Reference number(s)
C26621-A

HEMGENIX (etranacogene dezaparvovec-drlb)
Clover Health MedB QSet

1. Has the patient previously received treatment with the requested medication?
    a. Yes
    b. No

2. Has the patient had a minimum of 150 exposure days to a Factor IX agent?
    a. Yes
    b. No

3. Does the patient have a history of inhibitors to Factor IX greater than or equal to 0.6 Bethesda units [BU]?
    a. Yes
    b. No

4. Prior to administration of Hemgenix did the patient screen positive for active Factor IX inhibitors, defined as greater than or equal to 0.6 Bethesda units [BU]?
    a. Yes
    b. No

5. Has the patient undergone Immune Tolerance Induction (ITI)?
    a. Yes
    b. No

6. Have liver health assessments been performed to rule out radiological liver abnormalities and/or sustained liver enzyme elevations including, enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin)] and hepatic ultrasound and elastography?
    a. Yes
    b. No

7. Has the patient been evaluated for the presence of preexisting neutralizing antibodies to the adenovirus vector (e.g., AAV-5) used to deliver the therapy? **Action Required: If 'Yes', attach supporting chart note(s).**
    a. Yes
    b. No

8. Was evaluation of pre-existing anti-AAV5 neutralizing antibodies measured through the laboratory developed, CLIA validated AAV5 Neutralizing Antibody Test1 made available through CSL Behring?
    a. Yes
    b. No

9. Does the patient have high anti-AAV antibody (e.g., AAV-5) titers that may be associated with a lack of response to treatment based on published clinical evidence?
    a. Yes
    b. No

10. What is the patient's HIV status?
    a. Positive
    b. Negative

11. Is the patient virally suppressed with anti-viral therapy (i.e., less than 200 copies of HIV per mL)?
    a. Yes
    b. No

12. Is the patient negative for hepatitis B surface antigen?
    a. Yes
    b. No

13. What is patient's hepatitis C virus (HCV) antibody status?
    a. Positive
    b. Negative

14. Is patient negative for HCV RNA?
    a. Yes
    b. No

15. Is that patient currently using anti-viral therapy for hepatitis B or C?
    a. Yes
    b. No

16. Will Hemgenix be delivered by or in consultation with a Hemophilia Treatment Center (HTC)?
    a. Yes
    b. No

17. Has patient been determined to be an appropriate candidate for Hemgenix by the Hemophilia Treatment Center based on willingness to adhere to initial and long-term monitoring and management?
    a. Yes
    b. No

18. Will Hemgenix be dosed in accordance with the United States Food and Drug Administration approved labeling?
    a. Yes
    b. No

SUMMARY OF EVIDENCE

1. 1. Hemgenix [package insert]. King of Prussia, PA: CSL Behring LLC; November 2022.

EXPLANATION OF RATIONALE

1. Support for FDA-approved indications can be found in the manufacturer's prescribing information.

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