Issue 1 • July 2025 • ID in HF and IDA

# PEER perspectives

# THE PATH TO INFUSION:
## ADDRESSING ID IN HF AND IDA THROUGH IV IRON THERAPY

### INSIDE THIS ISSUE:

- Recognizing and diagnosing iron deficiency (ID) in heart failure (HF) and iron deficiency anemia (IDA) across patient populations
- The use of oral iron for ID in HF and IDA and how inflammation influences treatment efficacy
- Peer perspectives and best practices on how dextran-free IV irons can help address ID in HF and IDA
- How to navigate efficient patient referral with ID in HF and IDA to infusion centers

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**Peer perspectives come from healthcare professionals that are compensated by Daiichi Sankyo Inc.**

# How ID in HF and IDA Impact Patient Care Across Conditions

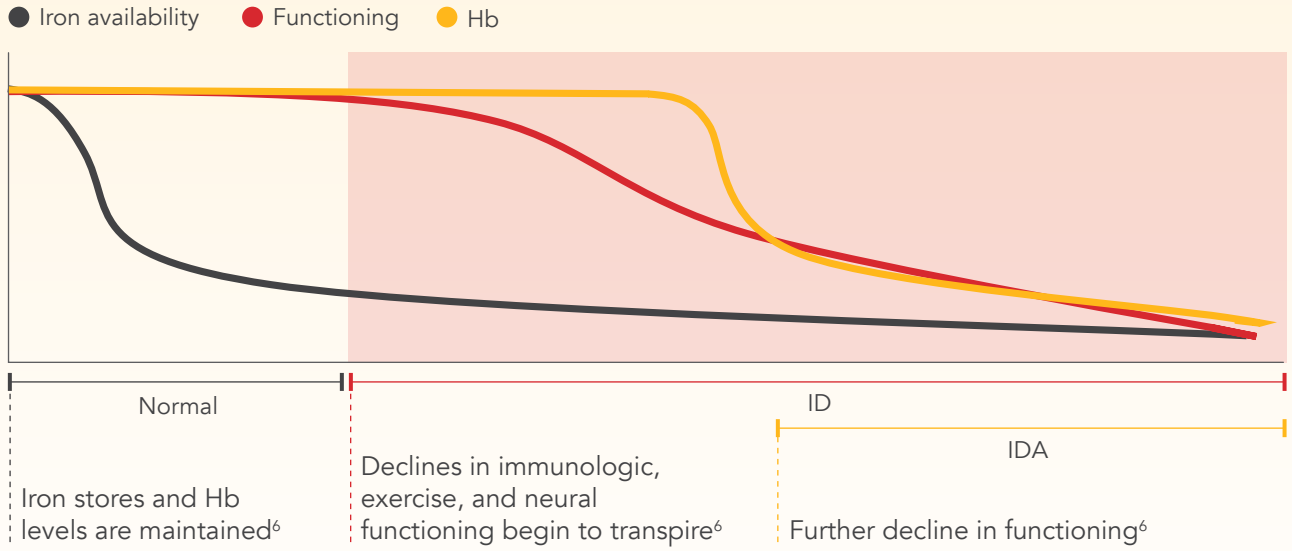
The causes of ID in HF and IDA primarily fall within 3 categories, which are blood loss, insufficient absorption, and inadequate intake. The manifestations are varied and may include heavy menstrual bleeding, bleeding ulcers, colon cancer, intestinal surgeries, Crohn's disease, or celiac disease. Inadequate nutritional intake due to eating disorders or a diet low in iron-rich foods can also lead to ID in HF or IDA.[1-4]

## The Causes of ID in HF/IDA Fall Into 3 Categories:

Blood loss | Insufficient absorption | Inadequate intake

## How ID in HF Impacts Functioning Before Anemia Develops

- Under normal conditions, iron stores and hemoglobin (Hb) levels are maintained, allowing for normal functioning[5]
- When ID in HF occurs, declines in immunologic, exercise, and neural functioning begin to transpire[6]
- Once iron stores fall below 100 mg (ferritin <10 ng/mL to 15 ng/mL) and transferrin saturation (TSAT) drops below 15%, IDA occurs, resulting in an even further decline in functioning[6]




*It is important to remember that ID and IDA are 2 different conditions. ID exists separately from IDA and will cause functional decline prior to a drop in hemoglobin.*

– Dr. Jeffrey Mandak, cardiologist

In the US, approximately **6.5 million** adults and over **850,000** pediatric patients have IDA.[7-9]
**~6 million** patients in the US have chronic HF[10]; **~50%** of all patients with HF **have ID.**[11]

## ID in HF and IDA: Uncovering Key Populations Impacted

### Cancer[12]

*44%-50% of tumor types have IDA*

- Anemia was detected in 50.4% of iron-deficient patients with solid tumors
- Anemia was detected in 43.7% of iron-deficient patients with hematologic malignancies
- 82% of iron-deficient patients had functional ID (across tumor types)

### Gastrointestinal Conditions

*36%-76% of patients with inflammatory bowel disease (IBD) have IDA[13]**

- Most common cause of anemia in IBD[14]

