	Johns Hopkins HealthCare LLC Pharmacy Public Medical Management Drug Policies	<i>Policy Number</i>	MMDP081
		<i>Effective Date</i>	05/01/2023
		<i>Review Date</i>	04/19/2023
	<i>Subject</i> Lumizyme	<i>Revision Date</i>	04/19/2023
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Lumizyme

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I. POLICY

- A. Lumizyme (Alglucosidase Alfa) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

- A. Lumizyme may be approved for patients meeting the following:
1. Documentation has been submitted showing both of the following:
 - a. Patient has a diagnosis of Pompe disease
 - b. The diagnosis was confirmed by an enzyme assay demonstrating a deficiency of acid alpha-glucosidase enzyme activity, or by genetic testing

III. AUTHORIZATION PERIOD/LIMITATIONS


- A. Initial approval will be limited to 12 months of therapy
- B. Continuation of therapy may be approved in 12-month intervals with documentation showing a beneficial response to therapy, such as any of the following:
1. Improvement, stabilization, or slowing of disease progression for motor function, walking capacity, and/or cardiorespiratory function
 2. Decrease in left ventricular mass index (LVMI)
 3. Delay in death

IV. EXCLUSIONS

- A. Lumizyme will not be covered for the following:
1. Any indications that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

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VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, alglucosidase alfa, (lumizyme), 10 mg	J0221

VII. REFERENCES

1. Lumizyme [prescribing information]. Cambridge, MA: Genzyme Corporation; February 2020.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/19/2023	Policy Creation

Review Dates: 04/19/2023

Revision Dates: 04/19/2023