Injectafer®
(ferric carboxymaltose injection)
CODING GUIDE

This guide contains information that may help navigate the access and reimbursement process.

The following information is being provided for informational purposes only and is not intended to provide reimbursement or legal advice. Healthcare providers are responsible for determining the appropriate codes and coverage-related documentation to use for individual patients on a case-by-case basis. Insurance coverage, coding, claims filing, and reimbursement vary by payer as well as setting of care.

By providing this information, American Regent® is not making any representations, warranties, promises, or guarantees about coverage, levels of reimbursement, or payments for any products or services. Billing and coding information is subject to change without notice. Healthcare providers should contact the relevant third-party payers for specific information on coding and billing requirements.

injectafer®
ferric carboxymaltose injection

Please see Important Safety Information, including BOXED WARNING, and accompanying Full Prescribing Information.

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

I

ICD-10-CM
Billing code for iron deficiency anemia or iron deficiency in heart failure

N

Number of units
(1 mg = 1 unit)

J

J1439
Unique J code for Injectafer® (ferric carboxymaltose injection)

E

Extra ICD-10-CM
Additional code required for underlying condition

C

CPT®* code for administration
96374 (slow IV push) or
96365 (IV infusion)

T

Thorough review
Ensure all content has been entered accurately and completely

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.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: SYMPTOMATIC HYPOPHOSPHATEMIA

- **INJECTAFER can cause severe, prolonged hypophosphatemia associated with serious outcomes, including hospitalization, osteomalacia, and fractures requiring clinical intervention.**
- **Hypophosphatemia has occurred in patients with normal baseline phosphate levels and without apparent risk factors for hypophosphatemia.**
- **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 repeat course of therapy within three months. Correct pre-existing hypophosphatemia prior to administering INJECTAFER.**
- **Advise patients receiving INJECTAFER about the risk of hypophosphatemia and to report any signs and symptoms of hypophosphatemia (e.g., fatigue, muscle weakness or pain, bone and joint pain, bone fractures).**

Billing and coding

Important information related to Injectafer® (ferric carboxymaltose injection) reimbursement

- Injectafer is 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)
	0517-0620-01	Injectafer 1,000 mg iron/20 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 codes, 2026 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.

CPT=Current Procedural Terminology; FARS/DFARS=Federal Acquisition Regulation/Defense Federal Acquisition Regulation Supplement; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

Healthcare providers are responsible for determining the appropriate codes and coverage-related documentation to use for individual patients on a case-by-case basis.

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

Please see Important Safety Information, including BOXED WARNING, and accompanying Full Prescribing Information.

injectafer® ferric carboxymaltose injection

Commonly used IDA- and ID-related diagnosis codes

Injectafer® (ferric carboxymaltose injection) 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.

CKD=chronic kidney disease; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ID=iron deficiency; IDA=iron deficiency anemia.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Symptomatic Hypophosphatemia

Symptomatic hypophosphatemia, including severe cases, with serious outcomes such as osteomalacia and fractures requiring clinical intervention have occurred in patients treated with INJECTAFER in the post-marketing setting. These cases have occurred after single and multiple doses of INJECTAFER. 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). However, individuals without apparent risk factors have experienced symptomatic hypophosphatemia. In most cases, hypophosphatemia resolved within three months.

Check serum phosphate levels prior to a repeat course of treatment if the patient is at risk for low serum phosphate or if the patient will receive a repeat course of therapy within three months of the prior course. Correct pre-existing hypophosphatemia prior to administering INJECTAFER.

Commonly used iron deficiency anemia (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)

*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.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (Cont'd)

Symptomatic Hypophosphatemia (Cont'd)

Monitor serum phosphate levels in patients at risk for chronic low serum phosphate. Treat hypophosphatemia as medically indicated. Consider permanent discontinuation of INJECTAFER for severe symptomatic hypophosphatemia or persistent hypophosphatemia.

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.

Please see Important Safety Information, including BOXED WARNING, and accompanying Full Prescribing Information.

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Commonly used codes for patients with IDA and an 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)
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
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

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SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (Cont'd)

Hypersensitivity Reactions (Cont'd)

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.

Commonly used codes 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 Injectafer.†

Code	Description
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

*Additional code suggestions only; appropriate codes not limited to those listed above. Injectafer 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.

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ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; IDA-iron deficiency anemia.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (Cont'd)

Hypertension (Cont'd)

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.

