Daiichi-Sankyo | access central

A single source for support

injectafer® ferric carboxymaltose injection

INJECTAFER PATIENT ENROLLMENT FORM

injectconnect™

HOW TO USE THIS FORM

- Complete all required fields
- Print the form
- Obtain physician and patient signatures on page 1
- Fax it to 888-354-4856
- Give patient a copy of the Patient Consent Form on page 3

Upon receiving the form, the IV Iron Hotline will be able to assess patient eligibility for Injectafer support programs as well as conduct a benefits verification if requested.

IV IRON HOTLINE

877-4-IV-IRON
(877-448-4766)

www.DSIAccessCentral.com

Fax: **888-354-4856**

Which programs does your patient need assistance with? Select all that apply.

☐ Benefits verification ☐ Prior authorization support ☐ Claims appeal ☐ Injectafer Patient Assistance Program

1 PATIENT INFORMATION

Full Name: **Date of Birth:** - - **Sex:** ☐ Male ☐ Female

Phone: - - **Phone Type:** ☐ Home ☐ Mobile ☐ Work **Email:**

Address: **City:** **State:** **Zip:**

Primary Diagnosis Code (ICD-10-CM): **Secondary Diagnosis Code (ICD-10-CM):**

Permission to contact patient? ☐ Yes ☐ No **Best time to contact patient?** ☐ Morning ☐ Afternoon ☐ Evening

2 PATIENT INSURANCE INFORMATION

☐ Uninsured **Insurance Type:** ☐ Commercial/Private ☐ Medicare ☐ Medicaid ☐ Medicare Advantage ☐ Veterans Affairs (VA) ☐ Other

HEALTH PLAN INFORMATION

Plan Name:

Plan Phone Number: - -

Beneficiary Name:

Beneficiary Date of Birth: - -

Policy ID: **Group No.:**

SECONDARY INSURANCE INFORMATION (optional)

Plan Name:

Plan Phone Number: - -

Policy ID: **Group No.:**

3 HEALTHCARE PROVIDER INFORMATION

Physician Name: **Practice Name:** **UPIN/NPI:**

Office Contact: **Phone:** - - **Fax:** - - **Email:**

Address: **City:** **State:** **Zip:**

4 PHYSICIAN ATTESTATION

I confirm that I have read and understood the Physician Attestation on page 2 of this form and agree to the terms explained therein.

Physician Signature: _____ **Date:** - -

5 PATIENT CONSENT

I confirm that I have read and understood the Patient Consent on page 3 of this form and agree to the terms explained therein.

Name: **Patient Signature:** _____ **Date:** - -

For Representatives: If a representative for the patient needs to sign this form, please indicate the representative's authority to sign on behalf of the patient (eg, healthcare power of attorney, healthcare proxy, court-appointed legal guardian). Healthcare office staff cannot sign on behalf of the patient.

Representative Name: **Phone:** - -

Reason for Authority:

Representative Attestation: I confirm that I have the legal right to sign this form (as stated above) on behalf of the patient. I confirm that I have read and understood the Patient Consent on page 3 of this form and agree to the terms explained therein. **Permission to contact representative?** ☐ Yes ☐ No

Representative Signature: _____ **Date:** - -

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PHYSICIAN ATTESTATION

By providing my signature on page 1 of this form, I attest that I am the prescribing healthcare provider and have determined that prescribing Injectafer® (ferric carboxymaltose injection) is medically appropriate and have explained the reasons for doing so to my patient. I also agree to submit requests to Daiichi Sankyo Access Central on behalf of my patient so that his or her eligibility can be evaluated to determine access to various assistance programs.

I certify that I have received the necessary consent from my patient to release the information referenced above and other protected health information (as defined by the Health Insurance Portability and Accountability Act [HIPAA] of 1996) to Daiichi Sankyo Access Central and/or its service providers. The patient has confirmed his or her consent by reading page 3 of this form and providing his or her signature on page 1 of this form.

I agree to notify Daiichi Sankyo Access Central or its service providers if I become aware at any time of changes in my patient's circumstances that would affect his or her eligibility for any Daiichi Sankyo Access Central programs, including, but not limited to, changes in health insurance status or coverage, financial status, residency status in the United States, or the indication for which Injectafer has been prescribed for my patient. I understand that Daiichi Sankyo, Inc., a parent company of American Regent, Inc. (AR), reserves the right to change or terminate any Daiichi Sankyo Access Central services (including the Injectafer Savings Program or Injectafer Patient Assistance Program) at any time or to refuse to provide Injectafer to any patient under the Injectafer Patient Assistance Program.

If my patient obtains Injectafer via the Injectafer Patient Assistance Program, I attest that I understand the following:

- No third party or patient can be charged for Injectafer under such program
- No free product should be sold, traded, or distributed for sale
- Any free drug provided is not contingent upon future purchase or prescribing of Injectafer

By signing page 1 of this form, I certify that a copy of the Patient Consent has been given to the patient named on page 1 or his or her representative.

injectafer® ferric carboxymaltose injection

PATIENT CONSENT

Release of Personal Information

By providing my signature on page 1 of this form, I authorize my physician(s), healthcare provider(s), and health insurance company to disclose information about me (for example, my name, address, and insurance policy number) and my medical condition (for example, my diagnosis or medications) to Daiichi Sankyo, Inc., a parent company of American Regent, Inc. (AR), and its third-party vendors, suppliers, and other service providers supporting Daiichi Sankyo Access Central (herein described collectively as "service providers"). I authorize service providers supporting Daiichi Sankyo Access Central to share information about me with each other. I recognize that this type of personally identifiable information (PII) could include spoken or written facts about my health or healthcare or copies of records about my health and insurance benefits provided by my healthcare provider(s) or health plan. My decision to sign this form (or not to sign this form) will not affect the treatment I receive from any healthcare professional or entity involved in my care or coverage.

