SENTARA COMMUNITY PLAN
(MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Roctavian® (valoctocogene roxaparvovec-rvox) **(J1412) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

- ❑ **Quantity Limit (max daily dose) [NDC Unit]:**
  - Roctavian 2 x 10^{13} vg/mL single-dose vial: 44 vials one-time only
  - 1 treatment = 44 vials
  - NDC: 68135-0927-xx
- ❑ **Max Units (per dose and over time) [HCPCS Unit]:**
  - 44 vials one time only

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Authorization Criteria: One treatment per lifetime. Coverage may NOT be renewed

- ❑ Member is at least 18 years of age
- ❑ Provider is a specialist in hematology with experience treating patients with Hemophilia A
- ❑ Member has a diagnosis of hemophilia A confirmed by a genetic panel **(laboratory documentation required)**
- ❑ Member has severe hemophilia A (congenital factor VIII deficiency) documented by a factor VIII activity level < 1 IU/dL (in the absence of exogenous factor VIII) **(Assay results for activity level documentation required)**
- ❑ Provider attests that any other bleeding disorder **NOT** related to hemophilia A has been ruled out
- ❑ Member must meet **ONE** of the following treatment scenarios:
  - ❑ Member is on a stable dose of routine prophylaxis, regularly administered exogenous factor VIII for the prevention and control of bleeding for at least 12 months prior to the request of this treatment, as assessed and documented by prescriber, **AND** the member has been treated with factor VIII replacement therapy for a minimum of 150 exposure days
  - ❑ Member is currently receiving chronic prophylactic Hemlibra® (emicizumab) therapy
- ❑ Member 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)
- ❑ Member must **NOT** be administered concurrently with live vaccines while on immunosuppressive therapies
- ❑ Member does **NOT** have significant hepatic fibrosis (stage 3 or 4) or cirrhosis
- ❑ If the member has 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], the provider will have regular (e.g., annually) liver ultrasounds performed and will be tested for alpha-fetoprotein (AFP) elevations following administration with Roctavian
- ❑ 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
- ❑ Member does **NOT** have a known hypersensitivity to mannitol
- ❑ Member has **NOT** received prior hemophilia AAV-vector–based gene therapy
- ❑ Member has is adeno-associated virus serotype 5 (AAV5) antibody negative as determined by an FDA-approved or CLIA-compliant test **(laboratory documentation required)**

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- ❑ Member 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)
- ❑ Provider documents a therapeutic plan to monitor the member's Factor VIII activity periodically, and discontinue routine prophylactic exogenous Factor VIII and any bispecific factor IXa- and factor X-directed antibody therapy when activity levels >5 IU/dL

Reauthorization: Coverage may NOT be renewed

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****