SEVENFACT® Free Trial Program
Instructions for Healthcare Providers

SevenFACT® Coagulation Factor VIIa (Recombinant)-jncw

Eligibility for this program requires an on-label diagnosis for a patient who is naive to SEVENFACT

Getting your patient started on SEVENFACT®:

1

Patient Authorization, Consent and Acknowledgment

After discussing SEVENFACT with your patient, have your patient read and sign sections I, II and III on page 2 of the Patient Authorization, Consent and Acknowledgment Form. By signing this form, your patient is requesting a free trial of SEVENFACT, if eligible to participate.

- Provide your patient pages 3 and 4 for their records.

2

Enrollment Form

You complete page 5. Fill out all sections of the Free Trial Form. Incomplete information may delay processing and shipment.

3

Submit

Fax the following completed and signed documents:

- Page 2 — Patient Authorization and Consent Form
- Page 5 — Free Trial Form

Fax: 1-833-390-1379

QUESTIONS?

Call 855-718-HEMA (4362), Option 3
Monday – Friday 9:00 AM – 6:00 PM ET

FAX this page

SevenFACT® Coagulation Factor VIIa (Recombinant)-jncw

Patient Authorization, Consent and Acknowledgment

Patient Name: _____ **DOB:** MM / DD / YYYY

Please read the following. If you agree, please sign and date the corresponding section below. This document is a legal document and as such, consent must be given by the patient or the patient's legal representative. A patient should sign his/her own name. If the patient is unable to sign and the document is signed by a legal representative of the patient, the legal representative should sign his/her own name and attach proof of patient representation such as Power of Attorney or another legal document.

I. Authorization to Share Health Information

By signing this Authorization, I authorize my healthcare provider, my health insurance company, and my pharmacy providers ("Healthcare Entities") to disclose to HEMA Biologics and companies working with HEMA Biologics, my contact information, health information relating to my medical condition which may also include the identification and/or evaluation of any potential drug interactions and allergies, adherence to my treatment, medical condition, history, my general health, as well as sensitive health information, including information related to the treatment of alcohol/drug abuse, HIV/AIDS, sexually transmitted diseases, mental health and genetic information to: (i) conduct data analytics, market research and other internal business activities including, but not limited to evaluating the services provided; and (ii) provide me with information about HEMA Biologics' products, services, and programs and other topics of interest for marketing, educational or other purposes; (iii) establish my benefit eligibility; (iv) contact me to evaluate therapy; (v) provide me with disease management and other education materials. Once my health information has been disclosed to HEMA Biologics, I understand that the information may be subject to further disclosure by HEMA Biologics. However, HEMA Biologics agrees to protect my health information by using and disclosing it only for purposes authorized in this Patient Authorization and Consent or as required by law or regulations.

I understand that my pharmacy provider may receive remuneration from HEMA Biologics in exchange for sharing information concerning any services that the pharmacy may provide to me.

I am entitled to a copy of this signed Authorization. I understand that I do not need to sign this authorization in order to receive healthcare treatment for my health care providers. However, I understand that if I refuse to sign this authorization I will not be eligible to participate in the SEVENFACT Free Trial Program.

I may cancel this Authorization at any time by mailing a letter to: HEMA Biologics Cares, 270 Cramer Creek Court, Dublin, OH 43017. Canceling this Authorization will end my consent to further disclosure of my health information to HEMA Biologics by my Healthcare Entities after they are notified of my cancellation but will not affect previous disclosures by them pursuant to this Authorization. Canceling this Authorization will not have any effect on any actions taken by my healthcare providers or my health plan before receiving the cancellation.

This Authorization expires December 31, 2030 or such shorter timeframe required by applicable law, from the day I sign it as indicated by the date next to my signature unless otherwise canceled earlier as set forth above.

I have read, understand, and agree to the terms of section I above, Authorization to Share Health Information.