### Non-dialysis Dependent Chronic Kidney Disease (NDD-CKD)

*57.8%-58.8% of men and 69.9%-72.8% of women with NDD-CKD have low iron tests (National Health and Nutrition Examination Survey III)[15]**

- Higher prevalence of anemia with advanced disease[16]

### HF

*~50% of HF patients exhibit ID; 17% of patients with chronic HF have ID and anemia[17,18]*

- Risk factors for ID in HF include female sex, advanced stages of HF, elevated N-terminal pro–B-type natriuretic peptide (NT-proBNP), chronic kidney disease (CKD), and C-reactive protein (CRP)[17,18]

### Women[19†]

*~20% (1 in 5) of childbearing-aged women in the United States have IDA*

- Women are at greater risk for IDA due to blood loss during menstruation and high iron demands during pregnancy

### Pediatric Patients

*20.1% of 0–4-year-olds and 5.9% of 5–14-year-olds have IDA[20‡]*

- Infants, preschool-aged children, and adolescents undergoing growth spurts are commonly impacted[21]

* Defined in reference as a serum ferritin <100 ng/mL or TSAT <20%. Authors concluded this remarkably high prevalence might indicate these indices may not be specific enough and may falsely identify too many patients as iron deficient.[15]

† Published studies and available data from postmarketing reports with IV Injectafer are insufficient to assess the risk for pregnant women of major birth defects and miscarriage.[22]

‡ In industrialized countries.[20]

# A Closer Look at Diagnosing ID in HF & IDA

## Common signs and symptoms of IDA may include[23]:

- Fatigue
- Weakness
- Dizziness
- Shortness of breath
- The signs and symptoms of IDA can overlap with those of other conditions[24-27]

## Other signs and symptoms[23,28]:

- Headache
- Chest pain
- Pale skin
- Arrhythmia
- Lightheadedness
- Brittle nails
- Coldness in extremities
- Pica (craving nonfood items such as dirt or ice)

***Early and accurate diagnosis of ID in HF and IDA is incredibly important. If your patients' Hb, ferritin, and TSAT values fall below normal levels, they may require iron supplementation.[29,30]***

## The American College of Cardiology (ACC)/ American Heart Association (AHA)/Heart Failure Society of America (HFSA) Guideline[1] states iron tests to diagnose ID in HF are a Class 1 recommendation[29]:

***Class 1 – recommendation (strong), benefit >>> risk***

**Routine baseline assessment of all patients with HF should include iron studies**

ID in HF is usually defined as ferritin level <100 ng/mL or 100 ng/mL to 300 ng/mL, if the TSAT is <20%

## ID in HF and IDA can be diagnosed by testing for 3 key indices[31,32]:

**Hb[33]:**
- Hb production requires sufficient levels of stored iron and adequate TSAT

**Ferritin[34]:**
- When the body requires more iron than the diet provides, ferritin supplies a reservoir from which iron can be metabolized

**TSAT[35]:**
- Transferrin transports iron through the body so that it can be used to produce Hb. TSAT is decreased in chronic ID

| NORMAL LEVELS IN HEALTHY ADULT PATIENTS* | |
|---|---|
| Hb[36] | **M:** 13.5 g/dL-17.5 g/dL<br>**F:** 12.0 g/dL-15.5 g/dL |
| Ferritin[37] | **M:** 40 ng/mL-300 ng/mL<br>**F:** 20 ng/mL-200 ng/mL |
| TSAT[38] | **M:** 20%-50%†<br>**F:** 20%-50%† |

*Normal lab values may vary based on patient characteristics/comorbidities and by laboratory.

†Injectafer is not indicated to treat patients with CKD who are on dialysis or patients with anemia of chronic disease. For adult patients with CKD and anemia, guidelines issued by National Kidney Foundation (NKF) recommend IV iron for patients with a TSAT ≤30% and ferritin ≤500 ng/mL. Consult the NKF guidelines for a complete list of recommendations for lab values when starting treatment.[22]

***"Because the symptoms of IDA are often nonspecific, patients may be underdiagnosed; in fact, some patients may be asymptomatic."***

**– Dr. Anita Krishnarao, gastroenterologist**

# Understanding Inflammation: Its Impact on Iron Absorption

## There are many different chronic conditions that can cause inflammation that may lead to anemia, including:

- Congestive heart failure (CHF)[39]
- Diabetes[40]
- Obesity[24]
- CKD[40]
- Autoimmune diseases, such as arthritis and lupus[40]
- Inflammatory bowel disease, such as Crohn's disease or ulcerative colitis[14]
- Cancer[39,40]

***Hepcidin levels are significantly elevated in individuals with inflammation, causing ferroportin degradation, blocking oral iron absorption, as well as iron release from macrophages[41]***

Chronic inflammation leads to a decrease in oral iron absorption and defective mobilization of iron stores[42]

