HELPING YOUR PATIENTS ACCESS INJECTAFER

injectafer® ferric carboxymaltose injection

Your patients and your practice are important to us. Daiichi Sankyo, Inc. is committed to helping appropriate patients get access to Injectafer by providing access and reimbursement support.

Offering support along the way

COVERAGE AND ACCESS SUPPORT

- **Insurance and claims assistance:** Expert help from reimbursement specialists
- **Billing and coding:** Important information related to Injectafer reimbursement

FINANCIAL ASSISTANCE

- **Injectafer Savings Program:** Copay savings may help reduce patients' out-of-pocket costs*
- **Patient Assistance Program:** Help for uninsured or commercially underinsured patients with financial need

CONTACT DAIICHI SANKYO ACCESS CENTRAL

1-866-4-DSI-NOW (1-866-437-4669)
DSIAccessCentral.com

Available Monday–Friday,†
8:00 AM–6:00 PM ET

*The Injectafer Savings Program is only available for patients who are commercially insured. Please see full Terms and Conditions on page 12.
†Excludes holidays.

INDICATIONS

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

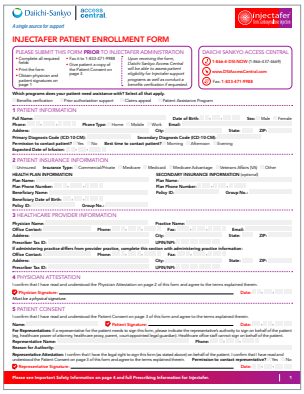
CONTRAINDICATIONS

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

Please see Important Safety Information on pages 14-15 and click here for full Prescribing Information for Injectafer.

Insurance and claims assistance

Expert help from reimbursement specialists


Daiichi-Sankyo | ACCESS central

A single source for support

INJECTAFER PATIENT ENROLLMENT FORM

PLEASE SUBMIT THIS FORM PRIOR TO INJECTAFER ADMINISTRATION

DAIICHI SANKYO ACCESS CENTRAL

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

1 PATIENT INFORMATION

2 PATIENT INSURANCE INFORMATION

3 HEALTHCARE PROVIDER INFORMATION

4 PHYSICIAN ATTESTATION

5 PATIENT CONSENT

Please see Important Safety Information on page 4 and full Prescribing Information for Injectafer.

To get help, **your first step is to fill out the Patient Enrollment Form** and check off the support you require for your patient. We will take it from there.

Based on the support you requested, we will offer you help with:

- Benefits verifications
- Prior authorizations
- Claims appeals
- Financial assistance options

Click here to download helpful resources, including the Patient Enrollment Form and Sample Letter of Medical Necessity. If you have any questions regarding reimbursement, call Daiichi Sankyo Access Central at 1-866-4-DSI-NOW.

IMPORTANT SAFETY INFORMATION

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, and malnutrition. 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.

injectafer® ferric carboxymaltose injection

Billing and coding

Important information related to Injectafer reimbursement

Proper billing and coding can help ensure eligible patients receive the proper program support. The following codes may be helpful to facilitate Injectafer reimbursement. The completion and submission of coverage-related documentation are the responsibility of the patient and healthcare provider.

Injectafer 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
  - adult patients who have non-dialysis dependent chronic kidney disease
- iron deficiency (ID) in adult patients with heart failure (HF) and New York Heart Association (NYHA) class II/III to improve exercise capacity

Product and administration codes

Code Type	Code	Description
Product Package Codes		
NDC	0517-0602-01	Injectafer 100 mg iron/2 mL single-use vial (individually boxed)
	0517-0650-01	Injectafer 750 mg iron/15 mL single-dose vial (individually boxed)
Product-Specific Billing Code		
HCPCS	**J1439**	**Injection, ferric carboxymaltose 1 mg**
Drug Administration Codes		
CPT®*	96374 or 96365	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour

CPT, Current Procedural Terminology; FARS/DFARS, Federal Acquisition Regulation/Defense Federal Acquisition Regulation Supplement; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

injectafer® ferric carboxymaltose injection

Examples of ID/IDA-related diagnosis codes

Injectafer claims forms require an appropriate ICD-10-CM code. The following table displays possible ICD-10-CM codes related to ID/IDA.*

