AvMed

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 1-877-535-1391**. 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 AvMed #: _____ **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)

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- **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

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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 male [**NOTE**: the specified gender is defined as follows: males are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression]
- ❑ Member is 18 years of age or older
- ❑ Medication is prescribed by a hemophilia specialist physician
- ❑ Member has **NOT** received a gene therapy for hemophilia B in the past **(verified by medical paid claims)** [**NOTE**: If no claim for Hemgenix® or Beqvez™ (fidanacogene elaparvovec intravenous infusion) is present (or if claims history is not available), the prescribing physician confirms that the member has not previously received Hemgenix® or Beqvez™]
- ❑ Member has moderately severe or severe hemophilia B as evidenced by a baseline (without Factor IX replacement therapy) Factor IX level ≤ 2% of normal **(submit documentation)**
- ❑ Member meets **ONE** of the following:
  - ❑ According to the prescribing physician, member has a history of use of Factor IX therapy for ≥ 150 exposure days
  - ❑ Member meets **BOTH** of the following:
    - ❑ Member has a history of life-threatening hemorrhage
    - ❑ On-demand use of Factor IX therapy was required for this life-threatening hemorrhage
  - ❑ Member meets **BOTH** of the following:
    - ❑ Member has a history of repeated, serious spontaneous bleeding episodes
    - ❑ On-demand use of Factor IX therapy was required for these serious spontaneous bleeding episodes
- ❑ Member meets **ALL** the following **(submit documentation)**:
  - ❑ Factor IX inhibitor titer testing has been performed within 30 days
  - ❑ Member is negative for Factor IX inhibitors
  - ❑ Member does **NOT** have a history of Factor IX inhibitors
- ❑ Prophylactic therapy with Factor IX will **NOT** be given after Hemgenix® administration once adequate Factor IX levels have been achieved [**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]
- ❑ Member meets **BOTH** of the following **(submit documentation)**:
  - ❑ Member does **NOT** have an active infection with hepatitis B virus or hepatitis C virus
  - ❑ Member is **NOT** currently receiving antiviral therapy for a prior hepatitis B virus or hepatitis C virus exposure
- ❑ According to the prescribing physician, member does **NOT** have uncontrolled human immunodeficiency virus infection

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- ❑ Member has undergone liver function testing within 30 days and meets **ALL** the following **(submit documentation)**:
  - ❑ Alanine aminotransferase level is ≤ two times the upper limit of normal
  - ❑ Aspartate aminotransferase level is ≤ two times the upper limit of normal
  - ❑ Total bilirubin level is ≤ two times the upper limit of normal
  - ❑ Alkaline phosphatase level is ≤ two times the upper limit of normal
- ❑ Member does **NOT** have evidence of advanced liver impairment and/or advanced fibrosis [**NOTE**: For example, liver elastography (e.g., ≥ 9 kPA) suggestive of or equal to METAVIR Stage 3 disease]
- ❑ Within the past 30 days, member platelet count was ≥ 50 x 10^9/L **(submit documentation)**
- ❑ Within the past 30 days, member meets **ONE** of the following **(submit documentation)**:
  - ❑ Member has an estimated creatinine clearance ≥ 30 mL/min
  - ❑ Member's creatinine level is ≤ two times the upper limit of normal
- ❑ Members' current body weight has been obtained within 30 days **(submit documentation)**

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 AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed'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.