Please see Important Safety Information, including BOXED WARNING, and accompanying Full Prescribing Information.

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Commonly used 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
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

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SELECT IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse reactions in adult patients (>2%) are nausea, hypertension, flushing, injection site reactions, erythema, hypophosphatemia, and dizziness.

The most common adverse reactions in pediatric patients (≥4%) are hypophosphatemia, injection site reactions, rash, headache, and vomiting.

Post-Marketing Experience

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 alwayspossible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Commonly used underlying condition codes specific for patients with IDA & ID in Heart Failure (HF)* *(cont'd)*

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

Code	Description
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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*Additional code suggestions only; appropriate codes not limited to those listed above. Injectafer is indicated to treat ID and 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.

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ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ID=iron deficiency; IDA=iron deficiency anemia.

SELECT IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (Cont'd)
Post-Marketing Experience (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.

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injectafer® ferric carboxymaltose injection

Commonly used underlying condition codes specific for patients with IDA & ID in Heart Failure (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
I50.83	High output heart failure
I50.84	End-stage heart failure
I50.89	Other heart failure

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SELECT IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS

Pregnancy – *Fetal/Neonatal Adverse Reactions*

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.

Commonly used underlying condition codes specific for patients with IDA & ID in Heart Failure (HF)* *(cont'd)*

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

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

*Additional code suggestions only; appropriate codes not limited to those listed above. Injectafer is indicated to treat ID and 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.

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injectafer® ferric carboxymaltose injection

IMPORTANT SAFETY INFORMATION

WARNING: SYMPTOMATIC HYPOPHOSPHATEMIA

- **INJECTAFER can cause severe, prolonged hypophosphatemia associated with serious outcomes, including hospitalization, osteomalacia, and fractures requiring clinical intervention.**
- **Hypophosphatemia has occurred in patients with normal baseline phosphate levels and without apparent risk factors for hypophosphatemia.**
- **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 repeat course of therapy within three months. Correct pre-existing hypophosphatemia prior to administering INJECTAFER.**
- **Advise patients receiving INJECTAFER about the risk of hypophosphatemia and to report any signs and symptoms of hypophosphatemia (e.g., fatigue, muscle weakness or pain, bone and joint pain, bone fractures).**

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Symptomatic Hypophosphatemia

Symptomatic hypophosphatemia, including severe cases, with serious outcomes such as osteomalacia and fractures requiring clinical intervention have occurred in patients treated with INJECTAFER in the post-marketing setting. These cases have occurred after single and multiple doses of INJECTAFER. 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). However, individuals without apparent risk factors have experienced symptomatic hypophosphatemia. In most cases, hypophosphatemia resolved within three months.

Check serum phosphate levels prior to a repeat course of treatment if the patient is at risk for low serum phosphate or if the patient will receive a repeat course of therapy within three months of the prior course. Correct pre-existing hypophosphatemia prior to administering INJECTAFER. Monitor serum phosphate levels in patients at risk for chronic low serum phosphate. Treat hypophosphatemia as medically indicated.

Consider permanent discontinuation of INJECTAFER for severe symptomatic hypophosphatemia or persistent hypophosphatemia.

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.

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ADVERSE REACTIONS

The most common adverse reactions in adult patients (>2%) are nausea, hypertension, flushing, injection site reactions, erythema, hypophosphatemia, and dizziness.

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USE IN SPECIFIC POPULATIONS

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INDICATIONS

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Please see Full Prescribing Information, including BOXED WARNING.

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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ADDITIONAL RESOURCES

AR Assist®

Support resources to help your patient access Injectafer

AR Assist Patient Support

Coverage and Access Support

Expert help from reimbursement specialists:

• Benefits verifications • Prior authorizations support
• Claims appeals support

Contact AR Assist®

1-877-448-4766 \\ AR-Assist.com

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

*Excludes holidays.

Injectafer Savings Program

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

PATIENTS MAY PAY AS LITTLE AS

$50 PER DOSE

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 AR-Assist.com

Your patient may be eligible if they:

- Have commercial insurance AND
- Are a resident of the US or its territories, including Puerto Rico

Your patient is NOT eligible if they:

- Have Medicare, Medicaid, or other federal or state healthcare insurance, OR
- Have private indemnity or HMO insurance that reimburses patients for the entire cost of prescription drugs, OR
- Are 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.

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Please see Full Prescribing Information and see Important Safety Information, including BOXED WARNING on pages 12–14.

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