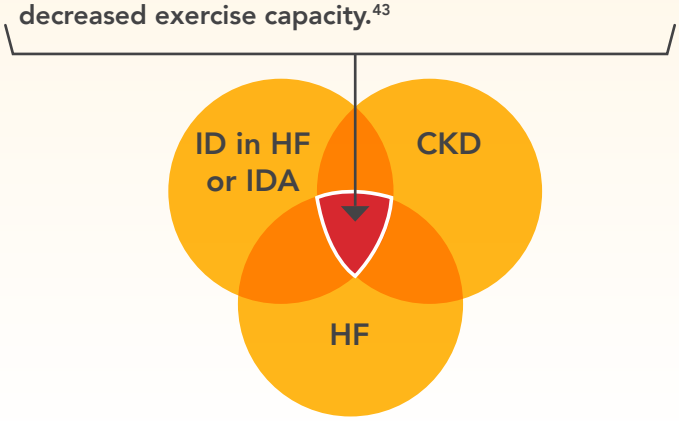
*"The inflammatory nature of both of these conditions [HF and NDD-CKD] alters the body's iron sequestering methods and modulates the relationship between iron stores and serologic markers; this renders conventional thresholds insensitive for detecting ID."*

–Dr. Gates Colbert, nephrologist

**Inflammatory conditions (such as CKD or HF) alter the body's iron sequestering methods.[42]**

**These conditions also modulate the relationship between iron stores and serologic markers, rendering conventional thresholds insensitive for detecting ID in HF and complicating clinical decision-making.[42]**

**The coexistence of CKD and HF with ID results in decreased exercise capacity.[43]**




Using oral iron may have limited efficacy in those with inflammation from chronic anemia. IV iron should be considered for these patients.[39] Inflammation is a key component of both the CHF and CKD syndrome and is a key contributor to anemia in patients with ID in HF or IDA in comorbid NDD-CKD.[44]

### Adherence issues

- Data show the adherence rate for oral iron is 40% to 60%[45]
- Adherence may be affected by side effects[46]

### Side effects

- 10%-40% of patients taking oral iron may experience side effects, which may necessitate dose reduction or modification[47]

### Absorption

Even in healthy patients, less than 10% of oral iron is absorbed.[3]

Per the American Gastroenterological Association Guidelines, a response (with improvements in Hb concentration) to oral iron supplementation is typically evident within 1 month of treatment. If a response is not seen, further assessments are needed.[48]

Consider testing your patients beginning 14-30 days after starting oral iron to see if they are having an adequate response[49,50]

# REVIEWING INJECTAFER: A DEXTRAN-FREE* IV IRON

**Injectafer has been studied in more than 8800 patients enrolled in more than 40 clinical trials, making it the most-studied IV iron therapy. Over 3 million patients in the US have been treated with Injectafer since its FDA approval in 2013.[7]**

**Injectafer is indicated for the treatment of IDA in[22]:**

- Adults and pediatric patients 1 year of age and older who have either intolerance to oral iron or an unsatisfactory response to oral iron
- Adult patients who have non-dialysis-dependent chronic kidney disease

**Injectafer is indicated for the treatment of ID in[22]:**

- Adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity


**Injectafer is available as a 750 mg iron/15 mL single-dose vial and 100 mg iron/2 mL single-dose vial[22]**

* Injectafer has a rate of serious anaphylactic/anaphylactoid reactions of 0.1% (2/1775). Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but not limited to, pruritus, rash, urticaria, wheezing, or hypotension were reported in 1.5% (26/1,775) of these subjects.[22]

## SELECTED SAFETY INFORMATION

### CONTRAINDICATIONS

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

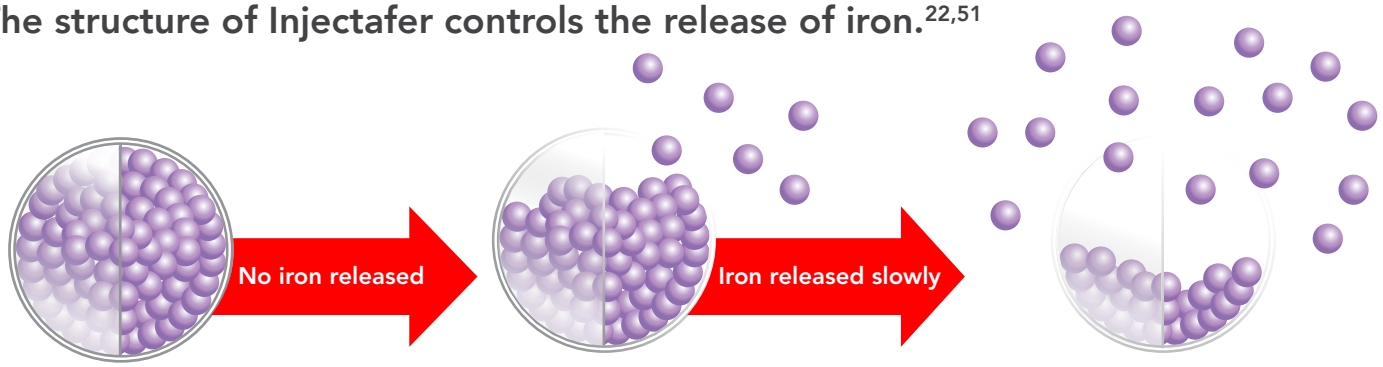
### WARNINGS AND PRECAUTIONS

*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.

