Instructions for Healthcare Providers

SevenFACT® Coagulation Factor VIIa (Recombinant)-jncw

Getting your patient started on SEVENFACT®:

1 **Patient Authorization and Consent**

After discussing SEVENFACT with your patient, have your patient read and sign sections I and II on page 2 of the Patient Authorization and Consent Form. By signing this form, your patient is electing to enroll in the HEMA Biologics Cares™ program, which may provide some product and financial support services for SEVENFACT to eligible patients.

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

2 **Enrollment Form**

You complete page 5. Fill out all sections of the Enrollment Form. Incomplete information may delay enrollment.

3 **Submit**

Fax the following completed and signed documents:

- Page 2 — Patient Authorization and Consent Form
- Page 5 — Enrollment Form
- Copy of patient's medical insurance card and pharmacy benefit card (front and back)

Fax: 1-833-390-1379

HEMA Biologics Cares™ Support Programs

SEVENFACT Co-pay Savings Program

If patients qualify for this program, HEMA Biologics Cares† can help them receive up to $12,000 in savings per calendar year*

Quick Start Program

For patients new to therapy who are experiencing an insurance coverage related delay in getting their prescription, HEMA Biologics may be able to provide SEVENFACT to assist in the interim

Bridge Program

For existing SEVENFACT patients who are experiencing a delay in getting their prescription due to a change in insurance coverage, HEMA Biologics may be able to provide SEVENFACT to assist in the interim

Patient Assistance Program‡

HEMA Biologics recognizes that not everyone has health insurance. The PAP provides SEVENFACT at no cost to patients who meet certain income requirements

* Pay as little as $0 per fill for up to 12 months from the date of SEVENFACT Co-pay Savings Card activation, subject to a maximum savings of $12,000 per calendar year. For full program requirements, visit SEVENFACT.com.

† For patients who prefer to work with their specialty pharmacy (SP) rather than HEMA Biologics Cares to access the SEVENFACT Co-pay Savings program, the SP should contact McKesson at 1-855-726-2283.

‡ This program is not available to patients who are covered under private health insurance or under Medicaid, Medicare, or any other federal, state, or government-funded benefit programs. For full program requirements, visit SEVENFACT.com.

QUESTIONS?

Call 855-718-HEMA (4362), Option 3 Monday – Friday 9:00 AM – 7:00 PM ET

Please see full Prescribing Information, including Boxed Warning.

FAX this page

SevenFACT® Coagulation Factor VIIa (Recombinant)-jncw

Patient Authorization and Consent

Patient Name: _____ **DOB:** _____

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, which may be branded as HEMA Biologics Cares (collectively, "HEMA Biologics"), my contact information, prescription information, health information relating to my medical condition which may also include the identification and/or evaluation of any potential drug interactions and allergies, and insurance coverage for HEMA Biologics, 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) provide me with support services (which may be branded as HEMA Biologics Cares) and related information and materials on any of HEMA Biologics' products, including, but not limited to, educational support provided in-person, online or by telephone, co-pay and financial assistance services, medication adherence services; (ii) conduct data analytics, market research and other internal business activities including, but not limited to evaluating the services provided; and (iii) provide me with information about HEMA Biologics' products, services, and programs and other topics of interest for marketing, educational or other purposes. 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 may refuse to sign this Authorization, and I further understand that my treatment (including with a HEMA Biologics' product), payment for treatment, insurance enrollment or eligibility for insurance benefits are not conditioned upon my agreement to sign this Authorization. However, if I do not sign this Authorization, or later cancel it, I will not be able to receive any support services from HEMA Biologics including those branded as HEMA Biologics Cares.

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 disclose 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 _____ _____

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, any of which may be branded as HEMA Biologics Cares (collectively "HEMA Biologics"), to provide me with support services related to any of HEMA Biologics' products, including but not limited to: educational support provided in-person, online or by telephone, co-pay and financial assistance services, medication adherence services, as well as any information or materials related to such services. I authorize HEMA Biologics, and companies working with HEMA Biologics, to contact me to provide such services and information 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. 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, insurance provider, or pharmacy. 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, any of which may be branded as HEMA Biologics Cares (collectively "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 _____ _____

Signature of Patient or Legal Representative **Date**

Email: _____

Please see full Prescribing Information, including Boxed Warning.

