HELPING YOUR PATIENTS ACCESS INJECTAFER

injectafer® ferric carboxymaltose injection

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

Offering support along the way

COVERAGE AND ACCESS SUPPORT

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

FINANCIAL ASSISTANCE

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

*The Injectafer Savings Program is only available for patients who are commercially insured. Please see full Terms and Conditions on page 14.

CONTACT AR ASSIST®

1-877-448-4766

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

To download Injectafer coverage and access resources, visit AR-Assist.com.

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

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).**

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

Insurance and claims assistance

Expert help from reimbursement specialists

To get help, **your first step is to work with your patient to fill out the Patient Enrollment Form**. Check off the support you are requesting on behalf of your patient. We will take it from there.

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

- Benefits verifications
- Prior authorization support
- Claims appeal support
- Financial assistance options

Visit www.ar-assist.com to download helpful resources, including the Patient Enrollment Form and Sample Letter of Medical Necessity.
If you have any questions regarding reimbursement, call AR Assist at 1-877-448-4766.

SELECT 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, 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.

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

Billing and coding

Important information related to Injectafer® reimbursement

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 is indicated for the treatment of:

- iron deficiency anemia (IDA) in:
  - adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron
  - adult patients who have non-dialysis-dependent chronic kidney disease
- iron deficiency (ID) in adult patients with heart failure (HF) and New York Heart Association (NYHA) class II/III to improve exercise capacity

Product and administration codes

Code Type	Code	Description
Product Package Codes		
NDC	0517-0602-01	Injectafer 100 mg iron/2 mL single-dose 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	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®, © 2026 American Medical Association (AMA). All rights reserved. CPT® is a registered trademark of the American Medical Association.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

injectafer® ferric carboxymaltose injection

Examples of ID/IDA-related diagnosis codes

Injectafer® claims forms require an appropriate ICD-10-CM code. The following table displays possible ICD-10-CM codes related to iron deficiency/iron deficiency anemia (ID/IDA).

Code	Description
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.1	Sideropenic dysphagia
D50.8	Other iron deficiency anemias
D50.9	Iron deficiency anemia, unspecified
E61.1	Iron deficiency (excludes iron deficiency anemia)
D63.0	Anemia in neoplastic disease CODE NEOPLASM FIRST (Confirm iron deficiency)
D63.1	Anemia in chronic kidney disease (CKD) 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)

Other codes may be appropriate.

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

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

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

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

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

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

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

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

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

HF=heart failure; NYHA=New York Heart Association.

A code for your adult patient with ID in HF*

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

Code	Description
I09.81	Rheumatic heart failure
I11.0	Hypertensive heart disease with heart failure
I50	Heart failure
I50.1	Left ventricular failure, unspecified
I50.2	Systolic (congestive) heart failure
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.3	Diastolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.4	Combined systolic and diastolic (congestive) heart failure
I50.40	Unspecified combined systolic and diastolic (congestive) heart failure
I50.41	Acute combined systolic and diastolic (congestive) heart failure
I50.42	Chronic combined systolic and diastolic heart failure
I50.43	Acute on chronic combined systolic and diastolic heart failure

Continued on the next page...

HF=heart failure; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ID=iron deficiency.

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

Continued from the previous page

Code	Description
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

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

We recommend verifying the coding policies for each individual health plan. Reimbursement specialists can provide information relating to payer-specific policies and address other questions at 1-866-437-4669.

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider.

American Regent, Inc.® makes no representation or guarantee concerning coverage or reimbursement for any service or item. A completed form includes signatures from both the physician and the patient. Before submitting, please ensure all required information is provided.

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

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

injectafer® ferric carboxymaltose injection

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

Be complete, precise, and accurate

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

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

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

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

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

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

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

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

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

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

We recommend verifying the coding policies for each individual health plan. Reimbursement specialists can provide information relating to payer-specific policies and address other questions at 1-866-437-4669.

