Medical Policy

Hemgenix® (etranacogene dezaparvovec-drlb)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-134
CURRENT VERSION EFFECTIVE DATE	March 1, 2023
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans *Policy applies to all markets where IFP, SG, or MA plans are offered

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity of HEMGENIX® (etranacogene dezaparvovec-drlb).

POLICY

Prior Authorization and Medical Review is required.

Coverage for Hemgenix will be provided for 1 dose and may not be renewed.

- Max Units (per dose and over time):
  - 1 kit (based on weight chart below)

Initial

A. Patient is 18 years of age or older **AND**
B. Patient has a diagnosis of moderately severe or severe Hemophilia B (congenital Factor

IX deficiency, defined as a factor IX level less than 2% of normal; **AND** meet one of the following criteria:
   a. Patient must currently be on factor IX therapy with greater than 150 prior exposure days to treatment; **OR**
   b. Current or historical life-threatening hemorrhage; **OR**
   c. History of episodes of repeated, serious, spontaneous bleeding; **AND**

C. Patient has not received prior hemophilia AAV-vector-based gene therapy; **AND**
D. Patient has been tested and found negative for Factor IX inhibitor titers (patients who are positive for Factor IX inhibitors are not eligible for therapy); **AND**
E. Patient must have a baseline anti-AAV5 antibody titer of ≤ 1:678 measured by ELISA (Note: this assay was used in the HOPE-B clinical trial and is assessable vi CSL Behring); **AND**
F. Patient will have baseline liver function assessed prior to and after therapy, weekly, for at least 3 months; **AND**
G. Patients with preexisting risk factors for hepatocellular carcinoma (e.g., patients with cirrhosis, advanced hepatic fibrosis, hepatitis C or B, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), and advanced age) will have abdominal ultrasound screenings and be monitored regularly (e.g., annually) for alpha-fetoprotein (AFP) elevations following administration

Renewal
No renewal allowed one infusion per lifetime.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value.

DEFINITIONS

1. Hemgenix (Etranacogene dezaparvovec-drlb) suspension, for intravenous infusion. Initial U.S. Approval: 2022.
   a. Hemgenix is a sterile, preservative-free, clear , and colorless suspension. Hemgenix has a nominal concentration of 1 x 10^{13} gc/ml
   b. HEMGENIX is provided as a customized kit to meet dosing requirements for each patient with each kit containing 10 (ten) to 48 (forty-eight) single-use vials (NDC 0053-0099-01), each with an extractable volume of no less than 10 mL of HEMGENIX. The total number of vials in each kit corresponds to the dosing requirement for the individual patient depending on the patient`s body weight. The customized kit is accompanied with patient`s specific identifier number (Lot) on the outer carton. Each HEMGENIX kit may contain different drug product lots.

CODING

Applicable NDC Codes

Total number of vials	Patient Weight (kg)	Total Volume (mL)	NDC
10	46-50	100	00053-0100-10
11	51-55	110	00053-0110-11
12	56-60	120	00053-0120-12
13	61-65	130	00053-0130-13
14	66-70	140	00053-0140-14
15	71-75	150	00053-0150-15
16	76-80	160	00053-0160-16
17	81-85	170	00053-0170-17
18	86-90	180	00053-0180-18
19	91-95	190	00053-0190-19
20	96-100	200	00053-0200-20
21	101-105	210	00053-0210-21
22	106-110	220	00053-0220-22
23	111-115	230	00053-0230-23
24	116-120	240	00053-0240-24
25	121-125	250	00053-0250-25
26	126-130	260	00053-0260-26
27	131-135	270	00053-0270-27
28	136-140	280	00053-0280-28
29	141-145	290	00053-0290-29
30	146-150	300	00053-0300-30
31	151-155	310	00053-0310-31
32	156-160	320	00053-0320-32
33	161-165	330	00053-0330-33

Applicable Procedure Code	
J3590	Unclassified Biologics

Applicable ICD-10 Codes	
D67	Hereditary factor IX deficiency

EVIDENCE BASED REFERENCES

1. Hemgenix [package insert]. King of Prussia, PA; CSL Behring, LLC., November 2022. Accessed January 2023.
2. U.S. Food and Drug Administration approves CSL's HEMGENIX® (etranacogene dezaparvovec-drlb), the first gene therapy for hemophilia B. KING OF PRUSSIA, PA, USA. November 22, 2022.

POLICY HISTORY

Original Effective Date	2/28/2023
Revised Date	
P&T Committee Endorsement	02/28/2023