JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP110
		Effective Date	07/17/2024
		Approval Date	07/17/2024
	Subject **Oxlumo**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Oxlumo

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I. POLICY

A. Oxlumo (lumasiran) 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. Oxlumo may be approved for patients who meet the following:
   1. Documentation has been submitted showing the following:
      a. Diagnosis of Primary hyperoxaluria type 1 (PH1)
      b. Diagnosis has been confirmed by either of the following:
         I. Molecular genetic test results demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene
         II. Liver enzyme analysis results demonstrating absent or significantly reduced alanine:glyoxylate aminotransferase (AGT) activity
      c. Oxlumo will not be used in combination with nedosiran (Rivfloza)

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 any of the following:
   1. Decrease or normalization in urinary and/or plasma oxalate levels
   2. Improvement in kidney function

IV. EXCLUSIONS

A. Oxlumo 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, lumasiran, 0.5 mg	J0224

VII. REFERENCES

1. Oxlumo [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; September 2023.
2. Milliner DS. The primary hyperoxalurias: an algorithm for diagnosis. Am J Nephrol 2005; 25:154.

VIII. APPROVALS

Signature on file at JHHP

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

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