GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

# Hemgenix *(etranacogene dezaparvovec-drlb)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses (FDA approved indication)** | Hemgenix is an adeno-associated virus (AAV) vector-based gene therapy indicated as a one-time treatment for adults with hemophilia B (congenital Factor IX deficiency) who use Factor IX prophylaxis therapy, have a current or historical life-threatening hemorrhage, or who have repeated, serious spontaneous bleeding episodes. |
| **Exclusion Criteria** | Hemgenix is not covered in patients who have received a previous treatment course of Hemgenix or another adeno-associated virus vector-based gene therapy. The safety and effectiveness of repeat administration have not been evaluated. |
| **Required Medical Information** | The following is required for approval:<br><br>Patient has a diagnosis of moderate to severe hemophilia B (a factor IX activity level less than or equal to 2 IU/dL or less than or equal to 2% of normal); AND<br><br>Patient has one of the following:<br><br>Current use of factor IX prophylaxis therapy; OR<br><br>Patient has current or historical life-threatening hemorrhage; OR<br><br>Patient has had repeated, serious spontaneous bleeding episodes.<br><br>Medical records supporting the request must be provided. |
| **Age Restriction** | Must be at least 18 years of age. |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a hematologist. |
| **Coverage Duration** | One lifetime dose. |
| **Other Criteria/Information** | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. |

| HCPCS | Description | Billing Units/How Supplied |
|---|---|---|
| J1411 | Injection, etranacogene dezaparvovec-drlb, per therapeutic dose | **Billing unit: per dose**<br><br>SD infusion bag |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 3/26/2025 | 3/26/2025 | Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG) | N/A |
| Approved | N/A | 5/15/2025 | Pharmacy & Therapeutics (P&T) Committee | 5/15/2025 |
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