Code	Description
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.1	Sideropenic dysphagia
D50.8	Other iron deficiency anemias
D50.9	Iron deficiency anemia, unspecified
E61.1	Iron deficiency (excludes iron deficiency anemia)
D63.0	Anemia in neoplastic disease CODE NEOPLASM FIRST (Confirm iron deficiency)
D63.1	Anemia in chronic kidney disease CODE CKD STAGE FIRST (Confirm iron deficiency)
D63.8	Anemia in other chronic diseases classified elsewhere CODE UNDERLYING DISEASE FIRST (Confirm iron deficiency)
D63.81	Antineoplastic chemotherapy-induced anemia (Confirm iron deficiency)

Other codes may be appropriate.

Coding for Injectafer is dependent on the insurer and the care setting in which the drug will be administered. These tables are provided for informational purposes only, and you have the responsibility to ensure that claims and codes submitted are accurate, complete, and applicable. Healthcare providers need to make coding decisions based on the diagnosis and treatment of each patient and the specific insurer. Please visit CMS.gov or other payers' websites to obtain additional guidance on their processes.

*A joint effort between the healthcare provider and the coder is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures. This information is provided to assist both the healthcare provider and the coder in identifying potential diagnoses. The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation, accurate coding cannot be achieved. The entire record should be reviewed to determine the specific reason for the encounter and the conditions treated.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

injectafer® ferric carboxymaltose injection

A code specific for your IDA patient's underlying condition*

The following table displays possible ICD-10-CM codes that may be appropriate for patients prescribed Injectafer.†

Code	Description
K50.0-K50.919	Crohn's disease [regional enteritis]
K51.0-K51.919	Ulcerative colitis
K90.0	Celiac disease
K90.4	Malabsorption due to intolerance not elsewhere classified
K90.9	Intestinal malabsorption unspecified
N18.1	Chronic kidney disease, stage 1
N18.2	Chronic kidney disease, stage 2
N18.30	Chronic kidney disease, stage 3 unspecified
N18.31	Chronic kidney disease, stage 3a
N18.32	Chronic kidney disease, stage 3b
N18.4	Chronic kidney disease, stage 4

Code	Description
N18.5	Chronic kidney disease, stage 5
N18.6	End-stage renal disease
N18.9	Chronic kidney disease, unspecified
N92.0	Excessive and frequent menstruation with regular cycle
N92.5	Other specified irregular menstruation
N92.6	Irregular menstruation, unspecified
T45.4X5A	Adverse effect of iron and its compounds, initial encounter
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter

*Secondary code suggestions only; appropriate codes not limited to those listed above. Injectafer is indicated to treat ID in adult patients with HF and NYHA II/III to improve exercise capacity; it is not indicated to treat the above-listed underlying conditions. Some listed diagnosis codes may indicate a subcategory and be nonbillable. For reporting purposes, only codes with the full number of required characters are permissible.

†A joint effort between the healthcare provider and the coder is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures. This information is provided to assist both the healthcare provider and the coder in identifying potential diagnoses. The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation, accurate coding cannot be achieved. The entire record should be reviewed to determine the specific reason for the encounter and the conditions treated.

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A code for your adult patient with ID in HF*

The following table displays possible ICD-10-CM codes that may be appropriate for patients prescribed Injectafer.†

Code	Description
I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure
I50	Heart failure
I50.1	Left ventricular failure, unspecified
I50.2	Systolic (congestive) heart failure
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.3	Diastolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure

Code	Description
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.4	Combined systolic and diastolic (congestive) heart failure
I50.40	Unspecified combined systolic and diastolic (congestive) heart failure
I50.41	Acute combined systolic and diastolic (congestive) heart failure
I50.42	Chronic combined systolic and diastolic heart failure
I50.43	Acute on chronic combined systolic and diastolic heart failure
I50.8	Other heart failure
I50.81	Right heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure

Continued on the next page.