# REVIEWING INJECTAFER: A DEXTRAN-FREE* IV IRON (CONT'D)

## The structure of Injectafer controls the release of iron.[22,51]




After administration, enzymes in the blood partially degrade the Injectafer carbohydrate shell.[52]

Injectafer is then likely taken up by macrophages of the reticuloendothelial system, where enzymes continue breaking down the carbohydrate shell.[51,52]

This slow release of iron prevents the transferrin available for uptake from becoming fully saturated with iron.[53]

**On the following pages, learn more about the 4 Ds that differentiate Injectafer as a treatment option for IDA and ID in HF**

**DATA:** Clinical trial data show Injectafer is an option for appropriate adult patients in both ID in HF and IDA in patients who are either intolerant or had an unsatisfactory response to oral iron and which has the only approval for ID in HF in the IV iron market[22,54-56]

**DOSING:** Injectafer may replenish your patients' iron deficit and provides the most iron per course of treatment—1500 mg (in two doses separated by at least 7 days)—in IDA and provides weight-based dosing and offers maintenance dosing beyond 6 weeks for patients with ID and HF[52,53]

**DELIVERY:** The only high dose IV iron that gives you options for administration[22,57-61]

**DILUTION:** Injectafer can be given up to 250 mL diluted for IV infusion or as an IV push[22]

## SELECTED SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS (CONT'D)

*Symptomatic Hypophosphatemia* (CONT'D)

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.

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# REVIEWING INJECTAFER: THE INFLUENCE OF THE 4 Ds

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## Injectafer is the only dextran-free* IV iron that can offer:

- Approval for the treatment of ID in HF for appropriate adult patients[22]
- The sole high-dose IV iron indicated in pediatric patients with IDA in patients who are either intolerant or had an unsatisfactory response to oral iron[22]
- 2 options for administration (IV push or IV infusion)[22]
- Diluted administration option[22]
  - When administered via infusion, dilute up to 1000 mg of iron in no more than 250 mL of sterile 0.9% sodium chloride injection, United States Pharmacopeia (USP), and administer over at least 15 minutes
- Undiluted administration option[22]
  - When administering Injectafer 500 or 750 mg as a slow intravenous push, give at the rate of approximately 100 mg (2 mL) per minute. For Injectafer 1000 mg, administer as a slow intravenous push over 15 minutes

- Over 3 million patients in the US have been treated with Injectafer[7]
- Approved in 86 countries since initial European Union approval in 2007[7]
- Injectafer is the most-studied IV iron treatment, with more than 40 clinical trials and >8800 patients treated worldwide[7]
- Injectafer has more than 24 million patient-years in post-marketing treatment experience worldwide[7]

***"Clinical trial data show that Injectafer is an option for both ID and IDA, with the only FDA-approval for HF in the IV iron space. Injectafer's controlled release of iron allows for a full delivery of the dose, providing fewer infusions and less chair time for the facility. Multiple administration options allow patients and providers to tailor Injectafer to their needs. Finally, Injectafer is the only high dose IV iron that allows for either push or IV drip administration in adult patients"***

**– Dr. Jeffrey Mandak, cardiologist**

* Injectafer has a rate of serious anaphylactic/anaphylactoid reactions of 0.1% (2/1775). Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but not limited to, pruritus, rash, urticaria, wheezing, or hypotension were reported in 1.5% (26/1,775) of these subjects.[22]

## SELECTED 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.

# REVIEWING INJECTAFER: THE INFLUENCE OF THE 4 Ds (CONT'D)

## Injectafer provides the most iron per course of treatment for IDA: up to 1500 mg in 2 doses of 750 mg separated by at least 7 days.[22,57-61]


**1500 mg**
in 1 course of treatment[22]

IV infusion over at least 15 minutes

**In adults:**

Slow IV push over 7.5 minutes

**For patients weighing less than 50 kg (110 lb), the recommended dosage is Injectafer 15 mg/kg body weight intravenously in 2 doses separated by at least 7 days per course.[22]**

***Injectafer treatment may be repeated if IDA or ID in HF reoccurs.[22] Please see full prescribing information for HF dosing, administration, and pharmacy specifications.***

- Over 90% of patients in pivotal trials received up to 1500 mg of total iron. Injectafer's 1500 mg dosing addresses average iron deficits, which are approximately 1500 mg. This average deficit was identified across 7 clinical trials that involved more than 4600 patients.[62] Clinical trial results showed that 1500 mg of iron resulted in a more rapid, robust Hb response, allowed more patients to reach target Hb levels, and required a longer mean time to retreatment with additional IV iron compared to 1000 mg of iron.[62]

## SELECTED SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS (CONT'D)

*Hypersensitivity Reactions* (CONT'D)

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.

