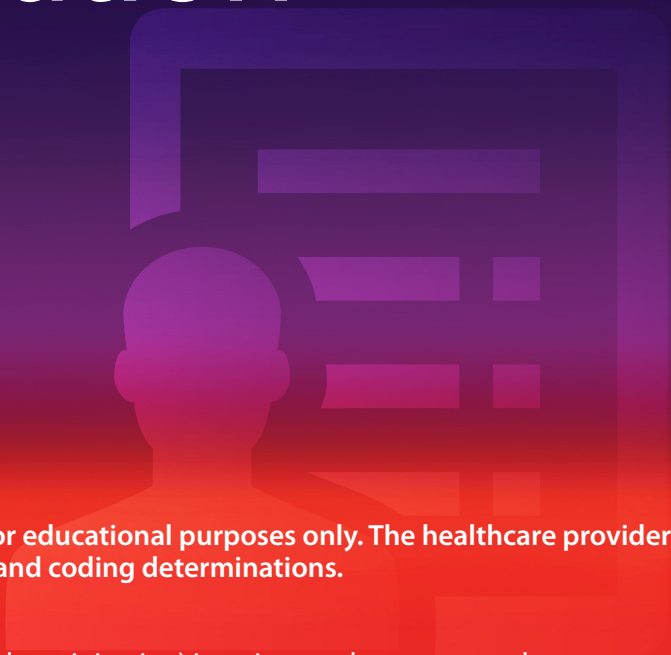
injectafer®
ferric carboxymaltose injection

Billing and Coding Information



The information provided is for educational purposes only. The healthcare provider is fully responsible for billing and coding determinations.

INDICATIONS

- Injectafer® (ferric carboxymaltose injection) is an iron replacement product indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, and in adult patients with non-dialysis dependent chronic kidney disease.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

Please see accompanying Full Prescribing Information and the Important Safety Information on page 5.

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Required Billing and Coding

J Code		
J Code	**Product**	**Indications**
J1439	Injection, ferric carboxymaltose, 1 mg	Injectafer® (ferric carboxymaltose injection) is an iron replacement product indicated for the treatment of IDA in adult patients: • who have intolerance to or have had unsatisfactory response to oral iron or • who have non-dialysis-dependent chronic kidney disease

FOR BILLING AND CODING ASSISTANCE, PLEASE CONTACT:

IV Iron Reimbursement Hotline

1-877-4-IV-IRON (*1-877-448-4766*)

Monday through Friday between 9:00 AM and 8:00 PM, ET

For more information, please visit **injectaferhcp.com.**

Accurate billing and coding is important to understand because not following the process can lead to denial of reimbursement for patients who are appropriate, eligible, and should be covered. Once you have determined Injectafer is appropriate for your patient, this booklet is intended to provide you with helpful information in completing the process.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

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 accompanying Full Prescribing Information for Injectafer and the Important Safety Information on page 5.

Required Product and Administration Codes		
Code Type	**Code**	**Description**
Product Package Codes		
National Drug Code (NDC)	**00517-0650-01**	Injectafer® (ferric carboxymaltose injection) 750 mg iron/15 mL single-use vial (individually boxed)
National Drug Code (NDC)	**00517-0650-02**	Injectafer 750 mg iron/15 mL single-use vial (packages of 2)
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 hr

*Healthcare Common Procedure Coding System.
†Current Procedural Terminology (CPT). CPT® codes 2015 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.

Examples of IDA-Related Diagnosis Codes: Choose a Primary Code	
ICD-10-CM Code‡	
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
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)
D64.81	Antineoplastic chemotherapy-induced anemia (Confirm iron deficiency)

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

A Code Specific to Your IDA Patient's Underlying Condition Is Required[§]

ICD-10-CM Code[‖¶]	
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
N18.3	Chronic Kidney Disease, Stage 3
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

[§] Secondary 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.

[‖] International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)

[¶] 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 guidance has been developed to assist both the healthcare provider and the coder in identifying those diagnoses that are to be reported. 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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In clinical studies, hypertension was reported in 3.8% (67/1775) of subjects. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/ 1775) of subjects. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Injectafer administration.

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

In two randomized clinical studies, a total of 1775 patients were exposed to Injectafer, 15 mg/kg of body weight, up to a single maximum 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 (3.8%); flushing/hot flush (3.6%); blood phosphorus decrease (2.1%); and dizziness (2.0%).

The following serious adverse reactions have been most commonly reported from the post-marketing spontaneous reports: urticaria, dyspnea, pruritus, tachycardia, erythema, pyrexia, chest discomfort, chills, angioedema, back pain, arthralgia, and syncope.

Please see accompanying Full Prescribing Information.

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To report adverse events, please contact American Regent at 1-800-734-9236. You may also contact the FDA at www.fda.gov/medwatch or 1-800-FDA-1088.

Daiichi-Sankyo

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