JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP109
		Effective Date	07/17/2024
		Approval Date	07/17/2024
	Subject **Nexviazyme**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Nexviazyme

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I. POLICY

A. Nexviazyme (avalglucosidase alfa-ngpt) 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. Nexviazyme may be approved for patients who meet the following:
   1. Patient is 1 year of age or older.
   2. Documentation has been submitted showing both of the following:
      a. Diagnosis of Late-onset Pompe disease
      b. Diagnosis was confirmed by 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 the patient has had a benefical response to treatment, evidenced by an improvement, stabilization, or slowing of disease progression for any of the following:
   1. motor function
   2. walking capacity
   3. respiratory function
   4. muscle strength

IV. EXCLUSIONS

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

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

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, avalglucosidase alfa-ngpt, 4 mg	J0219

VII. REFERENCES

1. Nexviazyme [prescribing information]. Cambridge, MA: Genzyme Corporation; August 2021.

VIII. APPROVALS

Signature on file at JHHP

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2024	Policy creation

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