

etranacogene dezaparvovec-drlb (Hemgenix)

HCPCS: J1411 Injection, etranacogene dezaparvovec-drib, per therapeutic dose (Hemgenix)

LOB:	MCAL
Duration of Approval:	One dose per lifetime
Quantity Limit:	Per FDA Approved/Compendia Supported Dosing
MCG Available:	Yes
DHCS Drug Policy:	No

Requires Prior Authorization

Hemgenix (etranacogene dezaparvovec-drlb) injection

****All requests must be approved by a Medical Director ******PA CRITERIA FOR APPROVAL:**

1. The member has a diagnosis for an FDA approved indication (*refer to package insert under References*) OR a compendia supported (Drugdex or AHFS) indication **AND**
2. The medication is prescribed by a Hematologist **AND**
3. The member has moderate to severe Factor IX deficiency defined $\leq 2\%$ of normal circulating Factor IX **AND**
4. The member meets ONE of the following:
 - a. Currently using Factor IX prophylaxis therapy (e.g., AlphaNine SD, Alprolix, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine SD, Rebinyn, Rixubis)
 - b. Current or history of life-threatening hemorrhage
 - c. Repeated, serious spontaneous bleeding episodes**AND**
5. Lab results showing negative results for Factor IX inhibitors [**Note:** In case of a positive test result for human Factor IX inhibitors, a re-test within approximately 2 weeks may be performed. If both the initial test and re-test results are positive, Hemgenix should not be used] **AND**
6. The member has received at least 150 exposure days to Factor IX therapy **AND**
7. The member has not been previously treated with any gene therapy for hemophilia B

OTHER INFORMATION:

HCPCS	Description	Brand name
J1411	Injection, etranacogene dezaparvovec-drib, per therapeutic dose	Hemgenix
**Refer to DHCS Physician-Administered Drugs (PADs) Special Billing for (Hemgenix) for billing information and follow allowable number of units to approve. **		

REFERENCES:

1. Hemgenix Prescribing Information. labeling.cslbehrling.com/PI/US/Hemgenix/EN/Hemgenix-Prescribing-Information.pdf 01/2025.
2. CSL Behring. HOPE-B: Trial of AMT-061 in Severe or Moderately Severe Hemophilia B Patients. clinicaltrials.gov/study/NCT03569891. NLM Identifier: NCT03569891.
3. DHCS Cell and Gene Therapy Overview. mcweb.apps.prd.cammi.medi-cal.ca.gov/assets/821726E2-2EAB-4A86-AA42-4778E89A38FD/celgenover.pdf?access_token=6UyVkkRRfByXTZEWIh8j8QaYyIPyP5ULO. 09/2025.

UMC REVIEW:

6/2026