SIGN HERE _____ MM / DD / YYYY

Signature of Patient or Legal Representative **Date**

II. Consent to Contact for Patient Services and Marketing/Other Communications

Patient Services: I authorize HEMA Biologics and companies working with HEMA Biologics to contact me to gather information on my experience with SEVENFACT as utilized via this free trial program by mail, e-mail, fax, telephone call, text message (including calls and text messages made with an automatic telephone dialing system or a prerecorded voice), and other mutually agreed upon means. I confirm that the telephone number provided on the enrollment form belongs to me or my legal representative and is not the number of a third party. By providing my phone number and signing below, I authorize the Authorized Representatives to deliver or cause to be delivered to me telephonic sales and marketing calls (including artificial voice calls) or text messages using an automated system for the selection and dialing of telephone numbers or the playing of a recorded message when a connection is competed to my number, or the transmission of a prerecorded voicemail. These messages may concern my prescription, including reminders, and other information related to your health, which may include telephonic sales calls. I further consent to automated or prerecorded messages being played when the telephone is answered whether by me or someone else. Telephone calls may be monitored or recorded for quality and other purposes. Consent to such calls and text messages is not a condition of receipt of services. I agree to promptly alert the Authorized Representatives whenever I stop using a particular telephone number. Reply STOP to opt out of text messaging. I am not required to directly or indirectly sign this written agreement or to agree to enter into such an agreement as a condition of purchasing any property, goods, or services. I also authorize HEMA Biologics, and companies working with HEMA Biologics, to use my health information in connection with the services, including, without limitation, sharing such information with my healthcare provider. I also authorize the disclosure of my health information to specific individuals that I have designated.

Marketing/Other Communications: I further authorize HEMA Biologics and companies working with HEMA Biologics to contact me by mail, email, fax, telephone call, and text message for marketing purposes or otherwise provide me with information about HEMA Biologics' products, services, and programs or other topics of interest, conduct market research or otherwise ask me about my experience with or thoughts about such topics. I understand and agree that any information that I provide may be used by HEMA Biologics to help develop new products, services, and programs. I also understand that I am not required to provide my number as a condition of purchase. Message and data rates may apply. Note that HEMA Biologics will not sell or transfer my personal data to any unrelated third party for marketing purposes without my express permission. I understand that I may revoke this consent and choose not to receive services or information from HEMA Biologics by mailing a letter to the address set forth above in Section I of this Patient Authorization and Consent.

I have read, understand, and agree to the terms of section II above, Consent to Contact for Patient Services and Marketing/Other Communications.

SIGN HERE _____ MM / DD / YYYY

Signature of Patient or Legal Representative **Date**

Email: _____

III. Acknowledgment of free trial program

By providing my signature, I understand that HEMA Biologics is providing me with a limited and complementary trial of SEVENFACT at no cost to me, to my healthcare provider, or to a third-party payer, including (if applicable) my health insurance provider. I understand my receipt of the free trial product is for my sole use and I warrant that I will not sell, resell, trade, barter, or otherwise seek reimbursement for such product. I understand there is no obligation for me to purchase SEVENFACT to enroll in the free trial program. I further understand that my enrollment in the free trial program is limited to one enrollment, and after I receive such free trial product, I will no longer be eligible to receive additional SEVENFACT under the free trial program.

SIGN HERE _____ MM / DD / YYYY

Signature of Patient or Legal Representative **Date**

Patient Authorization, Consent and Acknowledgment – Patient Copy

SevenFACT® Coagulation Factor VIIa (Recombinant)-jncw

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Marketing/Other Communications: I further authorize HEMA Biologics and companies working with HEMA Biologics to contact me by mail, email, fax, telephone call, and text message for marketing purposes or otherwise provide me with information about HEMA Biologics' products, services, and programs or other topics of interest, conduct market research or otherwise ask me about my experience with or thoughts about such topics. I understand and agree that any information that I provide may be used by HEMA Biologics to help develop new products, services, and programs. I also understand that I am not required to provide my number as a condition of purchase. Message and data rates may apply. Note that HEMA Biologics will not sell or transfer my personal data to any unrelated third party for marketing purposes without my express permission. I understand that I may revoke this consent and choose not to receive services or information from HEMA Biologics by mailing a letter to the address set forth above in Section I of this Patient Authorization and Consent.

