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 **P**rescribing **I**nformation, 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 and sample) _____	Sample Type (check all that apply)**:** ☐ Blood ○ Purified Lymphocytes ○ Mixed Leukocytes ☐ Muscle Tissue ☐ Cultured Skin Fibroblasts
2.	☐ *GAA* Gene Sequencing: Date:_____ List DNA sequence changes: 1._____ 2._____	

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: _____