	Johns Hopkins Health Plans Pharmacy Public Medical Management Drug Policies	<i>Policy Number</i>	MMDP112	
		<i>Effective Date</i>	07/17/2024	
		<i>Approval Date</i>	07/17/2024	
	<i>Subject</i>	Pombiliti	<i>Supersedes Date</i>	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Pombiliti

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I. POLICY

- A. Pombiliti (cipaglusosidase alfa-atga) 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. Pombiliti may be approved for patients who meet the following:
1. Patient is 18 years of age or older
 2. Patient weighs greater than or equal to 40kg.
 3. Documentation has been submitted showing 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
 - c. Patient is not improving on current enzyme replacement therapy (ERT) , such as Lumizyme or Nexviazyme
 - d. Pombiliti will be taken in combination with Opfolda (miglustat)

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 following:
1. Patient has had a beneficial response to treatment, evidenced by an improvement, stabilization, or slowing of disease progression for any of the following:
 - a. motor function
 - b. walking capacity
 - c. respiratory function
 - d. muscle strength
 2. Pombiliti will be taken in combination with Opfolda (miglustat)

IV. EXCLUSIONS

- A. Pombiliti will not be covered for the following:

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- 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, ciplaglusosidase alfa-atga, 5 mg	J1203

VII. REFERENCES

- Pombiliti [prescribing information]. Philadelphia, PA: Amicus Therapeutics US, LLC; September 2023

VIII. APPROVALS

Signature on file at JHHP

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

Review Date: 07/17/2024

Revision Date: