



Injectafer[®]

(ferric carboxymaltose injection)

CODING GUIDE

This guide can help facilitate accurate billing and coding to ensure eligible patients receive the proper program support.



For accurate claim submissions,
remember to **INJECT**



I
N
J
E
C
T

ICD-10-CM

Billing code for iron deficiency anemia (IDA) and iron deficiency (ID) in heart failure (HF)

Number of units

(1 mg = 1 unit) = 750

J1439

Unique J code for Injectafer® (ferric carboxymaltose injection)

Extra ICD-10-CM

Additional code required for underlying condition

CPT code for administration

96374 (slow IV push) or
96365 (IV infusion)

Thorough review

Billing and coding

Important information related to Injectafer reimbursement

- Available through your wholesaler or distributor -

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	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push single or initial substance/drug
	or 96365	Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour

*CPT® codes, 2022 American Medical Association (AMA). All rights reserved. CPT is a trademark of the AMA. No fee schedules, basic units, relative values, or related listings are included in the CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS restrictions apply to government use.

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

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.

[Click here](#) to see Full Prescribing Information and see Important Safety Information on pages 12-14.

SELECTED SAFETY INFORMATION

CONTRAINDICATIONS

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

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Examples of IDA- and ID-related diagnosis codes

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

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 (D50.0))

Other codes may be appropriate.

*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.

SELECTED 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, 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.

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Examples of 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 IDA.*

Code	Description
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)

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. 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.

[Click here](#) to see Full Prescribing Information and see Important Safety Information on pages 12-14.



A code specific for patients with IDA and an underlying condition*

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

Code	Description
K50.0-K50.919	Crohn's disease (regional enteritis)
K50.0-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

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*Additional code suggestions only; appropriate codes not limited to those listed above. Injestafer is indicated to treat IDA; 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.

SELECTED 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 Injestafer administration.

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A code specific for patients with IDA and an underlying condition* (cont'd)

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

Code	Description
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
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

SELECTED SAFETY INFORMATION WARNINGS AND PRECAUTIONS (CONT'D)

Laboratory Test Alterations

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

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Underlying condition codes specific for patients with IDA & ID in Heart Failure (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
I50.0	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

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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%).

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Underlying condition codes specific for patients with IDA & ID in HF* (cont'd)

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

Code	Description
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.3	Diastolic (congestive) heart failure
I50.30	Unspecific diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
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

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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%).

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Underlying condition codes specific for patients with IDA & ID in HF* (cont'd)

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

Code	Description
I50.42	Chronic combined systolic and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic and diastolic (congestive) 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
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure

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SELECTED SAFETY INFORMATION ADVERSE REACTIONS (CONT'D)

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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Underlying condition codes specific for patients with IDA & ID in HF* (cont'd)

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

Code	Description
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified

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SELECTED SAFETY INFORMATION ADVERSE REACTIONS (CONT'D)

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.

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Important Safety Information

INDICATIONS

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WARNINGS AND PRECAUTIONS

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ADVERSE REACTIONS

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Important Safety Information (cont'd)

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.

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

To see if your patient is eligible for these savings,* visit ChooseInjectafer.com/resources

- ✓ 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.



For more information, visit ChooseInjectafer.com/savings



[Click here](#) to see Full Prescribing Information.

injectconnect™

SUPPORT PROGRAM



COVERAGE AND ACCESS SUPPORT

INSURANCE & CLAIMS ASSISTANCE

Expert help from reimbursement specialists:

- Benefits verifications
- Prior authorizations
- Claims appeals



CONTACT DAIICHI SANKYO ACCESS CENTRAL

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

[ChooseInjectafer.com/savings](https://www.ChooseInjectafer.com/savings)

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

*Excludes holidays.



For more information, visit
[ChooseInjectafer.com/savings](https://www.ChooseInjectafer.com/savings)

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