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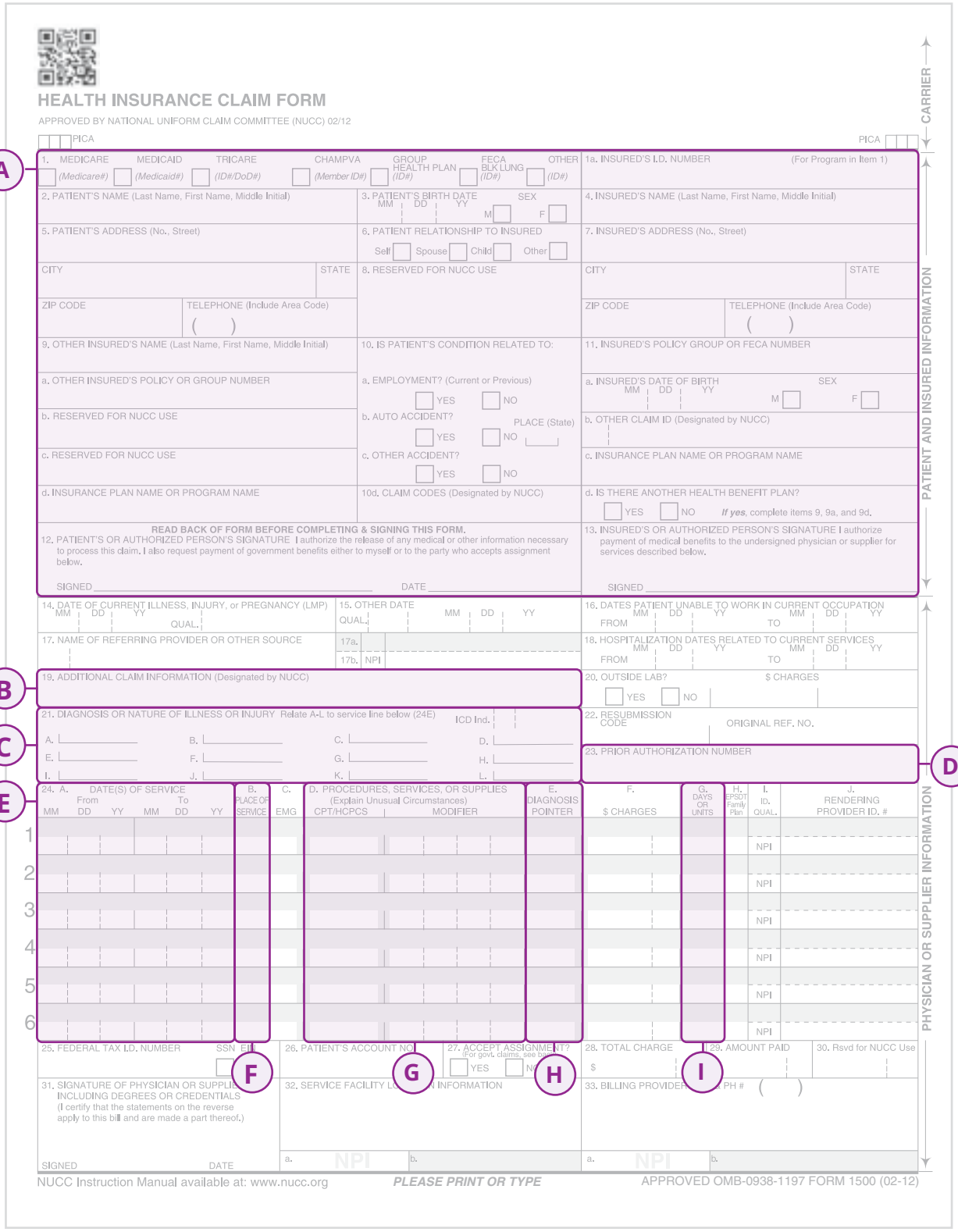
HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ID=iron deficiency; IDA=iron deficiency anemia; IV=intravenous; NDC=National Drug Code.

