



Hemgenix

CareFirst Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518**. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name: _____ Date: _____
Patient's ID: _____ Patient's Date of Birth: _____
Physician's Name: _____
Specialty: _____ NPI#: _____
Physician Office Telephone: _____ Physician Office Fax: _____

Referring Provider Info: ☐ Same as Requesting Provider

Name: _____ NPI#: _____
Fax: _____ Phone: _____

Rendering Provider Info: ☐ Same as Referring Provider ☐ Same as Requesting Provider

Name: _____ NPI#: _____
Fax: _____ Phone: _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____ kg

Patient Height: _____ cm

Please indicate the place of service for the requested drug:

☐ Ambulatory Surgical ☐ Home ☐ Off Campus Outpatient Hospital
☐ On Campus Outpatient Hospital ☐ Office ☐ Pharmacy

What is the ICD-10 code? _____

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

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CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

Criteria Questions:

1. What is the diagnosis?

- ☐ Hemophilia B (congenital factor IX deficiency), *Continue to 2*
☐ Other, please specify. _____, *Continue to 2*

2. Is the patient 18 years of age or older?

- ☐ Yes, *Continue to 3*
☐ No, *Continue to 3*

3. Will the requested medication be prescribed by or in consultation with a hematologist?

- ☐ Yes, *Continue to 4*
☐ No, *Continue to 4*

4. Does the patient have a history of Factor IX inhibitors (greater than or equal to 0.6 Bethesda units [BU])? **ACTION REQUIRED:** If No, please attach supporting documentation of absence of Factor IX inhibitors.

- ☐ Yes, *Continue to 5*
☐ No, *Continue to 5*

5. Does the patient have a negative Factor IX inhibitor test result within the past 30 days (less than 0.6 Bethesda units [BU])? **ACTION REQUIRED:** If Yes, please attach lab test results documenting the absence of Factor IX inhibitors.

- ☐ Yes, *Continue to 6*
☐ No, *Continue to 6*

6. Does the patient have severe or moderately severe Factor IX deficiency (less than or equal to 2% of normal circulating Factor IX)? **ACTION REQUIRED:** If Yes, please attach chart notes or lab tests documenting severe or moderately severe Factor IX deficiency (less than or equal to 2% of normal circulating Factor IX).

- ☐ Yes, *Continue to 7*
☐ No, *Continue to 7*

7. Does the patient have a history of prophylactic Factor IX (e.g., Alprolix, Ixinity, Rebinyn) use for at least 150 exposure days? **ACTION REQUIRED:** If Yes, please attach chart notes of current use of Factor IX prophylaxis therapy.

- ☐ Yes, *Continue to 8*
☐ No, *Continue to 8*

8. Does the patient have uncontrolled disease while currently using Factor IX prophylactic therapy?

- ☐ Yes, *Continue to 10*
☐ No, *Continue to 9*

9. Does the patient have a contraindication to receiving Factor IX prophylaxis?

- ☐ Yes, *Continue to 12*
☐ No, *Continue to 12*

10. Does the patient have a current or a history of a life-threatening hemorrhage? **ACTION REQUIRED:** If Yes, please attach chart notes documenting history of life-threatening hemorrhage(s).

- ☐ Yes, *Continue to 12*
☐ No, *Continue to 11*

11. Does the patient have a history of repeated, serious spontaneous bleeding episodes? **ACTION REQUIRED:** If Yes, please attach chart notes documenting history of repeated, serious spontaneous bleeding episodes.

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- ☐ Yes, *Continue to 12*
☐ No, *Continue to 12*

12. Does the patient have a platelet count of greater than or equal to 50,000 cells/microL at baseline? **ACTION REQUIRED:** If Yes, please attach chart notes, lab tests documenting baseline platelet count results.

- ☐ Yes, *Continue to 13*
☐ No, *Continue to 13*

13. Does the patient have alanine transaminase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), total bilirubin (unless there is a diagnosis of Gilbert's Syndrome and patient is otherwise stable), and creatinine levels greater than 2 times the upper limit of normal (ULN) at baseline? **ACTION REQUIRED:** If No, please attach chart notes, lab tests documenting baseline liver and renal assessments.

- ☐ Yes, *Continue to 14*
☐ No, *Continue to 14*

14. Does the patient have current unstable liver or biliary disease as defined by the presence of ascites, hepatic encephalopathy, coagulopathy, hypoalbuminemia, esophageal or gastric varices, persistent jaundice, or cirrhosis?

- ☐ Yes, *Continue to 15*
☐ No, *Continue to 15*

15. Has the patient undergone a hepatic ultrasound and/or elastography to rule out radiological liver abnormalities and/or sustained liver enzyme elevations?

- ☐ Yes, *Continue to 16*
☐ No, *Continue to 16*

16. Does the patient have an active infection with hepatitis B virus or hepatitis C virus?

- ☐ Yes, *Continue to 17*
☐ No, *Continue to 17*

17. Is the patient currently receiving antiviral therapy for a prior hepatitis B virus or hepatitis C virus exposure?

- ☐ Yes, *Continue to 18*
☐ No, *Continue to 18*

18. Does the patient have uncontrolled human immunodeficiency virus (HIV) infection as defined as a CD4 cell count less than or equal to 200 mm³ or viral load greater than 20 copies/mL?

- ☐ Yes, *Continue to 19*
☐ No, *Continue to 19*

19. Has the patient previously received the requested drug or any other gene therapy?

- ☐ Yes, *Continue to 20*
☐ No, *Continue to 20*

20. Will prophylactic use of Factor IX products be given after the requested drug administration once adequate Factor IX levels have been achieved (note: Factor IX therapy may be given in case of surgery, invasive procedures, trauma, or bleeds in the event that Hemgenix-derived Factor IX activity is deemed insufficient for adequate hemostasis)?

- ☐ Yes, *Continue to 21*
☐ No, *Continue to 21*

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21. Does the provider attest that liver enzymes and Factor IX activity will be followed per the protocol outlined in the prescribing information following receipt of the requested drug infusion?

☐ Yes, *No Further Questions*

☐ No, *No Further Questions*

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X

Prescriber or Authorized Signature

Date (mm/dd/yy)

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