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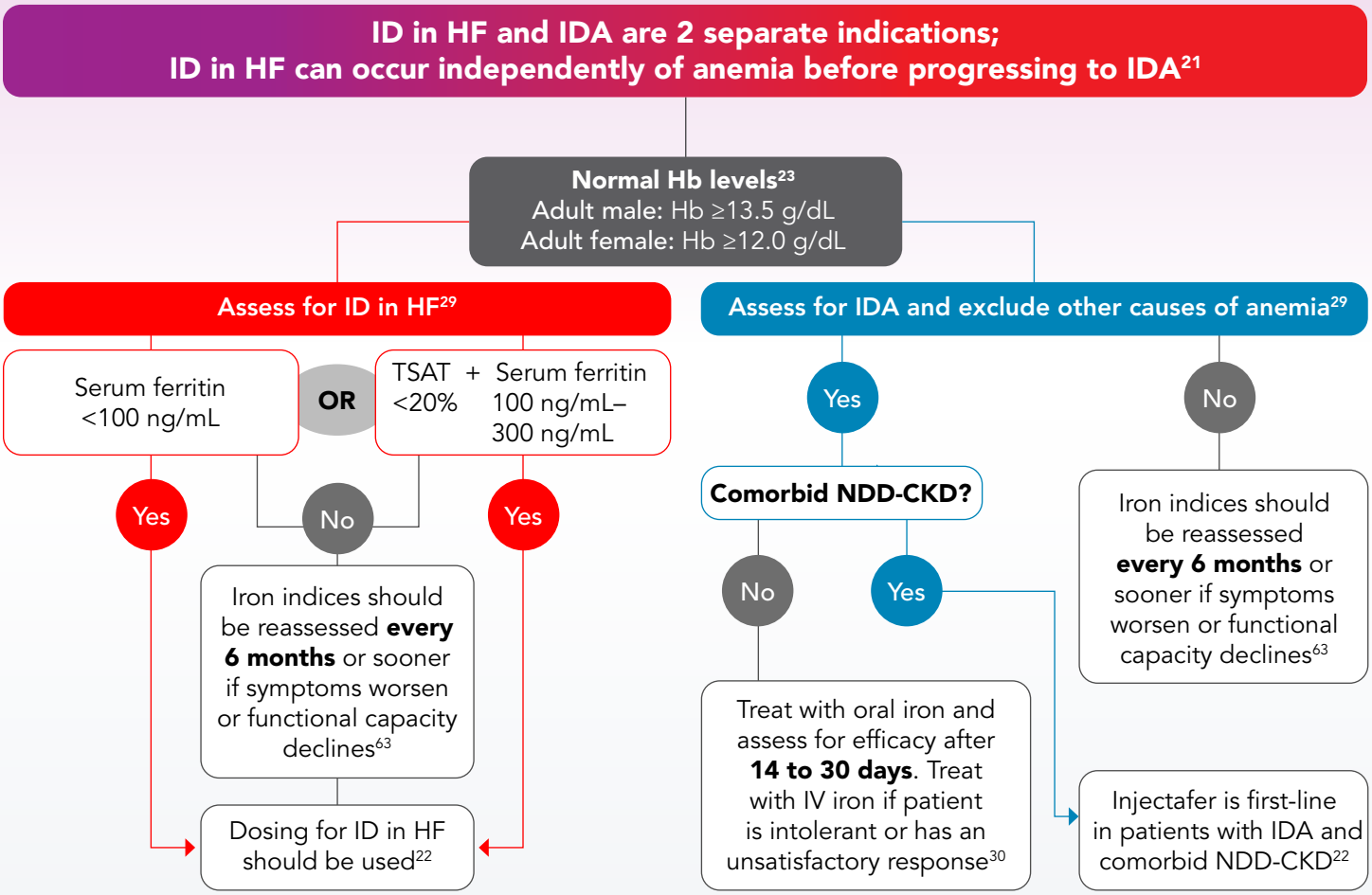
# FROM DIAGNOSIS TO TREATMENT: BEST PRACTICES FOR MANAGING ID IN HF & IDA

Daiichi Sankyo, Inc. created the clinical algorithm tool to provide a clear and consistent approach to managing ID in HF and IDA in patients who are either intolerant or had an unsatisfactory response to oral iron and may help streamline variability in care, ensuring that healthcare professionals are more informed on evidence-based guidelines, leading to more predictable and reliable outcomes. The algorithm can also help disseminate up-to-date clinical knowledge to healthcare providers who may not specialize in ID in HF or IDA, possibly reducing the likelihood of omissions or incorrect steps in diagnosis or treatment. Finally, it can serve as an educational tool for new staff or trainees, promoting rapid acclimatization to clinical protocols.




## SELECTED 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%).

# FROM DIAGNOSIS TO TREATMENT: BEST PRACTICES FOR MANAGING ID IN HF & IDA (CONT'D)

## Of note, Injectafer is considered first-line treatment in appropriate adult patients with ID in HF[22]

### ACC/AHA/HFSA Guideline states that IV iron is a Class 2a management for ID in patients with HF, regardless of anemia[29]

Therapy must be aimed at both the underlying condition and the treatment of IDA[64]

- Reduce or prevent continued iron loss[64]
- Restore Hb to normal levels[65,66]
- Replenish iron stores[65,66]

- Looking at serum ferritin and TSAT can help assess for ID. When the presence of ID is confirmed in a patient with HF, treatment with Injectafer should be initiated. Of note, Injectafer is considered first-line treatment in patients with HF and comorbid NDD-CKD who are diagnosed with IDA[22,29]
- In patients with IDA and comorbid NDD-CKD, treatment with Injectafer may be initiated. When the presence of IDA is confirmed in patients without NDD-CKD, treat with oral iron for 14 to 30 days. If the patient experiences intolerance or an unsatisfactory response, Injectafer may be administered[22,30]

*"The guideline does not recommend oral iron for the treatment of ID in patients with HF"*

**–Dr. Neil Gokal, family medicine**

## SELECTED 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%).

*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.