Fax pages 2 and 5 to: 1-833-390-1379.

Please provide pages 3 and 4, Patient Authorization and Consent and Important Safety Information, to the patient.

Patient Authorization and Consent – Patient Copy

SevenFACT® Coagulation Factor VIIa (Recombinant)-jncw

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

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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 may refuse to sign this Authorization, and I further understand that my treatment (including with a HEMA Biologics' product), payment for treatment, insurance enrollment or eligibility for insurance benefits are not conditioned upon my agreement to sign this Authorization. However, if I do not sign this Authorization, or later cancel it, I will not be able to receive any support services from HEMA Biologics including those branded as HEMA Biologics Cares.

I may cancel this Authorization at any time by mailing a letter to: HEMA Biologics Cares/HEMA Biologics, c/o BioMatrix Specialty Pharmacy, 855 SW 78th Avenue, Suite C200, Plantation, FL 33324. Canceling this Authorization will end my consent to further disclose 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.

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

Patient Services: I authorize HEMA Biologics and companies working with HEMA Biologics, any of which may be branded as HEMA Biologics Cares (collectively "HEMA Biologics"), to provide me with support services related to any of HEMA Biologics' products, including but not limited to: educational support provided in-person, online or by telephone, co-pay and financial assistance services, medication adherence services, as well as any information or materials related to such services. I authorize HEMA Biologics, and companies working with HEMA Biologics, to contact me to provide such services and information 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. 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, insurance provider, or pharmacy. 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, any of which may be branded as HEMA Biologics Cares (collectively "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 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 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 _____

Patient Insurance Information — *Attach copies of both sides of patient's insurance card(s).*

☐ Check here if no insurance

Policy Holder Name: _____ Relationship to Patient: _____

Primary Insurance: _____ ID #: _____ Group: _____

Secondary Insurance: _____ ID #: _____ Group: _____

Pharmacy Plan: _____ ID #: _____ Rx BIN #: _____ Rx PCN #: _____ Group: _____

Are you enrolled in any government, state or federally funded prescription benefit program? *(Medicare, Medicaid, Medigap, VA, DOD, Tricare)?* ☐ Yes ☐ No

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 _____

Current Therapy Status: ☐ New to Factor VIIa Therapy ☐ Switch from another Factor VIIa Therapy ☐ Existing SEVENFACT patient

SEVENFACT Prescription

Dosing Instructions (select one):

☐ **Mild and Moderate Bleeds:** 75 mcg/kg repeated every 3 hours PRN until hemostasis is achieved.

☐ **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**

Refills: _____

☐ HEPARIN 5 mL Flush UAD: ☐ 100 units/mL ☐ 10 units/mL

Dispense: _____ **Refills:** _____

☐ Sodium Chloride 0.9% 10 mL Flush UAD

Dispense: _____ **Refills:** _____

☐ All necessary ancillary infusion supplies required

SEVENFACT Quick Start Prescription *(Optional - Insurance Required)*

☐ *I authorize HEMA Biologics Cares to provide up to 600 mcg/kg of SEVENFACT to my patient at no cost in the event of a coverage delay. I authorize HEMA Biologics Cares to forward this prescription to the Quick Start Program designated pharmacy to dispense SEVENFACT directly to the above-named patient.*

Dosing Instructions (select one):

☐ **Mild and Moderate Bleeds:** 75 mcg/kg repeated every 3 hours PRN until hemostasis is achieved.

☐ **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 Authorization, 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.

I understand that HEMA Biologics and companies working with HEMA Biologics, any of which may be branded as HEMA Biologics Cares (collectively "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 enrollment or participation in any of the HEMA Biologics Cares support programs.

SIGN HERE **Prescriber Signature** _____ **Date** _____

(Dispense as Written)

Please see 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.