



## INFORMED CONSENT FOR INTRAVENOUS (IV) IRON SUCROSE INFUSION

Patient Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

### 1. PURPOSE OF TREATMENT

Your provider at Apotheosis Health has recommended intravenous (IV) iron sucrose (Venofer or generic equivalent) based on your symptoms, medical history, and/or laboratory results showing iron deficiency, iron deficiency anemia, or low iron stores. Iron is an essential mineral your body uses to make hemoglobin, the protein in your red blood cells that carries oxygen throughout your body. When oral iron is insufficient, not well tolerated, or not appropriate for you, IV iron delivers iron directly into your bloodstream for faster and more complete repletion.

The goal of treatment is to restore your iron levels and improve iron-related symptoms. Response to treatment varies from person to person, and improvement is not guaranteed.

#### Off-Label Use

Iron sucrose is FDA-approved for iron deficiency anemia associated with chronic kidney disease. Your provider may recommend iron sucrose for other iron-deficiency conditions when, in their clinical judgment, the potential benefits outweigh the risks. This may be considered an off-label use.

### 2. DESCRIPTION OF THE PROCEDURE

- **Medication:** Iron sucrose (Venofer or generic equivalent), 200 mg per session.
- **Route:** Intravenous (IV) slow push, given over 2 to 5 minutes.
- **IV access:** A small catheter will be placed in a vein in your hand or arm. This requires a needle stick.
- **Observation:** You will be monitored for at least 30 minutes after each infusion before you are discharged.
- **Monitoring:** Your blood pressure, heart rate, and oxygen level will be checked before, during, and after the infusion.
- **Number of sessions:** Your provider will determine the total number of sessions based on your labs and clinical assessment, typically 3 to 5 sessions.

### 3. POSSIBLE BENEFITS

Possible benefits may include improved iron stores, improvement in iron deficiency anemia, and relief of symptoms related to iron deficiency such as fatigue, weakness, and shortness of breath. Benefits are not guaranteed, and additional testing or treatment may still be needed.

### 4. RISKS OF IV ACCESS

Placing an IV catheter carries the following potential risks:

- Pain, bruising, redness, or discomfort at the insertion site
- Swelling or hematoma (a collection of blood under the skin)
- Infiltration or extravasation (leaking of fluid or medication into the surrounding tissue)

- Phlebitis (inflammation of the vein), which may cause redness, warmth, or tenderness along the vein
- Infection at the IV site (rare)
- Nerve irritation near the insertion site (rare)
- The need for more than one needle stick if the first attempt is not successful

## 5. RISKS AND SIDE EFFECTS OF IV IRON SUCROSE

### Common side effects (may occur during or shortly after the infusion):

- Metallic or unusual taste in the mouth
- Nausea or stomach discomfort
- Headache, dizziness, or lightheadedness
- Flushing, warmth, or redness of the skin
- Mild muscle cramps, joint aches, or back pain
- Temporary drop in blood pressure (hypotension)
- Mild injection site reactions (redness, swelling, or discomfort)

These are usually mild and resolve on their own within a few hours.

#### Fishbane Reaction

A small number of patients have a reaction within the first few minutes of the infusion that can include facial flushing and a feeling of tightness or pressure in the chest, back, or joints, sometimes with mild anxiety. This is known as a Fishbane reaction (a complement activation-related pseudo-allergy, or CARPA). It is NOT a true allergic reaction and is NOT anaphylaxis. It usually settles on its own. If it happens, staff will pause the infusion, monitor you, and let the symptoms pass before deciding whether to continue. Having a Fishbane reaction does not necessarily prevent you from receiving future iron infusions.

#### IV Leakage and Skin Staining (Extravasation)

Iron sucrose is highly concentrated and can irritate the skin if it leaks out of the vein. Leakage can cause pain, swelling, and a long-lasting or sometimes permanent brown or gray discoloration of the skin at or near the IV site. To reduce this risk, your IV site will be monitored closely during the infusion. Tell staff immediately if you feel any burning, stinging, or coldness at the IV site.

### Serious but rare risks:

- **True allergic (hypersensitivity) reaction:** This is rare but can be severe, life-threatening, or fatal. Symptoms include difficulty breathing, wheezing, swelling of the face, lips, tongue, or throat, and a sudden drop in blood pressure. Emergency medications and equipment are available onsite.
- **Severe hypotension:** A significant drop in blood pressure.
- **Iron overload:** If too much iron is given or if iron levels are not properly monitored.
- **Delayed reactions:** Rash, itching, joint pain, or muscle aches occurring hours to days after the infusion.
- **Cardiac arrhythmia:** Irregular heartbeat (rare).

I understand that serious reactions can occur even if I have received iron or IV medications before without any difficulty.