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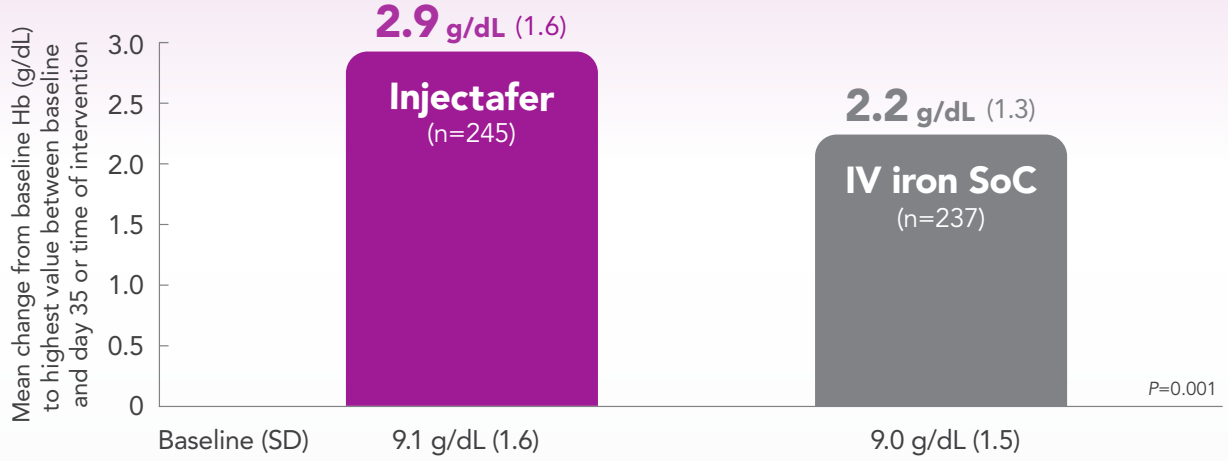
# EXPLORING THE EFFICACY AND SAFETY OF INJECTAFER

## Pivotal trial 1: IDA in patients who are intolerant to oral iron or have had unsatisfactory response to oral iron

- Injectafer 1500 mg demonstrated significantly greater increases in Hb levels as compared with oral iron, regardless of the underlying etiology of IDA. No meaningful differences were observed in rates of death or major cardiovascular events between Injectafer and oral iron. Injectafer carries specific safety risks, including hypersensitivity and hypertension.[54]
- Injectafer provided significantly greater increases in Hb levels vs oral iron to day 35 in cohort 1[22,54]
- Injectafer showed greater improvements in Hb levels vs IV iron standard of care (SoC) to day 35 from baseline in cohort 2[54]

**Hb: Mean change in absolute value from baseline to highest value between baseline and day 35 or time of intervention[22,54]**




- In cohort 1, Injectafer resulted in significantly greater increases in Hb levels compared to oral iron on day 35 from baseline. Patients receiving Injectafer had a mean Hb increase of 1.6 from baseline, compared to 0.8 for those on oral iron. Additionally, 57% of patients on Injectafer achieved Hb levels >12 g/dL by day 35, versus 29% of those on oral iron[22,54]
- In Cohort 2 on day 35, Injectafer-treated patients showed numerically greater mean increases in hemoglobin (2.9 vs 2.2 g/dL) and iron indices (218.15 vs 74.65) compared to IV iron SoC. While 51% of Injectafer patients achieved Hb >12 g/dL versus 25% with IV iron SoC, these were secondary endpoints and the study was not powered to demonstrate statistical superiority.[54]

## SELECTED SAFETY INFORMATION

### ADVERSE REACTIONS (CONT'D)

*Post-Marketing Experience*

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.

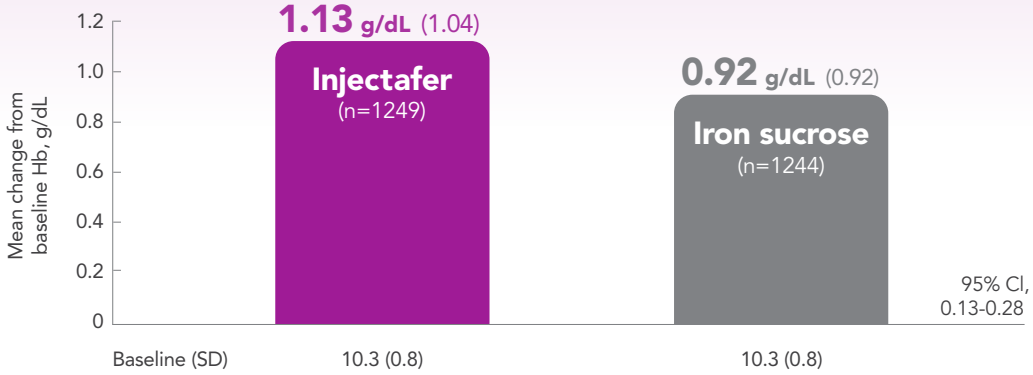
# EXPLORING THE EFFICACY AND SAFETY OF INJECTAFER (CONT'D)

