Statement of Medical Necessity (SMN)

for Pulmozyme® (dornase alfa)

Phone: (800) 690-3023 Fax: (800) 963-1792 www.PulmozymeAccessSolutions.com

Pulmozyme® dornase alfa INHALATION SOLUTION

Access Solutions™ Treatment made possible.™

Please complete with a ballpoint pen.

Services Requested

☐ Benefits Information/Prior Authorization ☐ Appeals Assistance ☐ Patient Assistance ☐ Starter

Patient Information

Last Name: First Name:

Street: City: State: ZIP:

Home Phone: ( ) Date of Birth (MM/DD/YR): ☐ Male ☐ Female

Primary Contact Name: **Relationship:**

Primary Phone: ( ) Work Phone: ( ) Cell Phone: ( )

Insurance Information

☐ **Insurance card attached (optional: see reverse for details)**

Primary Insurance				Secondary Insurance			
☐ HMO/EPO	☐ PPO	☐ POS	☐ Indemnity	☐ HMO/EPO	☐ PPO	☐ POS	☐ Indemnity
☐ Medicare	☐ Medicaid	☐ No Insurance		☐ Medicare	☐ Medicaid	☐ No Insurance	

Primary Insurance Name: Secondary Insurance Name:

Phone: ( ) Phone: ( )

Subscriber: Subscriber:

Subscriber ID #: Grp #: Subscriber ID #: Grp #:

Employer: ☐Retired Employer: ☐Retired

Diagnosis and Other Pertinent Medical Information

☐ **Additional pertinent medical information has been attached (optional)**

DIAGNOSIS: ☐ CYSTIC FIBROSIS (277.0) ☐ OTHER; PLEASE SPECIFY ICD-9

Forced Expiratory Volume (FEV1): ☐ Mild – greater than 70% ☐ Moderate – between 40% and 70% ☐ Severe – less than 40% ☐ Patient Under 6 Years Old

Prescription Type: ☐ New Start ☐ Continuing Therapy ☐ Restart Therapy

Has Patient Started Treatment? ☐Yes ☐No Anticipated Date of Treatment:

Prescription

Pulmozyme Regimen 2.5 mL (dornase alfa) Inhalation Solution ☐ Drug Allergies: _____ ☐ NKDA

DISPENSE: ☐ 30-day supply ☐ 60-day supply ☐ 90-day supply Refill: _____ times SIG: ☐ QD ☐ BID

Nebulizer (check ONE box only) ☐ Sidestream® Nebulizer (Part #MS2400) ☐ PARI LC® Jet Nebulizer

☐ PARI BABY™ Mask – specify size: ☐ size 0 ☐ size 1 ☐ size 2 ☐ size 3

(All masks come with one PARI LC Jet Nebulizer)

Starter Rx: ☐ Date to Be Shipped: _____ Ship to: ☐ Physician's Office Or ☐ Patient's Home

**The Starter Rx is a free, one-time, 30-day supply that is not intended for resale or insurance billing by the provider or patient.*

Prescriber Information

Prescriber's Full Name: DEA #: Tax ID #:

State License #: Individual NPI#: Group Billing NPI #:

Street: City: State: ZIP:

Reimbursement Contact Name: Phone: ( ) Fax: ( )

UNAPPROVED USE WARNING: Please read the FDA-approved label for Pulmozyme before prescribing. If the indication for which you are prescribing Pulmozyme is not listed in the label, you are prescribing Pulmozyme for an "unapproved" use. The fact that the use for which you are prescribing Pulmozyme is not listed in the FDA-approved label indicates that the FDA has not approved the efficacy, dosage amount or safety of Pulmozyme when used for such a use. Nevertheless, Genentech® Access to Care Foundation will consider providing Pulmozyme for your patient with this admonition, based upon your medical order, within program requirements.

- By signing below, I certify that (a) the above therapy is medically necessary, (b) I have received the necessary authorization to release the above referenced information and other protected health information (as defined in the Health Insurance Portability and Accountability Act of 1996 [HIPAA]) to Genentech USA, Inc., Pulmozyme® Access Solutions™ and contracted dispensing pharmacy or other contractors for the purpose of seeking reimbursement, assisting in initiating or continuing therapy and/or the evaluation of the patient's eligibility for the Genentech Access to Care Foundation related to Genentech products as a break in treatment would negatively impact the patient's therapeutic outcome, (c) I will not sell or bill for any free product received in my office for patients from the Genentech Access to Care Foundation or Starter Programs, and (d) I appoint Pulmozyme Access Solutions solely to convey on my behalf to the pharmacy chosen by the above-named patient the prescription described herein.
- I agree to comply with the program guidelines as established by Genentech USA, Inc. and understand that Genentech Access to Care Foundation, at its sole and absolute discretion, reserves the right to modify or discontinue the program at any time and to verify the accuracy of the information submitted.

