Clinical Oversight Review Board (CORB) Criteria for Prescribing

valoctocogene roxaparvovec-rvox (Roctavian)

Notes:

- Quantity Limits: Yes (one time dose)
- **Patients will need to continue prophylactic therapy for at least 4 weeks after valoctocogene roxaparvovec infusion.
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Non-Formulary **valoctocogene roxaparvovec-rvox (Roctavian)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria:

- Prescribed by Hematology provider
- Males ≥18 years of age
- Diagnosis of hemophilia A (congenital factor VIII deficiency)
- Baseline factor VIII levels <1 IU/dL or phenotypically severe hemophilia A requiring prophylaxis (recurrent spontaneous bleeding, regardless of factor VIII level).
- No history of factor VIII inhibitor, and results from a Bethesda assay with Nijmegen modification of <0.6 Bethesda Units (BU) on two consecutive occasions at least one week apart within the past 12 months.
- Have been on prophylactic hemlibra and altuviiio therapy for at least 12 months – AND – at risk for significant morbidity due to disease process.
- Willing and able to adhere to monitoring requirements for gene therapy administration.
- Agree to not donate semen, and to prevent or postpone pregnancy (including that of female partners) for six months after administration
- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel with the recommendation to use medication.