SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Hemgenix® (etranacogene dezaparvovec-drlb) **(J1411) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Quantity Limits: One infusion per lifetime

- Quantity Limit (max daily dose) [NDC Unit/HCPCS Unit]: 1 kit (based on weight chart below)
- Coverage will be provided for one infusion per lifetime and may **NOT** be renewed.

Recommended Dosage:

- The dose of Hemgenix is 2 x 10^{13} genome copies (gc) per kilogram (kg) of body weight (or 2 mL/kg body weight) administered as an intravenous infusion
- Calculate the dose as follows: Hemgenix dose (in mL) = patient body weight (in kilogram) x 2
  Vials needed = Hemgenix dose (in mL) divided by 10 (round up to next whole number of vials)

(Continued on next page)

- **NUMBER OF VIALS NEEDED:** _____

Total Number of Vials per Kit	Patient Body Weight (kg)	Total Volume per Kit (mL)
10	46-50	100
11	51-55	110
12	56-60	120
13	61-65	130
14	66-70	140
15	71-75	150
16	76-80	160
17	81-85	170
18	86-90	180
19	91-95	190
20	96-100	200
21	101-105	210
22	106-110	220
23	111-115	230
24	116-120	240
25	121-125	250
26	126-130	260
27	131-135	270
28	136-140	280
29	141-145	290
30	146-150	300
31	151-155	310
32	156-160	320
33	161-165	330
34	166-170	340
35	171-175	350
36	176-180	360
37	181-185	370
38	186-190	380
39	191-195	390
40	196-200	400
41	201-205	410
42	206-210	420
43	211-215	430
44	216-220	440
45	221-225	450
46	226-230	460
47	231-235	470
48	236-240	480

(Continued on next page)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member is at least 18 years of age
- ❑ Member is under the care of a specialist in hematology and/or in treating a patient population with Hemophilia B
- ❑ Member has a diagnosis of moderately severe or severe congenital Factor IX deficiency. The definition of moderately severe or severe must meet **BOTH** of the following conditions:
  - ❑ ≤ 2% of normal circulating factor IX (**must be confirmed by blood coagulation testing)**
  - ❑ Requiring continuous routine FIX prophylaxis (defined as the intent of treating with an a priori defined frequency of infusions (e.g., twice weekly, once every two weeks) as documented in the medical records), unless there is a detailed and fully documented contraindication or intolerance

    NOTE: member must be stabilized on FIX prophylaxis for at least 2 months having at least 150 days of exposure, prior to treatment with etranacogene dezaparvovec-drlb
- ❑ Member's conditions must satisfy **ONE** of the following:
  - ❑ Currently using Factor IX prophylaxis therapy
  - ❑ Current or historical life-threatening hemorrhage
  - ❑ Repeated, serious spontaneous bleeding episodes (past medical history record outlining the following: intramuscular hematomas requiring hospitalization, hemarthrosis, central nervous system (CNS) bleeding (including intracranial hemorrhage), pulmonary hemorrhage, life-threatening gastrointestinal (GI) hemorrhage and umbilical cord bleeding)
- ❑ Member has **NOT** received prior hemophilia AAV-vector–based gene therapy
- ❑ Member has been tested and found negative for Factor IX inhibitor titers. If test result is positive, re-test within approximately 2 weeks. If re-test is also positive, Hemgenix should not be given. **(test results must be attached to this request)**
- ❑ Factor IX activity will be monitored periodically (e.g., weekly for 3 months) as well as presence of inhibitors if bleeding is not controlled. **NOTE: patients will continue to require exogenous Factor IX until response to Hemgenix occurs**
- ❑ Member will discontinue Factor IX prophylaxis therapy upon achieving FIX levels of 5% from etranacogene dezaparvovec treatment
- ❑ Member 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 via CSL Behring**
- ❑ Member will have baseline liver function assessed prior to and after therapy, weekly, for at least 3 months
- ❑ Member has been screened for active infection with hepatitis B virus (HBV) or hepatitis C virus (HCV)

(Continued on next page)

- ❑ Members 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
- ❑ Member has been screened for human immunodeficiency virus (HIV), and if positive, must be therapeutically managed with anti-viral therapy

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.