Hemophilia A – AAVS 5

Roctavian (valoctocogene roxaparvovec-rvox) J1412

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

- ☐ Patient is at least 18 years of age
- ☐ Both of the following:
  - ☐ Diagnosis of severe hemophilia A
  - ☐ Documentation of endogenous factor VIII levels less than 1% of normal factor VIII (< 0.01 IU/mL, < 1 IU/dL);
- ☐ Evidence of any bleeding disorder NOT related to hemophilia A has been ruled out; AND
- ☐ Patient is on a stable dose of regularly administered exogenous factor VIII for the prevention and control of bleeding episodes; AND
- ☐ Patient does not have an active infection, either acute (such as acute respiratory infections or acute hepatitis) or uncontrolled chronic (such as chronic active hepatitis B); AND
- ☐ Must not be administered concurrently with live vaccines while on immunosuppressive therapies; AND
- ☐ Patient does not have significant hepatic fibrosis (stage 3 or 4) or cirrhosis; AND
- ☐ Patient does not have a known hypersensitivity to mannitol: AND
- ☐ Patient has not received prior hemophilia AAV-vector–based gene therapy; AND

- ☐ Patient is adeno-associated virus serotype 5 (AAV5) antibody negative as determined by an FDA-approved or CLIA-compliant test; AND
- ☐ Patient has been tested and found negative for active factor VIII inhibitors (i.e., results from a Bethesda assay or Bethesda assay with Nijmegen modification of less than 0.6 Bethesda Units (BU) on 2 consecutive occasions at least one week apart within the past 12 months) and is not receiving a bypassing agent (e.g., Feiba); AND
- ☐ Post administration monitoring of patient serum ALT levels will be performed according to the monitoring schedule outlined in the product labeling with corticosteroids (or other immunosuppressive therapy) administered in response to elevations; AND
- ☐ Patients with preexisting risk factors for hepatocellular carcinoma [e.g., patients with hepatitis C or B, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), and advanced age] will have regular (e.g., annually) liver ultrasounds performed and will be tested for alpha-fetoprotein (AFP) elevations following administration; AND
- ☐ Patient Factor VIII activity will be monitored periodically; AND
  - ☐ Patients with factor VIII activity levels >5 IU/dL should discontinue routine prophylactic exogenous factor VIII; OR
  - ☐ If Factor VIII activity levels decrease and/or if bleeding is not controlled, assess presence of factor VIII inhibitors and assess the need for hemostatic prophylaxis; AND
- ☐ Provider agrees to submit documentation or attestation, including but not limited to lab values or spontaneous or life-threatening bleeding events if Factor VIII is resumed and medically necessary for a patient following the administration of Roctavian.

Continuation Requests: (Clinical documentation required for all requests)

- Continuation coverage not available. One time administration only

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Roctavian (Hemophilia A – factor VIII Deficiency) PA

Drug Name(s):

ROCTAVIAN **VALOCTOCOGENE ROXAPARVOVEC-RVOX**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:

N/A

Prescriber Restrictions:

Hemotologist or other specialist

Coverage Duration:

Initial Approval for one injection only
Continuation not available.

FDA Indications:

Roctavian

- Hemophilia A (Severe), without antibodies to adeno-associated virus serotype 5

Off-Label Uses:

N/A

Age Restrictions:

The safety and effectiveness in pediatric patients have not been established

Other Clinical Consideration:

Contraindications:

- Active infections, either acute (such as acute respiratory infections or acute hepatitis) or uncontrolled chronic (such as chronic active hepatitis B)
- Known significant hepatic fibrosis (stage 3 or 4 on the Batts-Ludwig scale or equivalent), or cirrhosis
- Known hypersensitivity to mannitol

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=headerLogout#