Prescriber Signature Date

Original Signature Required – Stamped Signature Will Not Be Accepted

This form cannot be processed without prescriber's signature

*National Provider Identifier

Instructions: How to Complete the Statement of Medical Necessity (SMN) for Pulmozyme® (dornase alfa)

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Services Requested

Please write legibly and complete all sections to prevent delay.

- Please indicate the services that are being requested to allow Pulmozyme® Access Solutions™ to proceed accordingly.

Attach to Completed SMN

- Please attach a signed and dated PATIENT AUTHORIZATION AND NOTICE OF RELEASE OF INFORMATION (PAN) form. This form is needed to fully investigate coverage.

Insurance Information

- Fill out this section with the patient's insurance information, OR provide a front and back copy of the patient's insurance card (enlarged and legible), and fax this information with the SMN and PAN.
- Including both primary and secondary insurance will ensure that all potential coverage can be investigated.

Diagnosis and Other Pertinent Medical Information

- Check the appropriate diagnosis code.
- If "other" is checked, ICD-9 code is required.
- Check the appropriate box to indicate FEV1 level. If the patient is under 6 years old, check the appropriate box.
- Check the appropriate box to indicate whether the prescription is for new, continuing or restart of therapy.
- Check the appropriate box to indicate whether the patient has started treatment.
- Include the anticipated treatment start date, if applicable.

Prescription

- Please ensure that you complete all areas of the prescription portion clearly and completely. If requesting a Starter Rx, you must also select a nebulizer. Failure to select a nebulizer may delay shipment of the Starter.
- A nebulizer is provided with the Starter Rx only. Patients who are receiving free medication through Genentech® Access to Care Foundation will need to make separate arrangements to obtain a nebulizer.
- A prescription cannot be processed with a stamped signature. The prescriber must sign and date the form to make the prescription valid.
- Pulmozyme can be dosed monthly using 2.5 mL (dornase alfa inhalation solution) and administered either once (QD) or twice (BID) daily.
- The Starter Rx is a one-time, 30-day supply that is not intended for resale or insurance billing by the provider or patient (regardless of the days supply indicated in the prescription information).

Reminder

- This form cannot be processed without a prescriber's signature and date as well as a signed and dated PAN form.
- Pulmozyme must be stored in the refrigerator at 2-8°C (36-46°F) and protected from strong light. It should be kept refrigerated during transport and should not be exposed to room temperatures for a total time of 24 hours. The solution should be discarded if cloudy or discolored. Pulmozyme contains no preservative and, once opened, the entire contents of the ampule must be used or discarded. Patients should be instructed in the proper use and maintenance of the nebulizer and compressor system used in delivery.

PATIENT AUTHORIZATION AND NOTICE
OF RELEASE OF INFORMATION

Phone: (800) 530-3083 **Fax:** (650) 225-1366

Dear Patient:

The Genentech® Access to Care Foundation was established by Genentech USA, Inc. to help qualified patients who are not able to obtain a Genentech product for financial reasons. If a patient does not have insurance or is deemed uninsured due to denial by private and public payers, and the patient meets certain financial criteria, the Genentech Access to Care Foundation may provide Genentech products free of charge.

In order for Genentech Access to Care Foundation to provide the described services, we will need to review, use and disclose your protected health information (PHI). By law, only with your prior written authorization may your health care provider, health plan or health insurer disclose your PHI to Genentech Access to Care Foundation. As soon as we obtain your prior written authorization, we will work to provide you with the services.

You are not required to agree to this Authorization. However, failure to provide this Authorization may prevent you from becoming eligible for the Genentech Access to Care Foundation patient assistance program, which may result in your need to pay for certain products with your own funds. You will receive a copy of the Authorization you sign.

Please review this Authorization carefully. If you have any questions regarding this Authorization, please contact your health care provider's office. Contact information is included below.

I. Information to Be Disclosed or Used

This Authorization permits my health care providers, health plans and health insurers who provide services to me to use and disclose to Genentech Access to Care Foundation, its authorized agents and assignees, all medical records and financial information with respect to my treatment that may have bearing on the benefits payable for services or products provided through my health care provider, health plan or insurer under any plan providing benefits or services, including, without limitation, the dollar balance of benefits remaining under any applicable lifetime maximum benefits provisions, or that may have bearing on my medical condition or compliance with therapy. All of this information may be considered PHI, and may, if relevant, include information about HIV/AIDS and/or other communicable diseases, mental health information, and/or information concerning genetic test results.

