Medical Policy:

Hemgenix (etranacogene dezaparvovec-drlb) intravenous suspension

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.380	June 25, 2024	March 30, 2023

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc

Definitions

Hemgenix is an adeno-associated virus vector-based gene therapy indicated for treatment of adults with Hemophilia B (congenital Factor IX deficiency) who:

- Currently use Factor IX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes.

Length of Authorization

1 dose per lifetime

Dosing Limits [Medical Benefit]

2 x 10^{13} genome copies (gc) per kg (or 2 mL/kg) diluted in NS and administered as an IV infusion

Guideline

1. **Hemophilia B.** Approve a one-time per lifetime dose if the patient meets the following criteria (A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, and Q):
   A. Patient is male*; **AND**
   B. Patient is greater than or equal to 18 years of age; **AND**
   C. Patient has not received a gene therapy for hemophilia B in the past; **AND**
      Note: Verify through claims history that the patient has not previously received Hemgenix AND, if no claim for Hemgenix is present, the prescriber must attest that the patient has not previously received Hemgenix.
   D. Patient has moderately severe or severe hemophilia B as evidence by a Factor IX level of ≤ 2% of normal **AND**
   E. Patient meets one of the following (i, ii, **or** iii):
      i. Patient meets both of the following: (a **and** b):
         a. Patient has been receiving routine prophylaxis with Factor IX therapy continuously for at least 2 months **AND**
         b. According to the prescribing physician, the patient has a history of use of Factor IX therapy for at least 150 exposure days; **OR**
      ii. Patient meets both of the following (a **and** b):
         a. Patient has a history of life-threatening hemorrhage; **AND**
         b. On-demand use of Factor IX therapy was required for this life-threatening hemorrhage; **OR**
      iii. Patient meets both of the following (a **and** b):
         a. Patient has a history of repeated, serious spontaneous bleeding episodes; **AND**
         b. On-demand use of Factor IX therapy was required for these serious spontaneous bleeding episodes; **AND**
   F. Patient meets all of the following criteria (i, ii, **and** iii):
      i. Factor IX inhibitor titer testing has been performed within 30 days before receipt of Hemgenix; **AND**
      ii. Patient does not currently have an inhibitor to Factor IX; **AND**
      iii. Patient does not have a history of Factor IX inhibitors; **AND**
   G. Prescriber attests that prophylactic therapy with Factor IX will not be given after Hemgenix administration once adequate Factor IX levels have been achieved; **AND**
      Note: Use of episodic Factor IX therapy is acceptable for the treatment of bleeds and for surgery/procedures if needed as determined by the hemophilia specialist physician.
   H. Patient must meet both of the following (i **and** ii):
      i. Patient does not have an active infection with hepatitis B virus or hepatitis C virus; **AND**
      ii. Patient is not currently receiving antiviral therapy for a prior hepatitis B virus or C virus exposure; **AND**
   I. Patient does not have uncontrolled human immunodeficiency virus; **AND**
      Note: A patient testing positive for human immunodeficiency virus can still qualify for Hemgenix if controlled on antiviral therapy with CD4+ counts ≥ 200/µL or by a viral load of ≤ 200 copies/mL.
   J. Patient has undergone a liver health assessment within the last 30 days and meets all of the following (i, ii, iii, **and** iv):
      i. Alanine aminotransferase is ≤ 2 times the upper limit of normal; **AND**
      ii. Aspartate aminotransferase is ≤ 2 times the upper limit of normal; **AND**
      iii. Total bilirubin levels are ≤ 2 times the upper limit of normal; **AND**
      iv. Alkaline phosphatase levels are ≤ 2 times the upper limit of normal; **AND**
   K. Patient does not have evidence of advanced liver impairment and/or advanced fibrosis; **AND**
      Note: For example, liver elastrography (e.g., ≥ 9 kPA) suggestive of or equal to METAVIR Stage 3 disease.
   L. Within the last 30 days, platelet counts were evaluated and were ≥ 50 x 10^9/L; **AND**
   M. Patient has adequate renal function as defined by meeting both of the following (i **and** ii):
      i. Patient has an estimated creatinine clearance ≥ 30 mL/min; **AND**
      ii. Creatinine levels are ≤ 2 times the upper limit of normal; **AND**
   N. Physician attests that the patient does not have another coagulation disorder, besides hemophilia B; **AND**
   O. Medication is prescribed by a physician who specializes in hemophilia; **AND**

P. Current patient body weight has been obtained within 30 days; **AND**

Q. If criteria A through P are met, approve one dose (kit) of Hemgenix to provide for a one time (per lifetime) dose of 2 x 10^{13} genome copies based on body weight in kg by intravenous infusion. Table 1 provides the kit size and the National Drug Codes (NDCs).

