RX.PA.084.CCH ROCTAVIAN (VALOCTOCOGENE ROXAPARVOVEC-RVOX)

The purpose of this policy is to define the prior authorization process for Roctavian (valoctocogene roxaparvovec-rvox) for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA-approved test.

DEFINITIONS

Exposure Day (ED) – A unit of time (1 day) in which replacement therapy is given to a patient. in patients with severe hemophilia A, inhibitors develop after a median FVIII treatment time of 10– 15 days. During this period, regular screening for inhibitor development is recommended. After 50–75 EDs, the cumulative incidence of inhibitors reaches a plateau. The incidence rate of inhibitor development in patients with hemophilia A who have been previously treated for at least 150 EDs has been estimated to be approximately 2–5 per 1000 patient-years[1]

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Roctavian (valoctocogene roxaparvovec-rvox), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed below:

- Must be age 18 years or older
- Must be male sex assigned at birth
- Must be prescribed by, or in consultation with, a hematologist

- Must have a diagnosis of severe hemophilia A (congenital factor VIII deficiency), confirmed by a factor VIII activity level of < 1 IU/dL (in absence of exogeneous factor VIII)
- Must have documentation of BOTH the following:
    - The member has been receiving prophylactic FVIII replacement therapy over the last 12 months prior to the request AND
    - The member has been exposed to FVIII therapy for a minimum of 150 exposure days (i.e., has received a dose of FVIII therapy on at least 150 days in their lifetime)
- Must have documentation of ALL the following testing results, collected within the last 3 months:
    - Liver function tests <1.25 upper limit of normal
        - ALT/AST
        - Bilirubin
        - Alkaline phosphatase
    - INR <1.4
    - Negative Hepatitis B surface antigen*
    - Negative Hepatitis C virus antibody **OR** HCV antibody positive AND HCV RNA negative*
    - Negative HIV test **OR** HIV viral load <200 copies/mL and the member is on anti-retroviral therapy
    - Platelet count >100 x 10^9/L
    - Serum creatinine <1.5mg/dL
    - *If the member has a history of HBV or HCV exposure, the member must NOT be currently using antiviral therapy to treat
- Must have documentation of ALL the following results of testing/screening:
    - Negative for pre-existing antibodies to adeno-associated virus serotype 5 (AAV5) capsid, as determined by an FDA-approved or CLIA-compliant test
    - Negative for factor VIII inhibitors [must have a Bethesda titer of <0.6 Bethesda units (BU) for FVIII]
    - Liver ultrasound/biopsy confirming no fibrosis stage 3 or 4 and no cirrhosis
- Must have documentation or an attestation from the prescriber on all the following:
    - The member does not have a history of thrombosis or thrombophilia
    - The member does not have a hypersensitivity to mannitol
    - The member does not have active malignancy
    - The member does not have an active infection
    - The member will not receive live vaccines during treatment
    - The member has not previously been treated with Roctavian or another adeno-associated virus (AAV5)-vector-based gene therapy for

the management of hemophilia A
    - Following infusion, the member's liver enzymes and factor VIII activity will be monitored weekly for at least 26 weeks and periodically thereafter
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	1 time approval (up to 3 months)
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J1412	Roctavian	Injection, valoctocogene roxaparvovec-rvox, per ml, containing nominal 2 x 10¹³ vector genomes

References:

1. Hermans C, Astermark J, de Moerloose P. Exposure to factor VIII and prediction of inhibitor development: exposure days vs. danger days, or both? J Thromb Haemost 2012; 10: 2194–6.
2. Ozelo MC, Mahlangu J, Pasi KJ, et al; GENEr8-1 Trial Group. Valoctocogene roxaparvovec gene therapy for hemophilia A. N Engl J Med. 2022;386(11):1013-1025. doi:10.1056/NEJMoa2113708 [PubMed 35294811]
3. Roctavian (valoctocogene roxaparvovec) [prescribing information]. Novato, CA: BioMarin Pharmaceuticals Inc; June 2023.

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	04/2024

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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