*Secondary code suggestions only; appropriate codes not limited to those listed above. Injectafer is indicated to treat ID in adult patients with HF and NYHA II/III to improve exercise capacity; it is not indicated to treat the above-listed underlying conditions. Some listed diagnosis codes may indicate a subcategory and be nonbillable. For reporting purposes, only codes with the full number of required characters are permissible.

†A joint effort between the healthcare provider and the coder is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures. This information is provided to assist both the healthcare provider and the coder in identifying potential diagnoses. The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation, accurate coding cannot be achieved. The entire record should be reviewed to determine the specific reason for the encounter and the conditions treated.

injectafer® ferric carboxymaltose injection

A code for your adult patient with ID in HF* (*cont'd*)

The following table displays possible ICD-10-CM codes that may be appropriate for patients prescribed Injectafer.†

Code	Description
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified

We recommend verifying the coding policies for each individual health plan. Reimbursement specialists can provide information relating to payer-specific policies and can address other questions at 1-866-4-DSI-NOW.

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Daiichi Sankyo, Inc. makes no representation or guarantee concerning coverage or reimbursement for any service or item. A completed form includes signatures from both the physician and the patient. Before submitting, please ensure all required information is provided.

*Secondary code suggestions only; appropriate codes not limited to those listed above. Injectafer is indicated to treat ID in adult patients with HF and NYHA II/III to improve exercise capacity; it is not indicated to treat the above-listed underlying conditions. Some listed diagnosis codes may indicate a subcategory and be nonbillable. For reporting purposes, only codes with the full number of required characters are permissible.

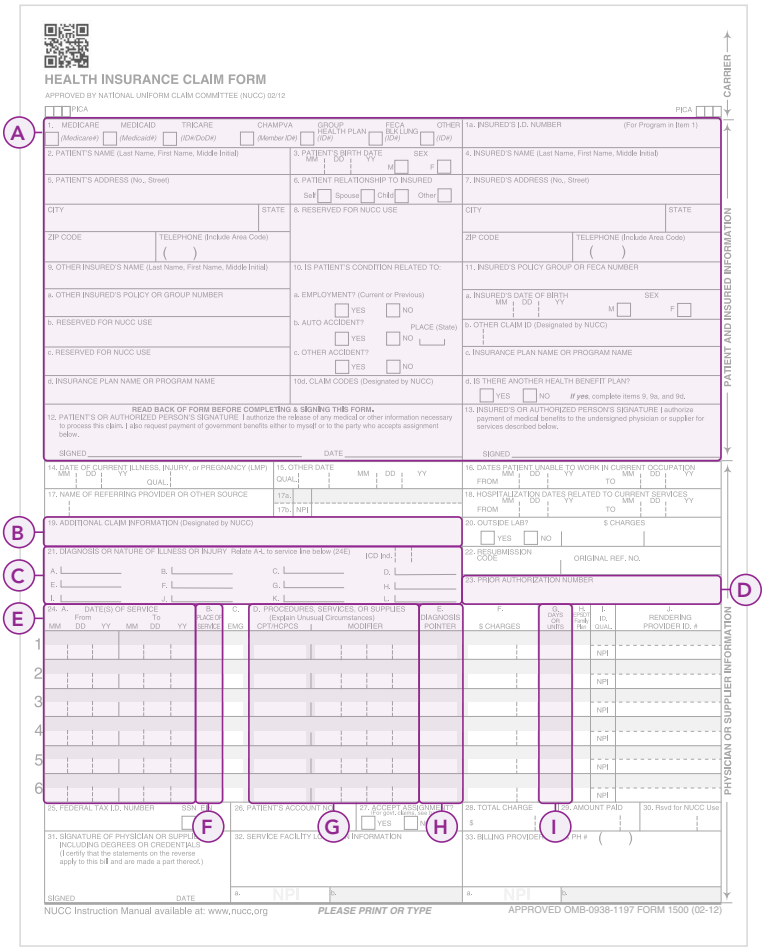
†A joint effort between the healthcare provider and the coder is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures. This information is provided to assist both the healthcare provider and the coder in identifying potential diagnoses. The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation, accurate coding cannot be achieved. The entire record should be reviewed to determine the specific reason for the encounter and the conditions treated.

injectafer® ferric carboxymaltose injection

Annotated claim form: CMS-1500 (to be used by physician offices)

Be complete, precise, and accurate

The annotations below are intended as a guide and are not comprehensive or conclusive for required entries.



