

Clinical Oversight Review Board (CORB) Criteria for Prescribing/
Criteria-Based Consultation (CBC) Criteria for Coverage

Etranacogene dezaparvovec-drlb (Hemgenix)

Notes:

- Quantity Limits: Yes (one time dose)
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Non-Formulary **Etranacogene dezaparvovec-drlb (Hemgenix)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-Formulary **Etranacogene dezaparvovec-drlb (Hemgenix)** will be covered on the prescription drug benefit when the following criteria are met:

- Patient has a diagnosis of congenital Hemophilia B classified as severe or moderately severe -AND-
- Patient is 18 years or older -AND-
- Currently on factor IX prophylaxis -AND-
- Has more than 150 previous exposure days of treatment with factor IX protein -AND-
- Has current or historical life-threatening hemorrhage -AND-
- Have repeated, serious spontaneous bleeding episodes -AND-
- Reviewed by the Interregional Consultative Physician Panel

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously -OR- Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-Formulary **Etranacogene dezaparvovec-drlb (Hemgenix)** will be covered on the prescription drug benefit when the following criteria are met:

- Patient has a diagnosis of congenital Hemophilia B classified as severe or moderately severe -AND-
- Patient is 18 years or older -AND-
- Currently on factor IX prophylaxis -AND-
- Has more than 150 previous exposure days of treatment with factor IX protein -AND-
- Has current or historical life-threatening hemorrhage -AND-
- Have repeated, serious spontaneous bleeding episodes -AND-
- Reviewed by the Interregional Consultative Physician Panel