

Applicable Drugs: Hemgenix (etranacogene dezaparvovec-drlb)

Preferred: N/A

Non-preferred: etranacogene dezaparvovec-drlb (Hemgenix)

Date of Origin: 5/12/2024

Date Last Reviewed / Revised: 10/06/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through X are met)

- I. Natal male with a diagnosis of congenital hemophilia with moderately severe or severe factor IX (FIX) deficiency with documentation of one of the following (A, B, or C):
 - A. Current use of FIX prophylaxis therapy with stable therapy for ≥ 2 months before request.
 - B. Current or historical life-threatening hemorrhage.
 - C. Repeated, serious spontaneous bleeding episodes.
- II. Documented history of > 150 previous exposure days of FIX protein treatment.
- III. No history of inhibitors to FIX (≥ 0.3 Bethesda units).
- IV. No history of previous gene therapy for hemophilia B.
- V. Documentation of baseline labs/testing results (A through G):
 - A. Liver function assessments including liver enzyme testing (AST, ALT, ALP, and total bilirubin) hepatic ultrasound, and elastography to rule out significant hepatic fibrosis (stage 3 or 4) or cirrhosis.
 - B. Hepatitis B serology to rule out active Hepatitis B infection.
 - C. Hepatitis C serology to rule out active Hepatitis C infection.
 - D. HIV screening and HIV-RNA levels (if applicable) to rule out active and virally unsuppressed HIV infection.
 - E. FIX activity level $\leq 2\%$ indicating moderately severe or severe FIX deficiency.
 - F. Negative FIX inhibitor titer screening (< 0.3 Bethesda units).
- VI. Minimal age requirement: 18 years old.
- VII. Treatment must be prescribed by or in consultation with a hematologist.
- VIII. Must be administered by a qualified treatment site trained by CSL Behring.
- IX. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- X. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Uncontrolled HIV infection.
- Advanced liver fibrosis (Metavir fibrosis score F3 or F4).
- Active hepatitis B infection or currently receiving Hepatitis B antiviral therapy.
- Active hepatitis C infection or currently receiving Hepatitis C antiviral therapy.

OTHER CRITERIA

- Documentation of an anti-adenovirus-associated viral vector serotype V5 (AAV5) titers $\leq 1:678$ is strongly suggested. The test is accessible through CSL Behring.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- The FDA-recommended dose of etranacogene dezaparvovec-drlb is 2×10^{13} genome copies per kg of body weight or 2mL/kg of body weight administered by IV infusion.
 - Kit that contains the number of vials corresponding to the dosing requirement based on body weight/ 1 day (see Appendix Table 1).

APPROVAL LENGTH

- **Authorization:** Approve for 1 treatment course for a 6-month duration. Limit 1 treatment course per lifetime.
- **Re-Authorization:** N/A

APPENDIX

Table 1. Hemgenix Multi-Vial Kits

Total Number of Vials per Kit	Patient Body Weight (kg)	Total Volume per Kit (mL)	NDC Number
10	46-50	100	0053-0100-10
11	51-55	110	0053-0110-11
12	56-60	120	0053-0120-12
13	61-65	130	0053-0130-13
14	66-70	140	0053-0140-14
15	71-75	150	0053-0150-15
16	76-80	160	0053-0160-16
17	81-85	170	0053-0170-17
18	86-90	180	0053-0180-18
19	91-95	190	0053-0190-19

20	96-100	200	0053-0200-20
21	101-105	210	0053-0210-21
22	106-110	220	0053-0220-22
23	111-115	230	0053-0230-23
24	116-120	240	0053-0240-24
25	121-125	250	0053-0250-25
26	126-130	260	0053-0260-26
27	131-135	270	0053-0270-27
28	136-140	280	0053-0280-28
29	141-145	290	0053-0290-29
30	146-150	300	0053-0300-30
31	151-155	310	0053-0310-31
32	156-160	320	0053-0320-32
33	161-165	330	0053-0330-33
34	166-170	340	0053-0340-34
35	171-175	350	0053-0350-35
36	176-180	360	0053-0360-36
37	181-185	370	0053-0370-37
38	186-190	380	0053-0380-38
39	191-195	390	0053-0390-39
40	196-200	400	0053-0400-40
41	201-205	410	0053-0410-41
42	206-210	420	0053-0420-42
43	211-215	430	0053-0430-43
44	216-220	440	0053-0440-44
45	221-225	450	0053-0450-45
46	226-230	460	0053-0460-46
47	231-235	470	0053-0470-47
48	236-240	480	0053-0480-48

REFERENCES

1. Hemgenix. Prescribing Information. CSL Behring LLC; 2022. Accessed October 06, 2025. <https://labeling.cslbehring.com/PI/US/Hemgenix/EN/Hemgenix-Prescribing-Information.pdf>
2. Pipe SW, Leebeek FWG, Recht M, et al. Gene Therapy with etranacogene dezaparvovec for Hemophilia B. *N Engl J Med*. 2023;388(8):706-718. doi: 10.1056/NEJMoa2211644
3. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. *Haemophilia*. 2020; 26(Suppl 6): 1-158. doi.org/10.1111/hae.14046
4. Hemgenix. Resources to support your practice. Hemgenix.com. Accessed October 16, 2025. <https://www.hemgenix.com/hcp/support-and-resources/your-practice>

MEDICATION POLICY:

Hemgenix (etranacogene dezaparvovec-drlb)



DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.