

Patient Enrollment and Acknowledgement Form

Complete one (1) form for each patient. All information must be completed on the form below prior to sending to Genzyme Corporation. Upon completion, print name, sign, and date the form at the bottom of the page then fax the form to 888-378-7667.

Patient Information (to be completed by the prescriber)

Name		Date of Birth (MM/DD/YYYY)	
Street Address	City	State	Zip Code
Parent/Guardian Name	Relationship	Phone Number	
Patient Gender (check below) <input type="checkbox"/> Male <input type="checkbox"/> Female	Date of Pompe Diagnosis (MM/DD/YYYY)		
Is the patient diagnosed with infantile-onset or late-onset Pompe disease (check below)?			
<input type="checkbox"/> Infantile-onset Pompe disease <input type="checkbox"/> Late-onset (non-infantile) Pompe disease			
<p>Lumizyme (alglucosidase alfa) is a lysosomal glycogen-specific enzyme indicated for patients 8 years and older with late (non-infantile) onset Pompe disease [acid α-glucosidase (GAA) deficiency] who do not have evidence of cardiac hypertrophy. The safety and efficacy of Lumizyme have not been evaluated in controlled clinical trials in infantile-onset patients, or in late (non-infantile) onset patients less than 8 years of age.</p> <p>Patients 8 years and older with late-onset disease may still receive Lumizyme if they have cardiac hypertrophy unrelated to their Pompe disease.</p>			

The Lumizyme ACE (Alglucosidase Alfa Control and Education) Program® will ensure that you receive Lumizyme® (alglucosidase alfa) as prescribed by your doctor/prescriber for treatment of your Pompe disease.

Your doctor/prescriber should have talked to you about the risks associated with use of Lumizyme:

- The risks of Lumizyme treatment include life-threatening or severe allergic reactions (hives [bumpy and itchy skin rash], problems breathing, low blood pressure, throat and lip swelling), and that severe skin reactions (e.g., deep skin tissue reaction with open sore) and systemic immune mediated reactions (e.g., kidney problems, and skin rashes) may occur with treatment.
- And other important safety information for Lumizyme.

Your doctor/prescriber should have talked to you about certain situations that may affect your treatment with Lumizyme, including the following:

- Previous infusion reactions that you may have experienced in the past.
- Other illnesses (e.g., cold or flu symptoms) you may have that may place you at higher risk for infusion reactions with Lumizyme.
- If you may be pregnant or are breast-feeding, your doctor needs to know as soon as possible.
- Any medical problems or allergies even if they are not related to your Pompe disease.
- Any medications, including over-the-counter medicines and dietary supplements you are taking.

Your doctor/prescriber should have talked to you about certain conditions that may arise during your infusion of Lumizyme, including the following:

- If you currently have trouble breathing or have heart problems, you may be at risk for worsening of your breathing problems or heart problems during the infusion, and you should be checked for this during the infusion by a trained infusion center staff member and/or doctor/prescriber.
- If you develop signs of a serious allergic reaction such as itching, rash, trouble breathing, or lip or throat swelling, you should be checked immediately by a trained infusion center staff member and/or doctor/prescriber.

By signing below, I acknowledge that:

- My doctor/prescriber (or my child's doctor/prescriber) has provided me with information about the benefits and risks of Lumizyme treatment and the Lumizyme ACE Program.
- I have asked my doctor/prescriber (or my child's doctor/prescriber) any questions I may have about Lumizyme.
- My doctor/prescriber (or my child's doctor/prescriber) has counseled me on the safety information in the product labeling for Lumizyme. I understand the risks of Lumizyme treatment including life-threatening or severe allergic reactions, and severe skin and systemic immune mediated reactions (as described above) associated with the use of Lumizyme.

Doctor/Prescriber Information *(to be completed by the prescriber)*

Name			
Name of Institution or Facility			
Secondary Contact Name	Phone Number	E-Mail Address	
Street Address	City	State	Zip Code
Site Where Infusion Will Be Administered	Infusion Site Contact	Phone Number	
Street Address	City	State	Zip Code

Doctor/Prescriber Signature: _____ Date: _____

Printed Name: _____

HIPAA/Release of Patient Information

(to be completed by patient/caregiver)

By signing below, you also allow Genzyme and its agents to:

- use your personal health information to help you to receive Lumizyme based on information provided by your doctor/prescriber;
- to release your personal health information to the doctor/prescriber, distributor/wholesaler, pharmacy, or health agency that sends out your medication, in order to help you to receive your Lumizyme based on information provided by your doctor/prescriber; and
- to release your personal health information to the United States Food and Drug Administration (“FDA”) and other governmental regulatory agents, as required by the FDA as a condition of participating in the Lumizyme ACE Program.

Signature of Patient or Patient’s Legal Representative: _____ Date: _____

Printed Name: _____

Complete the following only if the person signing this Authorization is not the Patient:

Person Authorizing Release: _____ Date: _____

Relationship to Patient (check one)

- Custodial Parent Legal Guardian or Representative Other (please explain) _____

**To complete your registration in the Lumizyme ACE Program,
sign and fax the completed form to Genzyme at 888-378-7667.**