Table 1. Hemgenix Multi-Vial Kits.[1]

Total Number of Vials per Kit	Patient Body Weight	Total Volume per Kit	NDC Number
10	46 to 50 kg	100	0053-0100-10
11	51 to 55 kg	110	0053-0110-11
12	56 to 60 kg	120	0053-0120-12
13	61 to 65 kg	130	0053-0130-13
14	66 to 70 kg	140	0053-0140-14
15	71 to 75 kg	150	0053-0150-15
16	76 to 80 kg	160	0053-0160-16
17	81 to 85 kg	170	0053-0170-17
18	86 to 90 kg	180	0053-0180-18
19	91 to 95 kg	190	0053-0190-19
20	96 to 100 kg	200	0053-0200-20
21	101 to 105 kg	210	0053-0210-21
22	106 to 110 kg	220	0053-0220-22
23	111 to 115 kg	230	0053-0230-23
24	116 to 120 kg	240	0053-0240-24
25	121 to 125 kg	250	0053-0250-25
26	126 to 130 kg	260	0053-0260-26
27	131 to 135 kg	270	0053-0270-27
28	136 to 140 kg	280	0053-0280-28
29	141 to 145 kg	290	0053-0290-29
30	146 to 150 kg	300	0053-0300-30
31	151 to 155 kg	310	0053-0310-31
32	156 to 160 kg	320	0053-0320-32
33	161 to 165 kg	330	0053-0330-33
34	166 to 170 kg	340	0053-0340-34
35	171 to 175 kg	350	0053-0350-35
36	176 to 180 kg	360	0053-0360-36
37	181 to 185 kg	370	0053-0370-37
38	186 to 190 kg	380	0053-0380-38
39	191 to 195 kg	390	0053-0390-39
40	196 to 200 kg	400	0053-0400-40
41	201 to 205 kg	410	0053-0410-41
42	206 to 210 kg	420	0053-0420-42
43	211 to 215 kg	430	0053-0430-43
44	216 to 220 kg	440	0053-0440-44
45	221 to 225 kg	450	0053-0450-45
46	226 to 230 kg	460	0053-0460-46
47	231 to 235 kg	470	0053-0470-47
48	236 to 240 kg	480	0053-0480-48

NDC – National Drug Code.

*In this context, the specified gender is defined as follows: men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

Applicable Procedure Codes

Code	Description
J1411	Injection, etranacogene dezaparvovec-drlb

Applicable NDCs

Code	Description
00053-0410-41	Hemgenix
00053-0440-44	Hemgenix
00053-0150-15	Hemgenix
00053-0140-14	Hemgenix
00053-0420-42	Hemgenix

00053-0130-13	Hemgenix
00053-0390-39	Hemgenix
00053-0310-31	Hemgenix
00053-0240-24	Hemgenix
00053-0250-25	Hemgenix
00053-0320-32	Hemgenix
00053-0480-48	Hemgenix
00053-0380-38	Hemgenix
00053-0290-29	Hemgenix
00053-0220-22	Hemgenix
00053-0170-17	Hemgenix
00053-0460-46	Hemgenix
00053-0180-18	Hemgenix
00053-0400-40	Hemgenix
00053-0100-10	Hemgenix
00053-0330-33	Hemgenix
00053-0260-26	Hemgenix
00053-0160-16	Hemgenix
00053-0450-45	Hemgenix
00053-0370-37	Hemgenix
00053-0360-36	Hemgenix
00053-0110-11	Hemgenix
00053-0190-19	Hemgenix
00053-0120-12	Hemgenix
00053-0470-47	Hemgenix
00053-0230-23	Hemgenix
00053-0300-30	Hemgenix
00053-0270-27	Hemgenix
00053-0340-34	Hemgenix
00053-0200-20	Hemgenix
00053-0430-43	Hemgenix
00053-0350-35	Hemgenix
00053-0210-21	Hemgenix
00053-0280-28	Hemgenix

ICD-10 Diagnoses

Code	Description
D67	Hereditary factor IX deficiency

Revision History

Company(ies)	DATE	REVISION

EmblemHealth & ConnectiCare	6/25/2024	Revision: Initial Criteria: Removed: "Patient has not received Hemgenix in the past; AND " and replaced with "Patient has not received a gene therapy for hemophilia B in the past"
EmblemHealth & ConnectiCare	5/3/2024	Annual Review: Initial Criteria: Removed: "Following Hemgenix infusion, the physician attests that the following will be performed (i, ii, and iii): Patient meets both of the following (a and b): Liver enzyme testing to monitor for liver enzyme elevations will be done at least weekly for the first 3 months and periodically thereafter; AND Implementing a course of corticosteroids will be considered if the patient experiences clinically relevant increases in alanine aminotransferase levels; AND Patient will undergo monitoring for Factor IX activity at least weekly for the first 3 months and periodically thereafter; AND Patients with preexisting risk factors for hepatocellular carcinoma will receive abdominal ultrasound screenings and be monitored at least annually for alpha fetoprotein elevations in the 5 years following receipt of Hemgenix; AND *Note: Risk factors include a patient with prior history of hepatitis B and/or C, non-alcoholic fatty liver disease, chronic alcohol consumption, non-alcoholic steatohepatitis, and advanced age."* Separated Current body weight into its own criteria (previously contained in dose criteria)
EmblemHealth & ConnectiCare	11/13/2023	Update: Removed all instances of "documentation required"- physician attestation accepted Removed: "by a baseline (without Factor IX replacement therapy) " from the line "Patient has moderately severe or severe hemophilia B as evidence by a baseline (without Factor IX replacement therapy) Factor IX level of ≤ 2% of normal **AND"** Added code J1411 Deleted: J3590 C9399
EmblemHealth & ConnectiCare	3/30/2023	New Policy

References

1. Product Information: HEMGENIX intravenous suspension, etranacogene dezaparvovec-drlb intravenous suspension. CSL Behring LLC (per FDA), King of Prussia, PA, 2022.