STATEMENT OF MEDICAL NECESSITY

FOR THE TREATMENT OF POMPE DISEASE

Patient Information

Patient Name:	Address:
Date of Birth:	City: State: ZIP:
Gender: ◯ Male ◯ Female	Phone No. (Home):
	Phone No. (Work):

Insurance Information

Insurance Co.:	Policy Holder Name:
Subscriber ID No.:	Insurance Phone No.:
Group No.:	

Medical Assessment

Patient Weight: _____ (kg/lb) **Patient Height**: _____ (cm/in)

Respiratory: _____ **Musculoskeletal:** _____

Cardiac: _____ **Other:** _____

Enclosures <include patient medical history, full Prescribing Information, additional supporting clinical documents>

***Attach copy of GAA enzyme assay or *GAA* gene sequencing**

Diagnosis

Pompe Disease E74.02: Date of Confirmed Diagnosis: _____

Please indicate Pompe disease subtype (if known): ◯ Infantile-onset Pompe disease (IOPD) ◯ Late-onset Pompe disease (LOPD)

How was the diagnosis confirmed? Confirmation REQUIRES the presence of #1 OR #2 below.

1.	☐ **GAA Enzyme Activity (must be reduced or absent):** Value:_____(units) Date:_____ Normal Reference Range: (for laboratory & sample) _____	**Sample Type:** ☐Blood ◯ Purified Lymphocytes ◯ Mixed Leukocytes ☐ Muscle Tissue ☐Cultured Skin Fibroblasts
2.	☐ ***GAA* Gene Sequencing:** Date:_____ List DNA sequence changes: 1._____ 2._____	**Additional Information (if needed):**

Treatment Recommendation

Lumizyme® (alglucosidase alfa)

Dose:_____ mg/kg

Therapy Start Date: _____

NDC #: 58468-0160-1 (carton of 1 single-use vial)
NDC #: 58468-0160-2 (carton of 10 single-use vials)
Frequency: _____

Physician Authorization

I certify that the above-indicated therapy is medically necessary, and the information provided is accurate to the best of my knowledge.

Physician Name (printed):_____ Date:_____

Address: _____ City: _____ State: _____ ZIP: _____

Phone No.: _____

Physician Signature: _____

Physician's Medical License No.: _____ **State Issued:** _____

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