TO: [PATIENT NAME]
SUBJECT: NovoSeven® RT (coagulation Factor VIIa, recombinant) and Novoeight® (antihemophilic factor, recombinant) U.S. Supply Disruptions

Dear [insert patient name],

I am reaching out to share an important update about NovoSeven® RT (coagulation Factor VIIa, recombinant) and Novoeight® (antihemophilic factor, recombinant) that I've received from Novo Nordisk, the company that makes the medicine, as part of their commitment to sharing timely and transparent information.

Novo Nordisk has identified an issue on a specific production line that is manufacturing NovoSeven® RT, Novoeight®, and Esperoct® [antihemophilic factor (recombinant),glycopegylated-exei]. This issue has resulted in the potential under-filling of some 1 mg and 2 mg NovoSeven® RT vials on the market. However, the likelihood of an underfilled vial reaching the market is very low due to extensive manual inspections during production, which resulted in most under-filled vials being identified and removed before release.

It is important to note that Novo Nordisk's medical evaluation concluded that treatment with under-filled doses will still have effect and the probability of serious adverse health consequences is remote. Additionally, there are no underfilled vials of Novoeight® or Esperoct®. If you have any questions about this issue, please contact our office.

This manufacturing issue has led to a temporary shortage of the NovoSeven® RT 1 mg and 2 mg vials and some strengths of Novoeight® at the Novo Nordisk Distribution Center (NNDC).

- Novo Nordisk expects NovoSeven® RT 1 mg vials to be back in stock at the NNDC by around June 24, 2024. However, during this time, supply of the 1 mg vial should remain available at some Novo Nordisk Authorized Distributors. The NovoSeven® RT 2 mg vials are expected to be available in the NNDC by Monday, June 17, 2024, and they also expect the supply of the 2 mg vial to be available at some Novo Nordisk Authorized Distributors
- The NovoSeven® RT 5 mg vials are fully available. Novo Nordisk is awaiting confirmation of the availability of the NovoSeven® RT 8 mg vial and will communicate promptly when they know more.
- Novoeight® 1000 IU and 2000 IU vial sizes are expected to be out of stock until the end of July 2024, and Novoeight® 500 IU and 3000 IU vial sizes are expected to be out of stock at the NNDC from mid-June until the end of July 2024. However, we do expect stock of the 500 IU, 1000 IU, 2000 IU, and 3000 IU vial sizes to be available

at authorized specialty distributors. We continue to have an adequate stock of Novoeight® 250 IU and 1500 IU vial sizes.

If you have questions about how to make up your dose using the currently available vial sizes, please consult our office.

Based on our current understanding and inventory levels of NovoSeven® RT and Novoeight®, additional shortages are expected to be intermittent and to continue at least throughout 2024 due to this manufacturing issue, combined with unrelated release delays from the packaging line, and other continued capacity constraints. Novo Nordisk will keep our office informed if any occur.

Novo Nordisk understands the impact this may have on you and your family, and is dedicated to continuing their support for the community and ensuring the availability of these therapies.

Thank you and please know our care team is here to support you in your treatment journey.

What is NovoSeven® RT?

NovoSeven® RT (coagulation Factor VIIa, recombinant) is an injectable medicine used for:

- Treatment of bleeding and prevention of bleeding for surgeries and procedures in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with a decreased or absent response to platelet transfusions
- Treatment of bleeding and prevention of bleeding for surgeries and procedures in adults with acquired hemophilia

Important Safety Information

What is the most important information I should know about NovoSeven® RT?

NovoSeven® RT may cause serious side effects, including:

- **Serious blood clots** that form in veins and arteries with the use of NovoSeven® RT have been reported
- Your healthcare provider should discuss the risks and explain the signs and symptoms of blood clots to you. Some signs of a blood clot may include pain, swelling, warmth, redness, or a lump in your legs or arms, chest pain, shortness of breath, or sudden severe headache and/or loss of consciousness or function
- Your healthcare provider should monitor you for blood clots during treatment with NovoSeven® RT

- You should not use NovoSeven® RT if you have ever had allergic (hypersensitivity) reactions, including severe, whole body reactions (anaphylaxis) to NovoSeven® RT, any of its ingredients, or mice, hamsters, or cows. Signs of allergic reaction include shortness of breath, rash, itching (pruritus), redness of the skin (erythema), or fainting/dizziness

What should I tell my healthcare provider before using NovoSeven® RT?

- Tell your healthcare provider if you have any of the following, as these may increase your risk of blood clots:
    - congenital hemophilia and are also receiving treatment with aPCCs (activated prothrombin complex concentrates)
    - are an older patient particularly with acquired hemophilia and receiving other agents to stop bleeding
    - history of heart or blood vessel diseases
- Tell your healthcare provider and pharmacist about all the medicines you take, including all prescription and non-prescription medicines, such as over-the-counter medicines, supplements, or herbal remedies

What are the possible side effects of NovoSeven® RT?

- The most common and serious side effects are blood clots
- Tell your healthcare provider about any side effects that bother you or do not go away, and seek medical help right away if you have signs of a blood clot or allergic reaction

Please click here for NovoSeven® RT Prescribing Information, including Boxed Warning. NovoSeven RT PI (novo-pi.com)

Please click here for Esperoct® Prescribing Information. Esperoct PI (novo-pi.com)

Please click here for Novoeight® Prescribing Information. Novoeight PI (novo-pi.com)

Sincerely,

[insert HCP name/contact information]

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