## 6. PATIENT HEALTH SCREENING

For your safety, please tell us if any of the following apply to you:

- A prior reaction or allergy to iron sucrose, Venofer, or any IV iron product
- Known iron overload, hemochromatosis, or high iron levels
- Anemia that is not caused by iron deficiency
- Fever, a current infection, or feeling acutely ill (IV iron is generally avoided during an active infection)
- Pregnancy, possible pregnancy, trying to conceive, or breastfeeding

- A history of severe allergies, anaphylaxis, asthma, a mast cell disorder, or multiple medication reactions
- Liver disease, kidney disease, heart disease, low blood pressure, or other significant medical conditions
- A recent blood transfusion or recent IV iron treatment elsewhere
- Any new medication, supplement, or change in your health since your last visit

I understand that IV iron may be delayed, modified, or declined if my provider determines it is not safe or appropriate for me.

## 7. MONITORING AND EMERGENCY CARE

I understand that Apotheosis Health staff will monitor me during treatment and that I must remain in the office for an observation period after treatment, typically at least 30 minutes, or longer if clinically needed.

I agree to tell staff right away if I develop any symptoms during or after treatment, including itching, rash, hives, swelling, chest pain or tightness, throat tightness, trouble breathing, dizziness, faintness, severe nausea, severe abdominal pain, weakness, confusion, or anything that feels concerning.

If a reaction occurs, I authorize Apotheosis Health staff to stop the treatment and provide appropriate emergency care within the clinic's scope. This may include vital sign monitoring, medications, oxygen, IV fluids, emergency response measures, and/or calling 911 for ambulance transport to an emergency department.

## 8. POST-INFUSION OBSERVATION

I understand I am required to remain in the clinic for at least 30 minutes after my infusion so that staff can monitor my vital signs and watch for any reaction. I understand I may not leave before the observation period is complete unless directed by my provider. If I choose to leave against medical advice before the observation period is finished, I do so at my own risk, and I release Apotheosis Health from liability for any adverse event that occurs after I leave the clinic.

## 9. INSTRUCTIONS AFTER YOU LEAVE

Minor symptoms such as mild headache, fatigue, muscle aches, or darker-colored stool can sometimes occur after an iron infusion and are usually not a cause for concern. Please contact Apotheosis Health through Spruce or by phone with any non-emergency concerns.

Call 911 or go to the nearest emergency department right away if you experience any of the following after leaving:

- Difficulty breathing, wheezing, or shortness of breath
- Swelling of the face, lips, tongue, or throat
- Chest pain or chest tightness
- Rapid or irregular heartbeat
- Severe dizziness, lightheadedness, or fainting
- Widespread hives, rash, or severe itching
- Severe nausea, vomiting, or abdominal pain
- Fever, chills, or shaking
- A feeling of impending doom or sudden severe anxiety

If you have an emergency symptom, seek emergency care first, then notify Apotheosis Health as soon as you are able.

## 10. ALTERNATIVES TO IV IRON

Alternatives have been discussed with me and may include:

- Oral iron supplements (which work more slowly and can cause stomach upset or constipation)

- Dietary changes to increase iron intake
- Monitoring without treatment
- Further evaluation to find the cause of iron deficiency (such as evaluation for bleeding or heavy menstrual periods)
- Referral to a specialist
- A blood transfusion (usually reserved for severe or urgent cases)
- Another type of IV iron medication
- No treatment, understanding that untreated iron deficiency may worsen and can cause fatigue, weakness, shortness of breath, strain on the heart, and reduced quality of life

I understand I may choose not to receive IV iron treatment.

## 11. FINANCIAL RESPONSIBILITY

I understand that Apotheosis Health is a Direct Primary Care (cash-pay) practice and does not bill insurance for this service. I understand the cost of treatment, including the medication, supplies, IV access, administration, and the observation period, has been explained to me before treatment. Payment is due at the time of service. I understand that payment does not guarantee a specific clinical result.

## 12. RIGHT TO WITHDRAW CONSENT

I understand I may refuse this treatment or withdraw my consent at any time, before or during the procedure, without penalty and without affecting my continued care at Apotheosis Health. If I stop the infusion once it has begun, the clinical team will ensure my safety and manage any immediate effects.

## 13. CONSENT

By signing below, I confirm that:

- ☐ I have read this form, or had it read to me, and I understand it. The reason for treatment, the expected benefits, the alternatives, and the risks have been explained to me, and I have had the opportunity to ask questions, which have been answered to my satisfaction. I understand the difference between a Fishbane reaction and a true allergic reaction, and that a Fishbane reaction, while uncomfortable, is not life-threatening. I understand I must remain in the clinic for at least 30 minutes after the infusion for observation, and I understand what symptoms to watch for after leaving and when to seek emergency care. I understand this is a cash-pay service and I am financially responsible for the cost of treatment. I understand the risks of this treatment, including the rare risk of a severe allergic reaction, emergency transfer, hospitalization, or death, and I voluntarily consent to receive IV iron sucrose treatment at Apotheosis Health.

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Patient Signature

\_\_\_\_\_  
Date & Time

\_\_\_\_\_  
Clinician Printed Name

\_\_\_\_\_  
Date & Time

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Clinician Signature