Healthcare Facility Enrollment and Attestation Form

Enrollment in the Lumizyme ACE Program permits healthcare facilities to order and dispense Lumizyme.

☐ Initial Enrollment ☐ Re-Enrollment

Healthcare Facility Contact Information			
	Name of Institution or Healthcare Facility		NPI#
	Institution or Healthcare Facility Address		
	City	State	Zip Code
	Phone	Fax	E-mail address
	Name of Healthcare Facility Representative		Title

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 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.

The healthcare facility representative acknowledges that:

- The Lumizyme ACE Program educational materials have been received by the healthcare facility and provided to the healthcare facility staff who are responsible for the ordering, dispensing and administration of Lumizyme.
- Healthcare facility staff has completed training that includes:
  - The procedure for ordering Lumizyme;
  - Procedures for dispensing Lumizyme only after completing Section 1 of the Lumizyme Infusion Confirmation Form (Healthcare Professional Preparing Lumizyme Infusion)
  - Procedures for administering Lumizyme only after verifying that the patient is enrolled in the Lumizyme ACE Program, completing Section 2 of the Lumizyme Infusion Confirmation Form (Healthcare Professional Administering Lumizyme Infusion Therapy), faxing the completed Lumizyme Infusion Confirmation Form to Genzyme and affixing the sticker section of the form to the patient's file or scanning the form and saving it in the patient's electronic medical record.
- The healthcare facility has system procedures and/or other measures in place for appropriate monitoring of patients for early recognition of anaphylaxis and severe allergic reactions.
- The healthcare facility has staff that is prepared to treat patients who experience anaphylaxis or severe allergic reactions to Lumizyme.
- Healthcare facility staff 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 disease patients less than 8 years of age.
- Healthcare facility staff will dispense and administer Lumizyme only after ensuring each patient receives his/her designated drug by completing the Lumizyme Infusion Confirmation Form.
- The Healthcare facility understands that Genzyme may periodically perform audits at this healthcare facility to verify compliance with the procedures detailed in the Lumizyme ACE Program.

The healthcare facility representative confirms that:

- He/she understands that this information will be used to enable Genzyme to verify that the healthcare facility is certified in the Lumizyme ACE Program and may be shared with others working with Genzyme, and may be shared with government agencies.
- He/she understands that their signature will be required on the Healthcare Facility Enrollment and Attestation Form on an annual basis to maintain enrollment of the healthcare facility in the Lumizyme ACE Program and to dispense and administer Lumizyme.

Healthcare Facility Representative'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.