## Pivotal trial 2: IDA in patients with NDD-CKD (REPAIR-IDA)

A higher percentage of subjects in the Injectafer group achieved an Hb increase of ≥1.0 g/dL by day 56 compared with the iron sucrose group (48.6% vs 41.0%; 95% CI, 3.6%–11.6%). There was no significant difference in the primary composite safety endpoint, including major adverse cardiac events such as death, myocardial infarction, or stroke.[22,55]

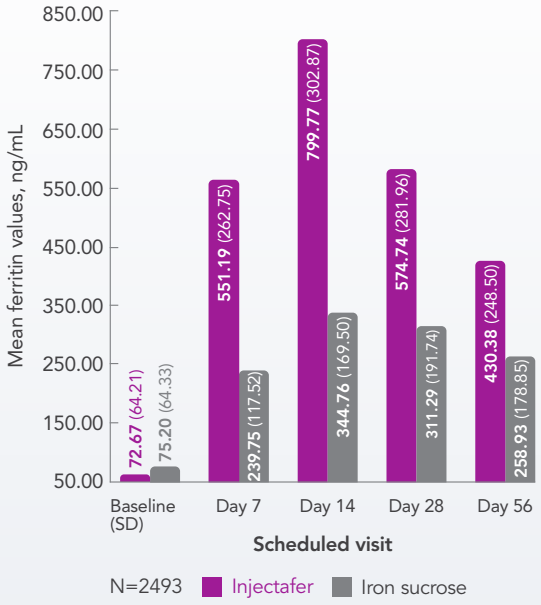
**Primary endpoint**

**Hb: Mean change from baseline to highest value between baseline and day 56 or time of intervention**[7,55]

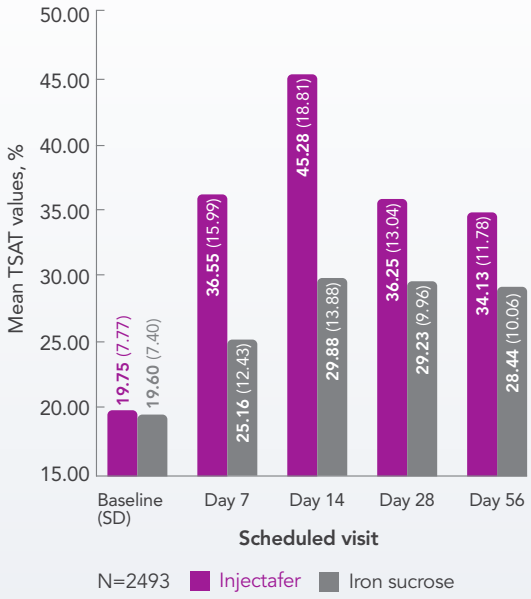



**Secondary endpoints** (secondary efficacy endpoints were not powered for superiority)[7,55]

**Ferritin: Mean value at each scheduled visit**




**TSAT: Mean value at each scheduled visit**



# EXPLORING THE EFFICACY AND SAFETY OF INJECTAFER (CONT'D)

The most common adverse reactions in adults (>2%) were nausea, hypertension, flushing, injection site reactions, erythema, hypophosphatemia, and dizziness.[22,54,55]

## Adverse reactions reported in ≥1% of patients in adult pivotal trials 1 and 2[22,54,55]

| Term | Injectafer, % (n=1775) | Pooled comparators, % (n=1783) | Oral iron, % (n=253) |
|---|---|---|---|
| Nausea | 7.2 | 2 | 1.2 |
| Hypertension | 4 | 2 | 0.4 |
| Flushing | 4 | 0.2 | 0 |
| Injection site reactions | 3 | 3.2 | 0 |
| Erythema | 3 | 0.6 | 0 |
| Hypophosphatemia | 2.1 | 0.1 | 0 |
| Dizziness | 2.1 | 1.3 | 0.4 |
| Vomiting | 2 | 1 | 0.4 |
| Injection site discoloration | 1.4 | 0.3 | 0 |
| Headache | 1.3 | 1.2 | 0.4 |
| Hepatic enzyme increased | 1.2 | 0.2 | 0 |
| Dysgeusia | 1.2 | 2.1 | 0 |
| Hypotension | 1 | 2 | 0 |
| Rash | 1 | 0.3 | 0 |
| Constipation | 0.5 | 0.9 | 3.2 |

## SELECTED SAFETY INFORMATION

### 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.**

# IV IRON INFUSION PROTOCOL: A CLINICAL ROADMAP

Navigating referrals efficiently for your patients with IDA or ID in HF is important to ensure timely treatment.

| | |
|---|---|
| **Step 1** | Obtain iron panels (including ferritin and TSAT) to determine IDA or ID in HF diagnosis |
| **Step 2** | Treat with oral iron and assess for efficacy after 14 to 30 days OR treat with Injectafer, if indicated for first-line treatment<br>• Injectafer is first-line in adult patients with IDA and NDD-CKD and ID in HF adult patients[22] |
| **Step 3** | Write a prescription for Injectafer and refer the patient to an infusion center (Heme-Onc, outpatient fusion center, or independent infusion center) |
| **Step 4** | Utilize Injectafer resources to find an infuser near you<br>• Tools include the infusion center locator and patient education brochures |