II. Persons Authorized to Disclose Information

The PHI identified in Paragraph I may be disclosed by my health care provider, health plan, health insurer or others who may hold my PHI.

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III. Persons to Whom Disclosure May Be Made

The PHI identified in Paragraph I may be disclosed to and/or used by Genentech Access to Care Foundation, their sponsor Genentech USA, Inc., a biopharmaceutical manufacturer located at 1 DNA Way, Mail Stop #210, South San Francisco, CA 94080, and its related entities, their agents or assignees, and certain Genentech business partners, as well as other companies involved in the administration of certain Genentech products.

IV. Description of Each Purpose

My PHI may be used for the purposes of reimbursement and/or participation in a reimbursement assistance or patient assistance program administered by Genentech Access to Care Foundation. My PHI may also be used for purposes of tracking the general use of a Genentech product, assessing and improving Genentech's reimbursement and patient assistance services, and proper management and administration of Genentech's business.

V. Expiration Date or Event

California residents only: This Authorization will be effective, unless revoked by me in writing, until December 31, 2015.

All other residents: This Authorization will be effective, unless revoked by me in writing, for up to one year from the date of this Authorization.

VI. Notices

I understand that once my health information is disclosed pursuant to this Authorization, there is no guarantee under federal law that the recipient will not redisclose my health information to a third party. Any such third party may not be required to abide by this Authorization or applicable federal law governing the use and disclosure of my health information.

I understand that I may refuse to sign or may revoke (at any time) this Authorization for any reason and that such refusal or revocation will not affect the commencement, continuation or quality of my health care provider's treatment of me. If I refuse to sign or revoke this Authorization, however, I may be responsible for costs that may have otherwise been covered by Genentech Access to Care Foundation.

I understand that this Authorization will remain in effect until it expires as described above or I provide a written notice of revocation via mail to Genentech Access to Care Foundation, 1 DNA Way, Mail Stop #210, South San Francisco, CA 94080, or via fax to (650) 225-1366. The revocation will be effective immediately upon my health care provider's receipt of my written notice, except that the revocation will not have any effect on any action taken by my health care provider or others referenced in this Authorization, including without limitation, Genentech Access to Care Foundation, in reliance on this Authorization before my health care provider received my written notice of revocation.

Phone: (800) 530-3083 **Fax:** (650) 225-1366

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VII. Distribution Acknowledgment

I also hereby state (or my parent/guardian hereby states) that if I should receive free product from Genentech Access to Care Foundation, I will utilize it for the reason that my physician has prescribed it to me. I will not sell or distribute a Genentech product, as I acknowledge it is unlawful to do so. I will be responsible to ensure that any Genentech product being delivered to me will be delivered to a secure address for purposes of receipt of shipment and I understand it is my duty to control any Genentech product while it remains in my possession.

VIII. Signature

SIGNATURE REQUIRED

I have read and I understand the terms of this Authorization, and I have had an opportunity to ask questions about the use and disclosure of my health information. By my signature below, I hereby, knowingly and voluntarily, authorize the use and/or disclosure of my health information in the manner described above.

Print Patient's Name (required) _____

Signature of Patient or Guardian* (required) _____

Description of Authority (required) _____

Patient's/Guardian's Address (required) _____

*If the patient is an unemancipated minor or otherwise incapacitated (physically or mentally).

Date (required) _____

IX. Financial Information

- Only uninsured patients (and patients whose insurance has denied treatment) who wish to apply to the Genentech Access to Care Foundation for assistance need to fill out this section.
- There is no need to complete this section if the patient has insurance coverage for the Genentech product in question.

COMPLETE IF NECESSARY

Household Adjusted Gross Income:

☐ $0-25K/yr ☐ $25,001-50K/yr
☐ $50,001-75K/yr ☐ $75,001-100K/yr

I understand that in order to qualify, my adjusted gross income may not exceed $100K/yr. I certify that the above statement of my previous year's income is true and that I have no medical insurance coverage for the Genentech product in question, including Medicare, Medicaid or other public programs, and that I have insufficient financial resources to pay for the prescribed therapy. I also agree to furnish my IRS 1040 (or if none, then my Social Security Benefit Statement or W-2) within 45 days of the submission of this form. I understand that failure to provide this documentation may result in an interruption in therapy.

Signature of Patient (complete if applicable) _____

Date Signed (complete if applicable) _____