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



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code)

ZIP CODE TELEPHONE (Include Area Code)

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1										NPI	
2										NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

A B C D E F G H I

injectafer® ferric carboxymaltose injection

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

Be complete, precise, and accurate

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

A **Boxes 8–15:** Enter the patient's personal information.

B **Boxes 42–43:** Enter the appropriate revenue codes and description corresponding to the HCPCS code listed in Box 44.

C **Box 44:** Enter CPT®* code for Injectafer administration: **96374** (slow IV push) or **96365** (IV infusion). On a separate line, enter the unique product-specific billing code (HCPCS) for Injectafer: **J1439**

D **Box 46:** Enter the appropriate number of units: For Injectafer, 1 mg = 1 unit. Total units reported will depend on total dosage administered.

E **Boxes 50–65:** Enter the patient's insurance information.

F **Box 56:** Enter the appropriate National Provider Identifier (NPI) number.

G **Box 67:** Enter the appropriate ICD-10-CM diagnosis codes (both ID/IDA-related and underlying) and the applicable ICD indicator identifying which ICD code version is being reported (ie, enter a "0" for ICD-10-CM). If payer does not accept the ICD-10-CM code(s), include the main reason for the encounter.

H **Box 80:** Payer may require additional information to support review and payment of the claim. This may include NDC, total dosage, and date Injectafer was administered.

We recommend verifying the coding policies for each individual health plan. Reimbursement specialists can provide information relating to payer-specific policies and address other questions at 1-866-437-4669.

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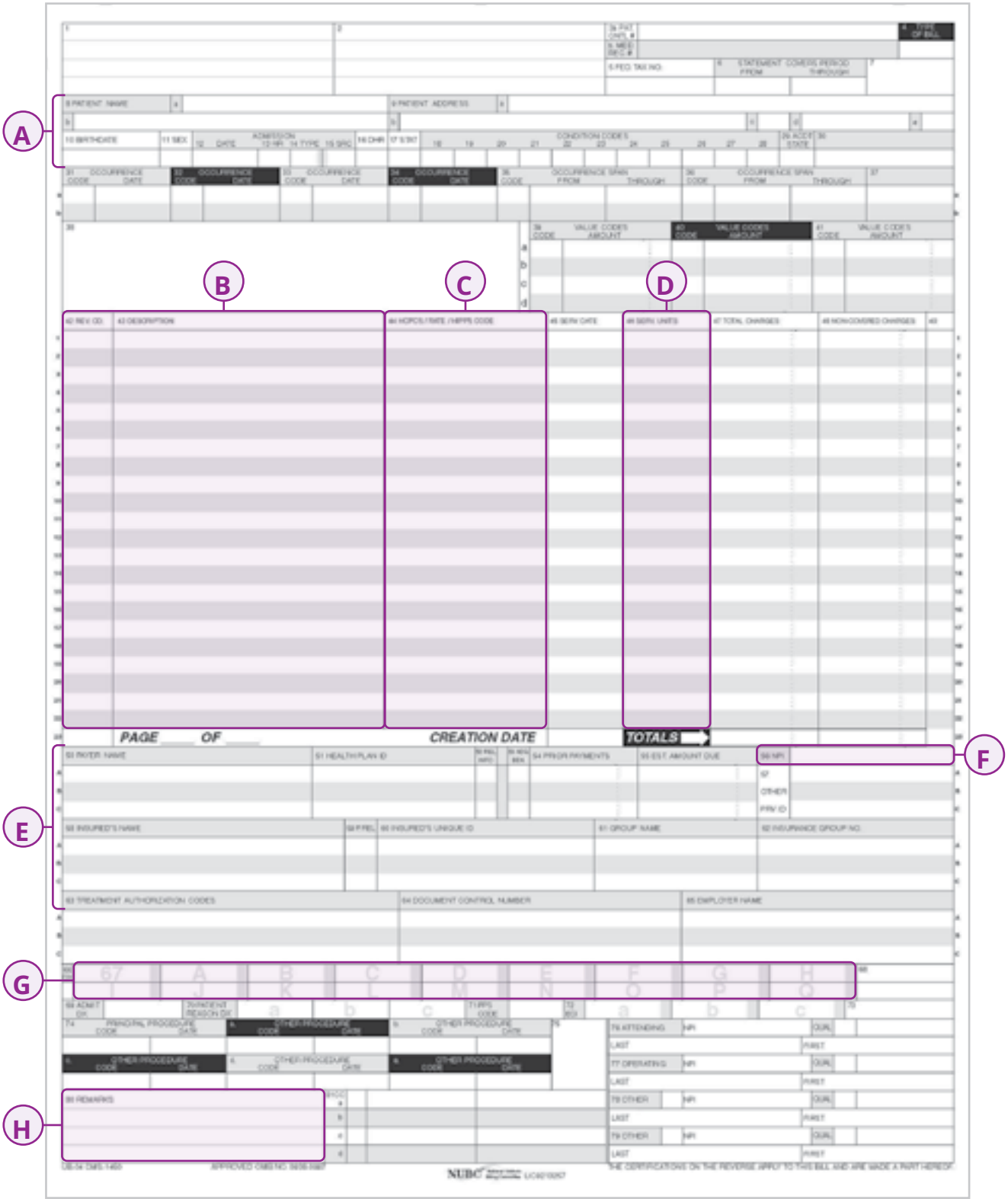
HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ID=iron deficiency; IDA=iron deficiency anemia; IV=intravenous; NDC=National Drug Code

