



FROM



Telephone: (800) 514-0083 option 2
Fax: (866) 374-1579

Etranacogene dezaparvovec-drlb (Hemgenix) PDAC Drug Review Form

The information below can be completed by the Health Plan and/or Centene Pharmacy Services (CPS) staff

Patient Information

*Last Name:	*First Name:	Middle:	*DOB: / /
Daytime Phone:		Evening Phone:	*Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female

Insurance Information

*Primary Insurance (Health Plan Name and State)	*ID #:
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Physician Information

*Name:	*Specialty:	*Phone #:
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Procedural Hospital

*Hospital Name:

Primary Diagnosis

*ICD-10 Code:
<input type="checkbox"/> Congenital hemophilia B (factor IX deficiency) <input type="checkbox"/> Other: _____

Prescription Information

MEDICATION	STRENGTH	*DIRECTIONS	QUANTITY	REFILLS
Hemgenix (etranacogene dezaparvovec-drlb)				

Clinical Information

***** Please submit supporting clinical documentation *****

* THERAPY Start Date: _____

- Is Hemgenix prescribed by or in consultation with a hematologist? ☐ Yes ☐ No
- Has patient had severe or moderately severe hemophilia? ☐ Yes ☐ No
- Please provide the following patient information:
 - Weight: _____ kg
 - Factor IX level: _____ %
 - Inhibitor level assay: _____ Bethesda units (BU), date: _____
 - Adeno-associated virus serotype 5 (AAV5) neutralizing antibody titer: _____ : _____
- Has patient been adherent to current use of a factor IX product for routine prophylaxis as assessed and documented by prescriber? ☐ Yes ****Mark all that apply**** ☐ No
☐ Alprolix ☐ Benefix ☐ Idelvion ☐ Ixinity ☐ Rebinyn ☐ Rixubis ☐ Other: _____
- Does patient have current or historical life-threatening hemorrhage? ☐ Yes ☐ No
- Has patient been treated with factor IX product for a minimum of 150 exposure days (ED)*? ☐ Yes ****Mark all that apply**** ☐ No
**ED defined days on which factor was infused with factor concentrate to treat or prevent a bleed on a person with hemophilia.*
- Does patient have repeated serious spontaneous bleeding episodes? ☐ Yes ****Mark all that apply**** ☐ No
☐ Intracranial ☐ Neck/throat ☐ Gastrointestinal ☐ Joints (hemarthrosis) ☐ Muscles (e.g., iliopsoas, calf, forearm)
☐ Mucous membranes of the mouth, nose & genitourinary tract ☐ Other: _____
- Is there documented history of a detectable factor IX inhibitor? ☐ Yes ☐ No
- Has patient had initial factor IX inhibitor positive test? ☐ Yes ☐ No
 - If yes, is there documentation of subsequent negative test within 2 weeks?
☐ Yes, positive test date: _____ and negative test date: _____ ☐ No
- Has patient had both of the following documented baseline liver assessments within the last 3 months? ☐ Yes ****Mark all that apply**** ☐ No
☐ Normal hepatic ultrasound and elastography
☐ Liver enzymes within normal limits (e.g., alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase & total bilirubin)



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11. Has patient had evidence of radiological liver abnormalities and/or sustained liver enzyme elevations? ☐ Yes ☐ No
a) If yes, does hepatologist attest that patient is eligible for Hemgenix? ☐ Yes ☐ No
12. Has patient received prior gene therapy? ☐ Yes ☐ No
13. Has the patient been tested for neutralizing anti-adenovirus serotype 5 (AAV5) antibodies and been deemed a suitable candidate for treatment? ☐ Yes ☐ No
14. How many Hemgenix infusions has patient received? ☐ 0 ☐ 1 ☐ ≥1

Please continue to page 2.

Patient Name: _____ **DOB:** _____

Complete this section ONLY for indications other than congenital hemophilia B:

15. Has patient tried and failed, or is contraindicated to, accepted standards of care? ☐ Yes ☐ No

If yes, submit documentation and answer the following:

- a. Please list all previous therapies: _____
b. Was patient adherent to previously tried therapies? ☐ Yes ☐ No ☐ No, patient intolerant to drug

Information

***Number:**

***Date of Request:**

***HCPCS Code:**

***Decision Due Date:**

*** Line of Business:**

- ☐ Commercial ☐ Health Insurance Marketplace
☐ Medicaid ☐ Medicare

*** Benefit:**

- ☐ Medical ☐ Pharmacy

*** Choose one criteria option below based on line of business:**

Medicare Criteria Only:

- ☐ Medicare Local Coverage Decision (LCD) specific for your region

Please include policy of link to LCD, followed by any applicable Medicare Part B step therapy requirements in MCPB.ST.00.

- ☐ Medicare National Coverage Decision (NCD).

Please include policy of link to NCD, followed by any applicable Medicare Part B step therapy requirements in MCPB.ST.00.

Medicaid, Commercial, Exchange (Ambetter) Criteria:

- ☐ Centene Policy [CP.PHAR.580 Etranacogene Dezaparvovec-drlb (Hemgenix)]

Date Policy last reviewed/approved by plan (we want to be sure we are using the version approved by your plan):

OR

- ☐ State or Health Plan Specific (please include policy)