Medical Policy:
Roctavian

Last review date: 3/25/2024

Applicable Products:
Roctavian (valoctocogene roxaparvovec)

Initial Approval Criteria:
Coverage may be approved if all of the following are met:

- Patient has 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; **AND**
- Patient is 18 years of age or older; **AND**
- 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**
- Roctavian will 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 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 will have regular (e.g., annually) liver ultrasounds performed and will be tested for alpha-fetoprotein (AFP) elevations following administration; **AND**
- Provider attests that the patient has been counseled or educated on both of the following:
    - Abstain from alcohol for at least one year following treatment; **AND**
    - Will not use any medications, herbal products, or supplements that are hepatotoxic; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:
None

Length of Authorization:
1 dose per lifetime

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.