	Johns Hopkins Health Plans Pharmacy Public Medical Management Drug Policies	<i>Policy Number</i>	MMDP114	
		<i>Effective Date</i>	01/15/2025	
		<i>Approval Date</i>	07/17/2024	
	<i>Subject</i>	Roctavian	<i>Supersedes Date</i>	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Roctavian

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I. POLICY

- A. Roctavian (valoctocogene roxaparvovec-rvox) 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. Roctavian may be approved for patients who meet the following:
1. Patient is 18 years of age or older
 2. Documentation has been submitted showing all the following:
 - a. Diagnosis of Hemophilia A
 - b. Patient has severe disease with factor VIII activity levels less than or equal to 1 IU/dL
 - c. There is an absence of pre-existing antibodies to adeno-associated virus serotype 5 (AAV5) as confirmed by an FDA-approved test
 - d. Patient does not have prior or active factor VIII inhibitors (inhibitor titer must be less than 0.6 Bethesda Units [BU])
 - e. Patient has not received treatment with the requested medication previously

III. AUTHORIZATION PERIOD/LIMITATIONS


- A. Approval will be limited to 3 months for a one-time single dose.

IV. EXCLUSIONS

- A. Roctavian 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.

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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, valoctogene roxaparvovec-rvox, per ml, containing nominal 2×10^{13} vector genome	J1412

VII. REFERENCES

1. Roctavian [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; June 2023.

VIII. APPROVALS

Signature on file at JHHP

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2024	Policy creation
01/15/2025	Removed prescriber specialty requirement

Review Date: 07/17/2024

Revision Date: 01/15/2025