

SPECIALTY GUIDELINE MANAGEMENT

ROCTAVIAN (valoctocogene roxaparvovec-rvox)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Roctavian is indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without antibodies to adeno-associated virus serotype 5 (AAV5) detected by an FDA-approved test.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Chart notes, medical records, or lab results documenting all of the following:

- A. Severe factor VIII deficiency (factor VIII activity levels less than or equal to 1 IU/dL).
- B. Absence of pre-existing antibodies to the adeno-associated virus serotype 5 (AAV5) capsid.
- C. Absence of factor VIII inhibitor confirmed by a Bethesda assay (lab test results required).

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a hematologist.

IV. CRITERIA FOR INITIAL APPROVAL

Hemophilia A

Authorization of 3 months for one dose total may be granted for treatment of severe hemophilia A when all of the following criteria are met:

- A. Member must be 18 years of age or older.
- B. Member has severe disease with factor VIII activity levels less than or equal to 1 IU/dL.
- C. Absence of pre-existing antibodies to AAV5 was confirmed by an FDA-approved test (e.g., AAV5 DetectCDx™).
- D. Member does not have prior or active factor VIII inhibitors (inhibitor titer must be less than 0.6 Bethesda Units [BU]).
- E. Member has not received treatment with the requested medication previously.

V. REFERENCES

1. Roctavian [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; June 2023.

Reference number(s)
6062-A

Roctavian 6062-A SGM P2024

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