III. Acknowledgment of free trial program

By providing my signature, I understand that HEMA Biologics is providing me with a limited and complementary trial of SEVENFACT at no cost to me, to my healthcare provider, or to a third-party payer, including (if applicable) my health insurance provider. I understand my receipt of the free trial product is for my sole use and I warrant that I will not sell, resell, trade, barter, or otherwise seek reimbursement for such product. I understand there is no obligation for me to purchase SEVENFACT to enroll in the free trial program. I further understand that my enrollment in the free trial program is limited to one enrollment, and after I receive such free trial product, I will no longer be eligible to receive additional SEVENFACT under the free trial program.

I have read, understand, and agree to the terms of section I above, Authorization to Share Health Information and section II above, Consent to Contact for Patient Services and Marketing/Other Communications.

Please see Important Safety Information on page 4, as well as full Prescribing Information, including Boxed Warning.

INDICATION:

SEVENFACT [coagulation factor VIIa (recombinant)-jncw] is a coagulation factor VIIa concentrate indicated for the treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitor.

Limitation of Use: SEVENFACT is not indicated for treatment of congenital factor VII deficiency.

Important Safety Information

What is the most important information I should know about SEVENFACT?

The most serious possible side effect of SEVENFACT is abnormal clotting involving blockage of blood vessels, which include stroke, blockage of the main blood vessel to the lung, and deep vein blood clots.

You should know the signs of abnormal clotting and seek medical help immediately if they occur.

Signs of clotting in places other than your site of bleeding can include new onset of swelling and pain in limbs, new onset of chest pain, shortness of breath, loss of sensation or motor power, or altered consciousness or speech.

What is SEVENFACT?

SEVENFACT is an injectable medicine used for the treatment and control of bleeding episodes occurring in adults and adolescents 12 years of age and older with Hemophilia A or B with inhibitors.

Injecting medicines requires special training; do not attempt to self-infuse unless you have been taught how by your healthcare provider.

Who should not use SEVENFACT (coagulation factor VIIa)?

You should not use SEVENFACT if you are allergic to rabbits, or if you have known allergies to SEVENFACT or any of its components. Seek immediate medical help if you experience hives, itching, rash, difficulty breathing with cough or wheezing, swelling around the mouth and throat, tightness of the chest, dizziness or fainting, or low blood pressure after taking SEVENFACT.

Tell your healthcare provider prior to using SEVENFACT if you have begun treatment of a bleeding episode with another bypassing agent.

What should I tell my healthcare provider before I use SEVENFACT?

Tell your healthcare provider if you are pregnant, are nursing, or plan to become pregnant; if you have had prior blood clots, heart disease or heart failure, abnormal heart rhythms, prior pulmonary clots, or heart surgery; or if you have or have had any other medical conditions.

What are the possible side effects of SEVENFACT?

The most common adverse reactions for SEVENFACT are headache, dizziness, infusion-site discomfort, infusion-site hematoma, and infusion-related reaction and fever.

Seek immediate medical help if you have signs of a blood clot or an allergic reaction.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact HEMA Biologics at 1-855-718-4362. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see attached full Prescribing Information, including Boxed Warning.

FAX this page

Enrollment Form

SEVENFACT® Coagulation Factor VIIa (Recombinant)-jncw

Patient Demographic Information

Patient Name: _____ DOB: MM / DD / YYYY Social Security #: ___–___–_____ Sex: ☐ M ☐ F

Mailing Address: _____ City: _____ State: _____ Zip: _____

Contact Person (if different from patient): _____ Relationship to Patient: _____

Home Phone: _____ Cell Phone: _____ OK to Leave Message: ☐ Yes ☐ No

Email: _____ Preferred Contact: ☐ Email ☐ Phone Best Time to Contact: ☐ AM ☐ PM

Language Preference: ☐ English ☐ Spanish ☐ Other _____

Current Specialty Pharmacy: _____ Current HTC (if applicable): _____

☐ By checking this box, I confirm that I have not used SEVENFACT in the past.