A **Boxes 1-13:** Enter the patient's personal and insurance information.

B **Box 19:** Payer may instruct you to provide additional information such as drug name, NDC, date of treatment, total dose administered, route of administration, amount of drug wasted, and more.

C **Box 21:** Enter the appropriate ICD-10-CM diagnosis codes (both ID/IDA-related and underlying condition) and the applicable ICD indicator identifying which ICD code version is being reported (ie, enter a "0" for ICD-10-CM).

D **Box 23:** If required, enter the prior authorization number.

E **Box 24A:** Enter dates of service for each Injectafer administration.

F **Box 24B:** Enter code for place of service for each date at the left (eg, 11 for physician offices).

G **Box 24D:** Enter CPT code for Injectafer administration: **96374** (slow IV push) or **96365** (IV infusion). On a separate row, enter the unique product-specific billing code (HCPCS) for Injectafer: **J1439**

H **Box 24E:** Enter the diagnosis code reference letter, as shown in Box 21. Enter only one reference letter per line item.

I **Box 24G:** Enter the appropriate number of units: For Injectafer, 1 mg = 1 unit. Total units reported will depend on total dosage administered.

We recommend verifying the coding policies for each individual health plan. Reimbursement specialists can provide information relating to payer-specific policies and can address other questions at 1-866-4-DSI-NOW (1-866-437-4669). Additionally, your Daiichi Sankyo, Inc. Associate Director, Field Reimbursement (ADFR) can serve as a point of contact for your practice.

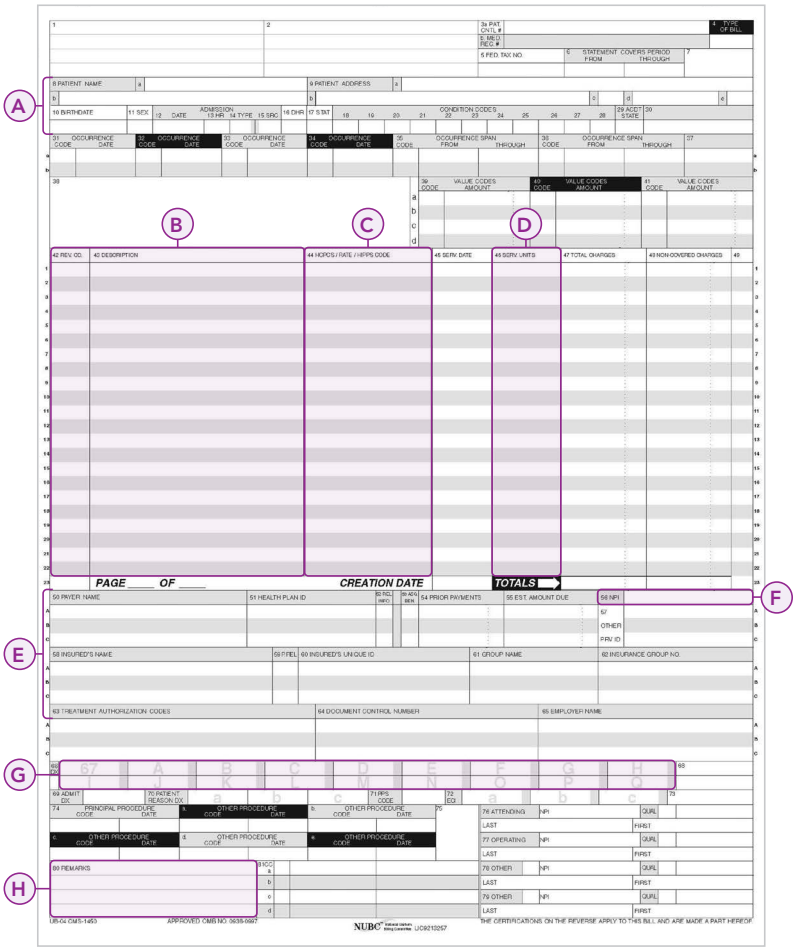
The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Daiichi Sankyo, Inc. makes no representation or guarantee concerning coverage or reimbursement for any service or item.