## Streamlined care

*Electronic health record (EHR) solutions allow providers to receive the latest evidence-based information directly at the point of care. Contact your DSI representative if interested in EHR implementation.*

**Embed dosing and administration details for Injectafer into order sets for IDA.**

**Embed blood tests for iron deficiency directly into your HF order set.**

**Set up clinical alerts at point of care to test for iron deficiency in appropriate HF patients.**

**Makes it easy for you to order lab tests for your patients with ID in HF or IDA.**

- An alert prompts you to test your patients with ID in HF or IDA and directs you to the order set where lab tests are embedded
- This reminder allows you to focus on patient care and takes the burden off you and your team to remember to routinely test HF patients for iron deficiency

**Order set and alert guides include step-by-step instructions that make these updates easy to implement. Updating your EHR can have a powerful impact on how you care for patients.**

injectafer® ferric carboxymaltose injection

# KEY TAKEAWAYS AND IMPACT TO CARE

## The 4 Ds of Injectafer:

Differentiated by data, dosing, delivery, and dilution, Injectafer provides controlled iron release for faster repletion in fewer infusions with flexible administration options. Clinical trial data shows Injectafer is an option for both ID in HF and IDA, with the only approval for in ID in HF for appropriate adult patients in the IV iron market[22,52-61]

## Efficacy across iron indices:

Clinical trials demonstrate Injectafer's efficacy in improving Hb, ferritin, and TSAT levels versus oral iron[54,55]

## Consistent safety profile:

Injectafer's clinical trials demonstrate a consistent safety profile across a range of patient populations and treatment settings. These findings may help inform treatment decisions for patients with ID in HF or IDA who are candidates for IV iron therapy[54,55]

**Injectafer is contraindicated in patients with hypersensitivity to Injectafer or any of its inactive components. Injectafer can cause serious adverse reactions including hypersensitivity reactions, symptomatic hypophosphatemia, and hypertension.**

**Please see additional Important Safety Information below. Please see additional Important Safety Information on pages 18-19.**

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# 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, 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.

## ADVERSE REACTIONS (CONT'D)

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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# To learn more about ID in HF, IDA, and Injectafer, please scan the QR code and complete the form on the page.

## Dr. Jeffrey Mandak, MD, FACC, FACP, FAACVPR

Dr. Jeffrey Mandak is a board-certified cardiologist and internist with extensive experience in cardiovascular rehabilitation and advanced imaging. He currently serves as the Founding Medical Director of cardiac rehab at Fulton County Medical Center in McConnellsburg, PA, and is a Clinical Assistant Professor for physician assistant programs at both Lock Haven University and Pennsylvania College of Technology. A graduate of the University of Pennsylvania School of Medicine, Dr. Mandak completed his residency at the Hospital of the University of Pennsylvania and a cardiology fellowship at Geisinger Medical Center. He is a founding member of the Society of Cardiovascular Computed Tomography and is actively engaged in advancing care across HF, ID, and chronic disease management.

## Dr. Anita Krishnarao, MD, MPH

Dr. Anita Krishnarao is a transplant hepatologist and gastroenterologist at UMass Memorial Medical Center and an Assistant Professor of Medicine at UMass Chan Medical School. Her clinical expertise includes cirrhosis, liver transplantation, and non-alcoholic fatty liver disease. She is fluent in English and Spanish and is actively involved in both patient care and medical education. Dr. Krishnarao holds a BA and BS from Duke University, an MPH from Columbia University, and earned her medical degree from the Warren Alpert Medical School of Brown University. Her integrative background positions her to address the complex interplay between liver disease, GI complications, and ID.

## Dr. Gates Colbert, MD

Dr. Gates Colbert is a board-certified nephrologist based in Dallas, Texas, with expertise in CKD and cardiorenal syndromes. He practices at Kidney and Hypertension Associates of Dallas and serves as Medical Director at Davita Kidney Care Central. Dr. Colbert holds faculty roles at Texas A&M Health Science Center and Baylor University Medical Center, where he also co-directs the nephrology program. He earned his medical degree from the University of Texas Medical School in Houston and completed his fellowship in nephrology at UT Southwestern Medical Center. A fellow of the Cardio Renal Society of America and an active member of the Texas Medical Association, Dr. Colbert is dedicated to advancing multidisciplinary care in nephrology and internal medicine.

## Dr. Neil Gokal, MD, FAAFP

Dr. Neil Gokal is a board-certified family medicine physician and Chief Medical Officer at Optum Nevada, where he leads population health initiatives with a focus on chronic disease management and care integration. He holds leadership roles as President of the Nevada Physician Wellness Coalition and serves on the executive board of the Nevada Academy of Family Physicians. Dr. Gokal earned his medical degree from St. George's University and holds a Master of Public Health from the Icahn School of Medicine at Mount Sinai. With a strong commitment to community health and physician mentorship, he brings a multidisciplinary perspective to advancing primary care strategies, including the role of IV iron in managing ID and anemia.

**Click here to see Full Prescribing Information.**

Daiichi-Sankyo



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