Prescriber Information

First Name: _____ Last Name: _____ ☐ MD ☐ PA ☐ NP ☐ DO

Specialty: ☐ Hematology ☐ Other: _____ State License #: _____ Expiration Date: MM / DD / YYYY

NPI #: _____ DEA: _____ PTAN: _____ TAX ID #: _____

Facility Name: _____

Facility Address: _____ City: _____ State: _____ Zip: _____

Office Contact: _____ Preferred Contact: ☐ Phone ☐ Email ☐ Fax

Office Phone: _____ Office Fax: _____ Email: _____

Patient Clinical Information

Primary Diagnosis: ☐ Hemophilia A or B with Inhibitors ☐ Other: _____ **ICD-10:** ☐ D66 ☐ D67 ☐ Other: _____

Drug Allergies: _____ Weight: _____ kg

Other Medications Taken: _____ IV Access: ☐ Peripheral IV ☐ Other _____

SEVENFACT *Free Trial Program*

☐ *I authorize HEMA Biologics Cares to provide up to 450 mcg/kg of SEVENFACT to my patient at no cost.*

Dosing Instructions (select one):

☐ **Mild and Moderate Bleeds:** Initial dose of 225 mcg/kg. If hemostasis is not achieved within 9 hours, administer additional 75 mcg/kg every 3 hours PRN until achieved.

☐ **Severe Bleeds:** 225 mcg/kg, followed if necessary 6 hours later with 75 mcg/kg every 2 hours PRN until hemostasis is achieved.

☐ Other: _____

Dispense: _____ dose(s) **75 mcg/kg;** _____ dose(s) **225 mcg/kg;** _____ dose(s) _____ **mcg/kg**

☐ HEPARIN 5 mL Flush UAD: ☐ 100 units/mL ☐ 10 units/mL **Dispense:** _____

☐ Sodium Chloride 0.9% 10 mL Flush UAD **Dispense:** _____

☐ All necessary ancillary infusion supplies required

Prescriber Authorization

By signing this Free Trial Form, I certify that the person named on this form is my patient, and I represent that information I have provided about this patient is complete, accurate and consistent with applicable privacy laws and regulations. I also certify that any medication received from HEMA Biologics is medically necessary for the patient named on this form and will be used only for this patient. I further certify that the dose requested for this patient is appropriate for this patient's medical condition.

Additionally, by signing this form, I request the free trial product listed herein and certify that I am a licensed practitioner currently authorized under applicable federal and state law to request these drug products. I also certify that I have requested these products for the legitimate medical needs of my patient. I understand the requested drug product is being provided free of charge and that the sale or offer to sell a drug product is a federal offense. I certify that I will not seek payment from a patient or third-party payor, including through federally reimbursed healthcare programs, for these drug products and I will not sell, resell, trade, barter, return for credit, or seek reimbursement for any drug product.

I understand that HEMA Biologics and companies working with HEMA Biologics may contact the applicant named in the Patient Information section for verification of applicant status and receipt of the indicated medication(s). I also agree to receive communications, including faxes, related to my patient's participation in this free trial program.

*If I am a Nurse Practitioner or Physician Assistant, I certify I am authorized and eligible, in the state in which I am now practicing, to request these drug products and I have my supervising Physician's approval to do so (if applicable).

SIGN HERE **Prescriber Signature** _____ **Date** MM / DD / YYYY

(Dispense as Written)

Please see attached full Prescribing Information, including Boxed Warning.

Prescriber must sign for the prescription(s) above and fax pages 2 and 5 to: 1-833-390-1379.