Use of Personal Information

I understand that the service providers could use or provide my information in one or more of the following ways:

- Assess my eligibility and assist with my enrollment in a Daiichi Sankyo support program, including the Injectafer Savings Program or the Injectafer Patient Assistance Program, and contact me (and/or my legal representative) about my eligibility and enrollment status
- Verify, investigate, and help coordinate my coverage for Injectafer with my health insurance company
- Assist with analyses of the efficiencies and performance of the services provided by service providers
- Provide me (and/or my legal representative) with educational materials, information, and support relating to the Daiichi Sankyo Access Central services
- Provide support to appeal any insurance denials

In some instances, the service providers may de-identify my information and use or disclose the de-identified information (in individual or aggregated form) for any legitimate business purposes. I understand that the service providers will make reasonable efforts to keep my information private; however, I understand that once my information has been disclosed to the service providers, how the service providers further disclose my information may no longer be protected under federal and state privacy laws. I understand that Daiichi Sankyo Access Central is a component of Daiichi Sankyo, Inc., a parent company of American Regent, Inc. (AR), and that the service providers may be compensated by Daiichi Sankyo, Inc., a parent company of American Regent, Inc. (AR). My healthcare providers may also receive remuneration, or payment, for disclosing my information pursuant to this consent document.

Consent Terms

This consent will last for 3 years from the date on this form or until I am no longer receiving Injectafer or enrolled in any Daiichi Sankyo Access Central services. I recognize that I do not have to sign the consent on page 1, but if I do not, I will not be able to have my insurance coverage verified, be given referrals for alternative funding sources, or have access to other services provided by or on behalf of Daiichi Sankyo Access Central. My decision to sign this form will not affect the treatment I receive from any healthcare professional or entity involved in my care or coverage. I may cancel this consent at any time by contacting the IV Iron Hotline at 877-4-IV-IRON (877-448-4766). By doing so, I revoke my consent for my healthcare provider to disclose my health information to Daiichi Sankyo, Inc., a parent company of American Regent, Inc. (AR), or its service providers as well as discontinue my participation in the support program. I recognize that revoking my consent will not affect the use or the disclosure of health information that was already disclosed before my cancellation. I confirm that I have received a copy of this consent, and I know I have a right to see or copy the information my healthcare providers or payers have given to the service providers.

Additional Information to Assess Eligibility for the Injectafer Patient Assistance Program

I agree to allow Daiichi Sankyo, Inc., a parent company of American Regent, Inc. (AR), and its associated service providers to use my demographic information, including, but not limited to, my name, date of birth, and/or address as needed to access my credit information and information derived from public and other sources. This includes information from a consumer reporting agency (credit bureau) to estimate my income in conjunction with the eligibility determination process performed to determine my eligibility under the Injectafer Patient Assistance Program. Daiichi Sankyo, Inc., a parent company of American Regent, Inc. (AR), and its associated service providers reserve the right to request additional documents and information at any time. I agree to notify my healthcare providers if I undergo any changes that would, to my knowledge, affect my eligibility, including, but not limited to, changes in health insurance status or coverage, financial status, and my residing status in the United States.

The terms of this document are governed by and interpreted in accordance with the laws of the state of New Jersey, excluding New Jersey conflict of law rules, and applicable federal law.

injectafer® ferric carboxymaltose injection

INDICATIONS

Injectafer® (ferric carboxymaltose injection) is an iron replacement product indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, and in adult patients with non-dialysis dependent chronic kidney disease.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Injectafer is contraindicated in patients with hypersensitivity to Injectafer or any of its inactive components.

WARNINGS AND PRECAUTIONS

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Injectafer. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Injectafer administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Injectafer when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. In clinical trials, serious anaphylactic/anaphylactoid reactions were reported in 0.1% (2/1775) of subjects receiving Injectafer. Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but were not limited to, pruritus, rash, urticaria, wheezing, or hypotension were reported in 1.5% (26/1775) of these subjects.

In clinical studies, hypertension was reported in 3.8% (67/1775) of subjects. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/1775) of subjects. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Injectafer administration.

In the 24 hours following administration of Injectafer, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in Injectafer.

ADVERSE REACTIONS

In two randomized clinical studies, a total of 1775 patients were exposed to Injectafer, 15 mg/kg of body weight, up to a single maximum dose of 750 mg of iron on two occasions, separated by at least 7 days, up to a cumulative dose of 1500 mg of iron. Adverse reactions reported by ≥2% of Injectafer-treated patients were nausea (7.2%); hypertension (3.8%); flushing/hot flush (3.6%); blood phosphorus decrease (2.1%); and dizziness (2.0%).

The following serious adverse reactions have been most commonly reported from the post-marketing spontaneous reports: urticaria, dyspnea, pruritus, tachycardia, erythema, pyrexia, chest discomfort, chills, angioedema, back pain, arthralgia, and syncope.

To report adverse events, please contact American Regent at 1-800-734-9236. You may also contact the FDA at www.fda.gov/medwatch or 1-800-FDA-1088.

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