

DEPARTMENT OF HEALTH SERVICES

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November 30, 2001

N.L.: 21-1101
Index: Drugs
Supersedes N.L.06-0195

TO: ALL COUNTY CALIFORNIA CHILDREN'S SERVICES (CCS)
ADMINISTRATORS, AND MEDICAL CONSULTANTS, AND STATE
CHILDREN'S MEDICAL SERVICES (CMS) STAFF

SUBJECT: PULMOZYME (DORNASE FULFATE)

Background:

Pulmozyme (dornase alfa) Inhalation Solution was first licensed by the Federal Food and Drug Administration (FDA) on December 30, 1993, for the management of patients with cystic fibrosis who are five years of age and older. It was to be used with standard therapies to reduce the frequency of respiratory infections requiring parenteral antibiotics and to improve pulmonary function. On March 2, 1998, the FDA approved a change in labeling to allow for use in children less than five years of age in whom there is a potential for benefit in pulmonary function or in reduced risk of respiratory infection. This numbered letter supercedes NL 06-0195 which allowed authorization of Pulmozyme based on specific medical criteria.

Articles that have been published address safety and efficacy in children as young as two weeks of age. However, the medical literature has not presented clinical criteria for use of Pulmozyme in this younger age group. There is also very limited medical literature on the use of Pulmozyme in children with pulmonary conditions other than cystic fibrosis¹.

Policy:

Pulmozyme is a benefit of the CCS program for a CCS client with Cystic Fibrosis (CF) or other CCS eligible pulmonary conditions when the request to authorize Pulmozyme comes from the CCS-approved CF and Other Chronic Pulmonary Conditions Special Care Center (SCC) which is authorized to provide care for the client.

Policy Implementation:

1. The request to authorize Pulmozyme, either initial or subsequent, must come from

the treating physician in the CF and Other Chronic Pulmonary Disease SCC at which the client is authorized to receive center care.

2. Authorizations for Pulmozyme may be issued for a period of up to one year but shall not exceed the period of the client's CCS program eligibility.
3. Requests for authorization of Pulmozyme that are received from other than a CCS approved CF and Other Chronic Pulmonary Conditions SCC are to be reviewed by the County Medical Consultant with the CMS Branch regional Medical Consultant prior to a decision on approval or denial of the request.

If you have any questions please contact your Regional Office Medical Consultant.



Maridee A. Gregory, M.D., Chief
Children's Medical Services Branch

Reference:

¹ Ten Berge, M.D., Maartje, Brinkhorst, M.D., Govert, Kroon, M.D., Andre, and Johan C. de Jongste, M.D., "DNase Treatment in Primary Ciliary Dyskinesia – Assessment by Nocturnal Pulse Oximetry," Pediatric Pulmonology (1999). 27:59-61.