(s); per 30 days
	Q0514		Pharmacy dispensing fee for inhalation drug(s); per 90 days

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

These codes are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

Many payers will not accept unspecified codes. If you use an unspecified code, please check with your payer.

INDICATION & IMPORTANT SAFETY INFORMATION

Indication

Pulmozyme (dornase alfa) is indicated for daily administration in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function.

In CF patients 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.

Important Safety Information

Pulmozyme is contraindicated in patients with known hypersensitivity to dornase alfa, Chinese Hamster Ovary cell products, or any component of the product.

The most common adverse reactions associated with the use of Pulmozyme include: voice alteration, pharyngitis, rash, laryngitis, chest pain, conjunctivitis, rhinitis, decrease in FVC of ≥ 10%, fever, dyspepsia, and dyspnea. There have been no reports of anaphylaxis attributed to the administration of Pulmozyme. Mild to moderate urticaria and mild skin rash have been observed and have been transient.

For further information, please see the Pulmozyme full Prescribing Information.

Important Safety Information (cont)

PEDIATRIC USE

The safety and effectiveness of Pulmozyme have been established in pediatric patients 5 years of age and older. The safety of Pulmozyme, 2.5 mg by inhalation, was studied with 2 weeks of daily administration in 65 patients with cystic fibrosis aged 3 months to < 5 years. While clinical trial data are limited in pediatric patients younger than 5 years of age, the use of Pulmozyme should be considered for pediatric CF patients who may experience potential benefit in pulmonary function or who may be at risk of respiratory tract infection.

The safety of Pulmozyme, 2.5 mg by inhalation, was studied with 2 weeks of daily administration in 98 pediatric patients with cystic fibrosis 3 months to 10 years of age (65 aged 3 months to < 5 years, 33 aged 5 to ≤ 10 years). The PARI BABY™ reusable nebulizer (which uses a facemask instead of a mouthpiece) was utilized in patients unable to demonstrate the ability to inhale or exhale orally throughout the entire treatment period (54/65, 83% of the younger; and 2/33, 6% of the older patients). Overall, the nature of adverse reactions was similar to that seen in the placebo-controlled trials in older patients. The number of patients reporting cough was higher in the younger age group as compared to the older age group (29/65, 45%; compared to 10/33, 30%) as was the number reporting moderate to severe cough (24/65, 37%; compared to 6/33, 18%). The number of patients reporting rhinitis was higher in the younger age group as compared to the older age group (23/65, 35%; compared to 9/33, 27%) as was the number reporting rash (4/65, 6% as compared to 0/33, 0%).

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

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