Roctavian

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.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

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

 CareFirst MR C28683-A, Roctavian C26813-A – 06/2025.

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

Exception Criteria Questions:

A. The preferred products for your patient's health plan are Eloctate, Hemlibra, Xyntha (including Solofuse), and Nuwiq. Can the patient's treatment be switched to one of the preferred products?
- ❑ Yes – Eloctate, *Please obtain Form for preferred product and submit for corresponding PA.*
- ❑ Yes – Hemlibra, *Please obtain Form for preferred product and submit for corresponding PA.*
- ❑ Yes – Nuwiq, *Please obtain Form for preferred product and submit for corresponding PA.*
- ❑ Yes – Xyntha, *Please obtain Form for preferred product and submit for corresponding PA.*
- ❑ Yes – Xyntha Solofuse, *Please obtain Form for preferred product and submit for corresponding PA.*
- ❑ No, *Continue to Question C*

B. Did the patient have a documented inadequate response, contraindication, or intolerable adverse event to all preferred products (Eloctate, Hemlibra, Xyntha (including Solofuse), and Nuwiq)?
Action Required: If Yes, attach supporting chart note(s). ❑ Yes ❑ No *If Yes or No, Continue to Clinical Criteria Questions*

Criteria Questions:

1. What is the diagnosis?

❒ Hemophilia A (congenital factor VIII 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 drug be prescribed by or in consultation with a hematologist?
❒ Yes, *Continue to 4*
❒ No, *Continue to 4*

4. Does the patient have severe disease with factor VIII activity levels less than or equal to 1 IU/dL? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical records, or lab results documenting severe factor VIII deficiency (factor VIII activity levels less than or equal to 1 IU/dL).
❒ Yes, *Continue to 5*
❒ No, *Continue to 5*

5. Does the patient have an absence of pre-existing antibodies to adeno-associated virus serotype 5 (AAV5) that was confirmed by an FDA-approved test (e.g., AAV5 DetectCDx)? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical records, or lab results documenting the absence of pre-existing antibodies to the adeno-associated virus serotype 5 (AAV5) capsid.
❒ Yes, *Continue to 6*
❒ No, *Continue to 6*

6. Does the patient have a history of factor VIII inhibitors (greater than or equal to 0.6 Bethesda Units [BU])? ***ACTION REQUIRED***: If No, please attach lab results documenting the absence of factor VIII inhibitor confirmed by a Bethesda assay.
❒ Yes, *Continue to 7*
❒ No, *Continue to 7*

7. Does the patient have a negative factor VIII inhibitor test result within the past 30 days (less than 0.6 Bethesda Units [BU])? ***ACTION REQUIRED***: If Yes, please attach lab results documenting the absence of factor VIII inhibitor confirmed by a Bethesda assay.
❒ Yes, *Continue to 8*
❒ No, *Continue to 8*

8. Is the patient currently using factor VIII prophylaxis therapy (e.g., Advate, Adynovate, Eloctate)?
❒ Yes, *Continue to 9*
❒ No, *Continue to 9*

9. Does the patient have a history of prophylactic factor VIII use for at least 150 exposure days?
❒ Yes, *Continue to 10*
❒ No, *Continue to 10*

10. Does the patient have uncontrolled disease despite the use of prophylactic Factor VIII or has a clinical reason to avoid therapy with Factor VIII prophylaxis?
❒ Yes, *Continue to 11*
❒ No, *Continue to 11*

11. Please indicate platelets lab values at baseline: ***ACTION REQUIRED***: Please attach baseline lab results.
❒ Greater than or equal to 100,000 cells/microL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 12*

❒ Less than 100,000 cells/microL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 12*

12. Please indicate creatinine lab values at baseline: ***ACTION REQUIRED***: Please attach baseline lab results.

❒ Greater than or equal to 1.5 mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 13*

❒ Less than 1.5 mg/dL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 13*

13. Does the patient have alanine transaminase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT), or total bilirubin (unless there is a diagnosis of Gilbert's Syndrome and member is otherwise stable) greater than 1.25 times the upper limit of normal (ULN)?
❒ Yes, *Continue to 14*
❒ No, *Continue to 14*

14. Please indicate the patient's INR (international normalized ratio): ***ACTION REQUIRED***: Please attach INR (international normalized ratio) lab results.

❒ Greater than or equal to 1.4 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 15*

❒ Less than 1.4 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 15*

15. Does the patient have stage 3 or 4 liver fibrosis?
❒ Yes, *Continue to 16*
❒ No, *Continue to 16*

16. 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 17*
❒ No, *Continue to 17*

17. Does the patient have a chronic or active infection with hepatitis B virus or hepatitis C virus?
❒ Yes, *Continue to 18*
❒ No, *Continue to 18*

18. Is the patient currently receiving antiviral therapy for a prior hepatitis B virus or hepatitis C virus exposure?
❒ Yes, *Continue to 19*
❒ No, *Continue to 19*

19. Does the patient have uncontrolled human immunodeficiency virus (HIV) infection?
❒ Yes, *Continue to 20*
❒ No, *Continue to 20*

20. Does the patient have an active infection or other immunosuppressive disorder?
❒ Yes, *Continue to 21*
❒ No, *Continue to 21*

21. Does the patient have an active malignancy?
❒ Yes, *Continue to 22*
❒ No, *Continue to 22*

22. Does the patient have a history of arterial or venous thromboembolic events (e.g., deep vein thrombosis, non-hemorrhagic stroke, pulmonary embolism, myocardial infarction, arterial embolism)?
❒ Yes, *Continue to 23*
❒ No, *Continue to 23*

23. Does the patient have a known inherited or acquired thrombophilia, including conditions associated with increased thromboembolic risk (e.g., atrial fibrillation)?
❒ Yes, *Continue to 24*
❒ No, *Continue to 24*

24. Has the patient previously received the requested drug or any other gene therapy?
❒ Yes, *Continue to 25*
❒ No, *Continue to 25*

25. Will prophylactic use of Factor VIII products be given after the requested drug administration once adequate Factor VIII levels have been achieved (note: Factor VIII therapy may be given in case of surgery, invasive procedures, trauma, or bleeds in the event that Roctavian-derived Factor VIII activity is deemed insufficient for adequate hemostasis)?
❒ Yes, *Continue to 26*
❒ No, *Continue to 26*

26. Does the provider attest that liver enzymes and Factor VIII 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*

Step Therapy Override: Complete if Applicable for the state of Maryland.	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

Step Therapy Override: Complete if Applicable for the state of Virginia.	Please Circle	
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition?	Yes	No

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)**

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