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| JOHNS HOPKINS HEALTH PLANS | Johns Hopkins Health Plans<br>**Pharmacy Public**<br>**Medical Management Drug Policies** | *Policy Number* | MMDP111 |
| | | *Effective Date* | 07/17/2024 |
| | | *Approval Date* | 07/17/2024 |
| | *Subject*<br>**Opfolda** | *Supersedes Date* | N/A |
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This document applies to the following Participating Organizations:

US Family Health Plan

**Keywords**: Opfolda

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## I. POLICY

A. Opfolda (miglustat) 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. Opfolda 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. Opfolda will be taken in combination with Pombiliti (cipaglucosidase alfa-atga)

## 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. Opfolda will be taken in combination with Pombiliti (cipaglucosidase alfa-atga)

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## IV. EXCLUSIONS

A. Opfolda 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 |
|---|---|
| Miglustat, oral, 65 mg | J1202 |

## VII. REFERENCES

1. Opfolda [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

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