injectafer® ferric carboxymaltose injection

Annotated claim form: CMS-1450 UB-04 for institutions, either inpatient or outpatient hospital settings

Be complete, precise, and accurate

The annotations below are intended as a guide and are not comprehensive or conclusive for required entries.



- **A** **Boxes 8-15:** Enter the patient's personal information.
- **B** **Boxes 42-43:** Enter the appropriate revenue codes and description corresponding to the HCPCS code listed in Box 44.
- **C** **Box 44:** Enter CPT code for Injectafer administration: **96374** (slow IV push) or **96365** (IV infusion). On a separate line, enter the unique product-specific billing code (HCPCS) for Injectafer: **J1439**
- **D** **Box 46:** Enter the appropriate number of units: For Injectafer, 1 mg = 1 unit. Total units reported will depend on total dosage administered.
- **E** **Boxes 50-65:** Enter the patient's insurance information.
- **F** **Box 56:** Enter the appropriate National Provider Identifier (NPI) number.
- **G** **Box 67:** Enter the appropriate ICD-10-CM diagnosis codes (both ID/IDA-related and underlying) and the applicable ICD indicator identifying which ICD code version is being reported (ie, enter a "0" for ICD-10-CM). If payer does not accept the ICD-10-CM code(s), include the main reason for the encounter.
- **H** **Box 80:** Payer may require additional information to support review and payment of the claim. This may include NDC, total dosage, and date Injectafer was administered.

We recommend verifying the coding policies for each individual health plan. Reimbursement specialists can provide information relating to payer-specific policies and can address other questions at 1-866-4-DSI-NOW (1-866-437-4669). Additionally, your Daiichi Sankyo, Inc. Associate Director, Field Reimbursement (ADFR) can serve as a point of contact for your practice.

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Daiichi Sankyo, Inc. makes no representation or guarantee concerning coverage or reimbursement for any service or item.

injectafer® ferric carboxymaltose injection

Injectafer Savings Program

Copay savings may help reduce eligible patients' out-of-pocket costs*

PATIENTS RECEIVE **EACH DOSE** FOR AS LITTLE AS

$50

For eligible patients

- Assistance of up to $500 per dose
- Enrollment is valid for 2 courses of treatment per 12-month period

Is your patient eligible?*

- ✓ Has commercial insurance **AND**
- ✓ Is a resident of the USA or its territories, including Puerto Rico
- ✗ Has Medicare, Medicaid, or other federal or state healthcare insurance, **OR**
- ✗ Has private indemnity or HMO insurance that reimburses patients for the entire cost of prescription drugs, **OR**
- ✗ Is Medicare-eligible and enrolled in an employer-sponsored health plan or medical or prescription drug benefit program for retirees

*The Injectafer Savings Program is only available for patients who are commercially insured. Please see full Terms and Conditions on page 12.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (*cont'd*)

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.

injectafer® ferric carboxymaltose injection

Register your office by calling a Daiichi Sankyo Access Central coordinator (1-866-4-DSI-NOW)

- A Daiichi Sankyo Access Central coordinator will provide you with a login for injectafercopay.com
- Registration only needs to be completed once

Before administering Injectafer, enroll your patient

- Log in to injectafercopay.com (you can also enroll the patient at 1-866-4-DSI-NOW)
- Enter required patient information
- For each patient, you'll receive a 16-digit code for a virtual debit card on approval

After treatment, log in and submit the Explanation of Benefits (EOB) form

- Log in to injectafercopay.com
- Submit the EOB form, along with a CMS-1500/UB-04 form, to assist in timely processing of claims
- There are 3 ways to send the EOB form*:

