Medical Policy:
Hemgenix

Last review date: 5/20/2024

Applicable Products:
Hemgenix (etranacogene dezaparvovec-drlb)

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

- Patient has a diagnosis of moderately severe or severe congenital factor IX deficiency, as confirmed by blood coagulation testing, for which the subject is on continuous routine factor IX prophylaxis, unless there is a contraindication or intolerance; **AND**
- Patient is at least 18 years of age; **AND**
- Must be prescribed by or in consultation with a hematologist; **AND**
- Patient has not received prior hemophilia AAV-vector–based gene therapy; **AND**
- Patient has at least one of the following:
    - Currently use Factor IX prophylaxis therapy;
    - Have current or historical life-threatening hemorrhage;
    - Have repeated, serious spontaneous bleeding episodes*;* **AND**
- Patient has been tested and found negative for Factor IX inhibitor titers (if test result is positive, re-test within approximately 2 weeks. If re-test is also positive, Hemgenix should not be given); **AND**
- Patient Factor IX activity will be monitored periodically (e.g., weekly for 3 months) as well as presence of inhibitors if bleeding is not controlled; **AND**
- Patient will discontinue Factor IX prophylaxis therapy upon achieving FIX levels of 5% from Hemgenix treatment; **AND**
- Prescriber attests they have performed liver health assessments, including enzyme testing and hepatic ultrasound and elastography; **AND**
- Patient has all of the following:
    - Patient does not have an active infection with hepatitis B virus or hepatitis C virus; **AND**
    - Patient is not currently receiving antiviral therapy for a prior hepatitis B virus or C virus exposure; **AND**
    - Patient does not have uncontrolled human immunodeficiency virus (*Note: A patient testing positive for human immunodeficiency virus can still qualify for Hemgenix if controlled on antiviral therapy with CD4+ counts ≥ 200/µL or by a viral load of ≤ 200 copies/mL)*; **AND**
- Patient will have liver function assessed after therapy, weekly for at least 3 months; **AND**
- Patients with preexisting risk factors for hepatocellular carcinoma will have abdominal ultrasound screenings and be monitored regularly (e.g., annually) for alpha-fetoprotein (AFP) elevations following administration; **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.