

Prescriber Enrollment and Attestation Form

Initial Enrollment     Re-Enrollment

|                                |  |       |                |
|--------------------------------|--|-------|----------------|
| Prescriber Contact Information | Name/Degree (first, middle, last)          |       | NPI#           |
|                                | Street Address                             |       |                |
|                                | City                                       | State | Zip Code       |
|                                | Phone                                      | Fax   | E-mail address |
|                                | Name of Institution or Healthcare Facility |       |                |
|                                | Street Address (if different than above)   |       |                |
|                                | City                                       | State | Zip Code       |
|                                | Phone                                      | Fax   | E-mail address |

**The Lumizyme ACE (alglucosidase alfa control and education) Program is designed to:**

- Mitigate the potential risk of rapid disease progression in infantile-onset Pompe disease patients and patients with late (non-infantile) disease less than 8 years of age for whom the safety and effectiveness of Lumizyme™ (alglucosidase alfa) have not been evaluated.
- Ensure that the known risks of anaphylaxis and severe allergic reactions associated with the use of Lumizyme are communicated to patients and prescribers and to ensure that the potential risks of severe cutaneous and systemic immune mediated reactions to Lumizyme are communicated to patients and prescribers.

**Prescriber Attestation**

- I have completed educational training about Lumizyme™ (alglucosidase alfa) and understand the risks and benefits of Lumizyme.
- I understand that Lumizyme is indicated for patients 8 years and older with late (non-infantile) onset Pompe disease 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-onset patients less than 8 years of age.
- I understand that by completing the training program and signing this attestation form, I am now enrolled in the Lumizyme ACE Program and can prescribe and administer Lumizyme.
- I understand that I must enroll all patients being treated with Lumizyme into the Lumizyme ACE Program by completing a Patient Enrollment and Acknowledgement Form.
- I understand that I am responsible for providing the Patient Enrollment and Acknowledgement Form to patients (or, as appropriate, their parents/guardians) and for obtaining their signature on the Patient Enrollment and Acknowledgement Form prior to initiating them on treatment with Lumizyme.
- I will advise patients and caregivers about the known (e.g., anaphylaxis and severe allergic reactions) and potential risks (e.g., severe cutaneous and systemic immune mediated reactions) associated with administration of Lumizyme and will review the risks and benefits of Lumizyme as per the product labeling.
- I understand that patients may experience anaphylaxis or severe allergic reactions to Lumizyme and I have access to appropriate medical support measures.
- I understand that I will be required to sign a Prescriber Enrollment and Attestation Form on an annual basis to maintain my enrollment in the Lumizyme ACE Program and to prescribe Lumizyme.

Prescriber's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

**Adverse events should be reported promptly to Genzyme Medical Information at 800-745-4447, option 2.  
To complete your registration in the Lumizyme ACE Program, fax this completed form to Genzyme at 888-378-7667.**