Daiichi-Sankyo | access central

A single source for support

injectafer® ferric carboxymaltose injection

INJECTAFER PATIENT ENROLLMENT FORM

PLEASE SUBMIT THIS FORM **PRIOR** TO INJECTAFER ADMINISTRATION

- Complete all required fields
- Print the form
- Obtain physician and patient signatures on page 1
- Fax it to 1-833-471-9988
- Give patient a copy of the Patient Consent on page 3

Upon receiving the form, Daiichi Sankyo Access Central will be able to assess patient eligibility for Injectafer support programs as well as conduct a benefits verification if requested.

DAIICHI SANKYO ACCESS CENTRAL

1-866-4-DSI-NOW (1-866-437-4669)

www.DSIAccessCentral.com

Fax: **1-833-471-9988**

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

☐ Benefits verification ☐ Prior authorization support ☐ Claims appeal ☐ 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

Expected Date of Infusion: - -

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:**

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

Address: **City:** **State:** **ZIP:**

Prescriber Tax ID: **UPIN/NPI:**

If administering practice differs from provider practice, complete this section with administering practice information:

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

Address: **City:** **State:** **ZIP:**

Prescriber Tax ID: **UPIN/NPI:**

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:** - -

Must be a physical signature.

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, parent, 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 Patient Assistance Program) at any time or to refuse to provide Injectafer to any patient under the Patient Assistance Program.

If my patient obtains Injectafer via the 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 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 Daiichi Sankyo Access Central at 866-4-DSI-NOW (866-437-4669). 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 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 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

INDICATION

Injectafer® (ferric carboxymaltose injection) is indicated for the treatment of iron deficiency anemia (IDA) in adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron, and in adult patients who have non-dialysis dependent chronic kidney disease. Injectafer is also indicated for iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Symptomatic Hypophosphatemia

Symptomatic hypophosphatemia with serious outcomes including osteomalacia and fractures requiring clinical intervention has been reported in patients treated with Injectafer in the post-marketing setting. These cases have occurred mostly after repeated exposure to Injectafer in patients with no reported history of renal impairment. However, symptomatic hypophosphatemia has been reported after one dose. Possible risk factors for hypophosphatemia include a history of gastrointestinal disorders associated with malabsorption of fat-soluble vitamins or phosphate, inflammatory bowel disease, concurrent or prior use of medications that affect proximal renal tubular function, hyperparathyroidism, vitamin D deficiency, malnutrition, and hereditary hemorrhagic telangiectasia (HHT or Osler-Weber-Rendu syndrome). In most cases, hypophosphatemia resolved within three months.

Correct pre-existing hypophosphatemia prior to initiating therapy with Injectafer. Monitor serum phosphate levels in patients at risk for chronic low serum phosphate. Check serum phosphate levels prior to a repeat course of treatment in patients at risk for low serum phosphate and in any patient who receives a second course of therapy within three months. Treat hypophosphatemia as medically indicated.

Hypersensitivity Reactions

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.

Hypertension

In clinical studies, hypertension was reported in 4% (67/1775) of subjects in clinical trials 1 and 2. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/1775) of subjects in these two clinical trials. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Injectafer administration.

Laboratory Test Alterations

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

Adults

In two randomized clinical studies [Studies 1 and 2], a total of 1775 patients were exposed to Injectafer, 15 mg/kg of body weight, up to a maximum single 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 (4%); flushing (4%); injection site reactions (3%); erythema (3%); hypophosphatemia (2.1%); and dizziness (2.1%).

Pediatric

The safety of Injectafer in pediatric patients was evaluated in Study 3. Study 3 was a randomized, active-controlled study in which 40 patients (1 to 12 years of age: 10 patients, 12 to 17 years of age: 30 patients) received Injectafer 15 mg/kg to a maximum single dose of 750 mg (whichever was smaller) on Days 0 and 7 for a maximum total dose of 1500 mg; 38 patients evaluable for safety in the control arm received an age-dependent formulation of oral ferrous sulfate for 28 days. The median age of patients who received Injectafer was 14.5 years (range, 1-17); 83% were female; 88% White and 13% Black. The most common adverse reactions (≥4%) were hypophosphatemia (13%), injection site reactions (8%), rash (8%), headache (5%), and vomiting (5%).

Patients with Iron Deficiency and Heart Failure

The safety of Injectafer was evaluated in adult patients with iron deficiency and heart failure in randomized controlled trials FAIR-HF (NCT00520780), CONFIRM-HF (NCT01453608) and AFFIRM-AHF (NCT02937454) in which 1016 patients received Injectafer versus 857 received placebo. The overall safety profile of Injectafer was consistent across the studied indications.

Post-Marketing Experience

The following adverse reactions have been identified during post approval use of Injectafer. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions have been reported from the post-marketing spontaneous reports with Injectafer: *cardiac disorders*: tachycardia; *general disorders and administration site conditions*: chest discomfort, chills, pyrexia; *metabolism and nutrition disorders*: hypophosphatemia; *musculoskeletal and connective tissue disorders*: arthralgia, back pain, hypophosphatemic osteomalacia; *nervous system disorders*: syncope; *respiratory, thoracic and mediastinal disorders*: dyspnea; *skin and subcutaneous tissue disorders*: angioedema, erythema, pruritus, urticaria; *pregnancy*: fetal bradycardia.

CLINICAL CONSIDERATIONS IN PREGNANCY

Untreated IDA in pregnancy is associated with adverse maternal outcomes such as postpartum anemia. Adverse pregnancy outcomes associated with IDA include increased risk for preterm delivery and low birth weight.

Severe adverse reactions including circulatory failure (severe hypotension, shock including in the context of anaphylactic reaction) may occur in pregnant women with parenteral iron products (such as Injectafer) which may cause fetal bradycardia, especially during the second and third trimester.

You are encouraged to report Adverse Drug Events to American Regent, Inc. at 1-800-734-9236 or to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

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