Upload at injectafercopay.com
Best way to submit EOBs and manage all patients

OR **Fax** to 1-888-257-4673 **OR** **Mail** to Injectafer Savings Program
100 Passaic Ave, Suite 245
Fairfield, NJ 07004

- It usually takes 2 to 3 days for an EOB to be approved
- Then, funds will be uploaded onto the virtual 16-digit debit card

*When forms are uploaded to injectafercopay.com, the process may potentially be expedited. For patients who wish to directly submit their EOB form, please direct them to fax or mail the form to the Injectafer Savings Program.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (*cont'd*)

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.

injectafer® ferric carboxymaltose injection

Injectafer Savings Program Terms and Conditions

1. This offer is valid for commercially insured patients. Uninsured and cash-paying patients are NOT eligible for this Program.
2. Depending on insurance coverage, eligible patients may pay no more than $50 per dose for up to four doses per calendar year. There is a maximum savings limit of $500 per dose, with an overall program limit of $2,000 per calendar year. Check with your pharmacist or healthcare provider for your co-pay discount. Patient out-of-pocket expense may vary.
3. This offer is not valid for patients enrolled in Medicare Part B or Medicare Part D, Medicaid, or other federal or state healthcare programs, or private indemnity or HMO insurance plans that reimburse you for the entire cost of your prescription drugs. Patients may not use this card if they are Medicare-eligible and enrolled in an employer-sponsored health plan or medical or prescription drug benefit program for retirees.
4. An explanation of benefits (EOB) statement must be faxed, uploaded in the portal, or mailed in prior to transacting on the account numbers for co-pay assistance.
5. Offer is invalid for claims or transactions more than 180 days from the date on the EOB.
6. Patients will be automatically re-enrolled in the next calendar year. If there is no copay claim activity for 18 months, the enrollment will be canceled.
7. Daiichi Sankyo, Inc. reserves the right to rescind, revoke or amend this offer without notice. Offer good only in the USA, including Puerto Rico, at participating pharmacies or healthcare providers.
8. Void if prohibited by law, taxed, or restricted.
9. This account number is not transferable. The selling, purchasing, trading, or counterfeiting of this account number is prohibited by law.
10. This account number is not insurance.
11. By redeeming this account number, you acknowledge that you are an eligible patient and that you understand and agree to comply with the terms and conditions of this offer.
12. Qualified patients receiving Injectafer will be allowed a 180-day retroactive enrollment period from the **date of EOB (eligibility of benefit form)** to receive benefits under the program rules.

IMPORTANT SAFETY INFORMATION

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%).

injectafer® ferric carboxymaltose injection

Patient Assistance Program

Help for uninsured or commercially underinsured patients with financial need

If your patients are uninsured or commercially underinsured and need help paying for their Injectafer treatment, they may be eligible for the Patient Assistance Program (PAP). The PAP is a product replacement program.*

✔ Eligibility

To qualify, a patient must:

- Meet established income limits
- Lack health insurance completely or be commercially underinsured
- Be a resident of the USA or its territories, including Puerto Rico

✔ How to apply

Enroll your patient in the program in 1 of 2 ways:

- Download the **Patient Enrollment Form** in English or Spanish on DSIAccessCentral.com. Have the patient sign the enrollment form, then fax it to 1-833-471-9988 (preferred method for fastest support)
  OR
- Call **1-866-4-DSI-NOW**

Important timing notice

- Submit the Patient Enrollment Form **before** the patient's infusion and confirm enrollment
- **After** the patient's infusion, submit the **Product Request Form**
- **Plan at least 8 days in advance.** In most cases, if you submit the Product Request Form by EOD Wednesday, the product will be shipped overnight the following Wednesday (holidays and weather may cause delays)

*The company reserves the right to modify or cancel the program immediately with respect to any patient, or in its entirety, at any time.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (*cont'd*)

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%).

injectafer® ferric carboxymaltose injection

Indications and Important Safety Information

INDICATIONS

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, and malnutrition. 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.

injectafer® ferric carboxymaltose injection

Important Safety Information (*cont'd*)

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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PP-US-IN-4104 02/24