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

COVERAGE AND ACCESS SUPPORT: BILLING AND CODING



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

Your patient may be eligible:*

- Has commercial insurance **AND**
- Is a resident of the USA or its territories, including Puerto Rico

Your patient is NOT eligible:*

- Has Medicare, Medicaid, or other federal or state healthcare insurance, **OR**
- Has private indemnity or HMO insurance that reimburses patients for the entire cost of prescription drugs, **OR**
- Is Medicare-eligible and enrolled in an employer-sponsored health plan or medical or prescription drug benefit program for retirees

*The Injectafer Savings Program is only available for patients who are commercially insured. Please see full Terms and Conditions on page 14.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (Cont'd)
Symptomatic Hypophosphatemia (Cont'd)
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.

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

FINANCIAL ASSISTANCE: INJECTAFER® SAVINGS PROGRAM

Register your office by calling an AR Assist care coordinator at: 1-877-448-4766

- An AR Assist care coordinator will provide you with a login for injectafercopay.com
- Registration only needs to be completed once

Before administering Injectafer, work with your patient to enroll in the program

- Log into injectafercopay.com (you can also enroll the patient at: 1-877-448-4766)
- Enter required patient information
- Upon approval, your patient will recieve a 16-digit code for a virtual copay card that can be used as payment toward Injectafer treatment

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

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

Upload to injectafercopay.com
Most convenient way to submit EOBs and manage all patients

OR **Fax** to: 1-888-257-4673 **OR** **Mail** to:
Injectafer Savings Program
PO Box 2355
Morristown, NJ 07962

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

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

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. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each INJECTAFER administration.

Laboratory Test Alterations

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

injectafer® ferric carboxymaltose injection

Injectafer Savings Program Terms and Conditions

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

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

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

Patient Assistance Program

Help for uninsured or commercially underinsured patients with financial need

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

Eligibility

To qualify, a patient must:

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

How to apply

Work with your patient to enroll in the program in 1 of 2 ways:

- Download the **Patient Enrollment Form** from AR-Assist.com, and work with your patient to complete it. Have the patient sign the enrollment form, then fax it to 1-833-471-9988 (preferred method for fastest support)

  OR

- Call **1-877-448-4766**

Important timing notice

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

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

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

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

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
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 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.

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.

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.

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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injectafer® ferric carboxymaltose injection

CONTACT AR ASSIST

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

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

*Excludes holidays.

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AR Assist

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