

HOSPITAL OUTPATIENT BILLING & CODING



Medicare, Medicaid, and Commercial

This information is intended to provide information regarding billing and coding. Health care providers may use this information, in addition to other sources of information, to determine for themselves the appropriate claims to file for MonoFerric and related services. A health care provider should contact patients' payers directly for any revised or additional requirements, information, or guidance.

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes

The following tables display selected diagnosis codes that may be associated with iron deficiency anemia*

Primary Diagnosis Codes		Secondary Diagnosis Codes	
ICD-10-CM ¹ diagnosis code	Description	ICD-10-CM ¹ diagnosis code	Description
D50.0	Iron deficiency anemia secondary to blood loss (chronic)	K50.0-K50.919	Crohn's disease [regional enteritis]
D50.1	Sideropenic dysphagia	K51.0-K51.919	Ulcerative colitis
D50.8	Other iron deficiency anemias	K90.0	Celiac disease
D50.9	Iron deficiency anemia, unspecified	K90.4	Malabsorption due to intolerance not elsewhere classified
D63.0	Anemia in neoplastic disease	K90.9	Intestinal malabsorption unspecified
CODE NEOPLASM FIRST (Confirm iron deficiency)		N18.1	Chronic kidney disease, stage 1
D63.1	Anemia in chronic kidney disease	N18.2	Chronic kidney disease, stage 2
CODE CKD STAGE FIRST (Confirm iron deficiency)		N18.3	Chronic kidney disease, stage 3
D63.8	Anemia in other chronic diseases classified elsewhere	N18.4	Chronic kidney disease, stage 4
CODE UNDERLYING DISEASE FIRST (Confirm iron deficiency)			
D64.81	Antineoplastic chemotherapy-induced anemia (Confirm iron deficiency)		

Current Procedural Terminology (CPT) code

CPT [†] code	Description
96365 ⁴	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)

Healthcare Common Procedure Coding System (HCPCS) level II codes

HCPCS code	Descriptor	Site of care	Additional information
J1437 ³	Injection, ferric derisomaltose, 10 mg	All sites of care	Include the N4 qualifier, NDC number, unit of measure qualifier, and amount administered to the patient in Box 43. Example: N473594931001ME1000

Revenue codes

Revenue code	Description	Revenue code	Description
0250	General Pharmacy	0510	Clinic, general
0260	IV therapy	0636	Pharmacy, drugs requiring detailed coding

National Drug Code (NDC)

The National Drug Code is a unique 10-digit, three-segment number. It is a universal product identifier for drugs in the United States present on all over-the-counter and prescription medication packages and inserts.

Many NDC numbers listed on drug packaging are in a 10 digit format. The NDC number is essential for proper claim processing when submitting claims for drugs used; however, **to be recognized by payers, it must be formatted into an 11 digit 5-4-2 sequence**. This requires a zero to be placed in a specific position to meet the 5-4-2 format requirement.⁵ As not all NDC numbers are set up the same, **the table below demonstrates how to achieve the 11 digit NDC code for MonoFerric**.

Please note, because many practice management systems automatically remove the hyphens, be sure they are excluded from submission on the claim.

10 digit format	Tradename	Package strength	NDC number	New format	NDC number for payer
5-4-1	MonoFerric ⁶	1,000 mg iron /10 mL (100 mg/mL) single-dose vial ⁶	73594-9310-1	5-4-2	73594-9310- <u>01</u>

* Sample diagnosis codes for the appropriate patient prescribed MonoFerric
[†] CPT © 2020 American Medical Association. All rights reserved.

IMPORTANT INFORMATION: The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate health care setting, and to submit true and correct claims for those products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials are provided to assist health care providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the provider.

SAMPLE UB-04 (CMS-1450) CLAIM FORM² FOR MONOFERRIC

Medicare and Medicaid

The UB-04 claim form (also known as CMS-1450) is the standard claim form to bill Medicare Fee-For-Service (FFS). The sample here is intended to educate you on completing the form for billing MonoFerric and associated services. Although this sheet provides information that should facilitate the claims process, all coding information is for reference purposes only. Pharmacosmos Therapeutics Inc. does not guarantee payment.

Box 42: Enter the appropriate revenue code corresponding with the HCPCS code in box 44, 0510 for clinic services and 0636 revenue code for pharmacy drugs that require detailed coding.

Box 43: Enter a detailed drug description: the N4 indicator, the 11-digit National Drug Code number, a code describing the unit of measurement qualifier (eg, ME for milligrams), and the unit quantity. Example: N473594931001ME1000.

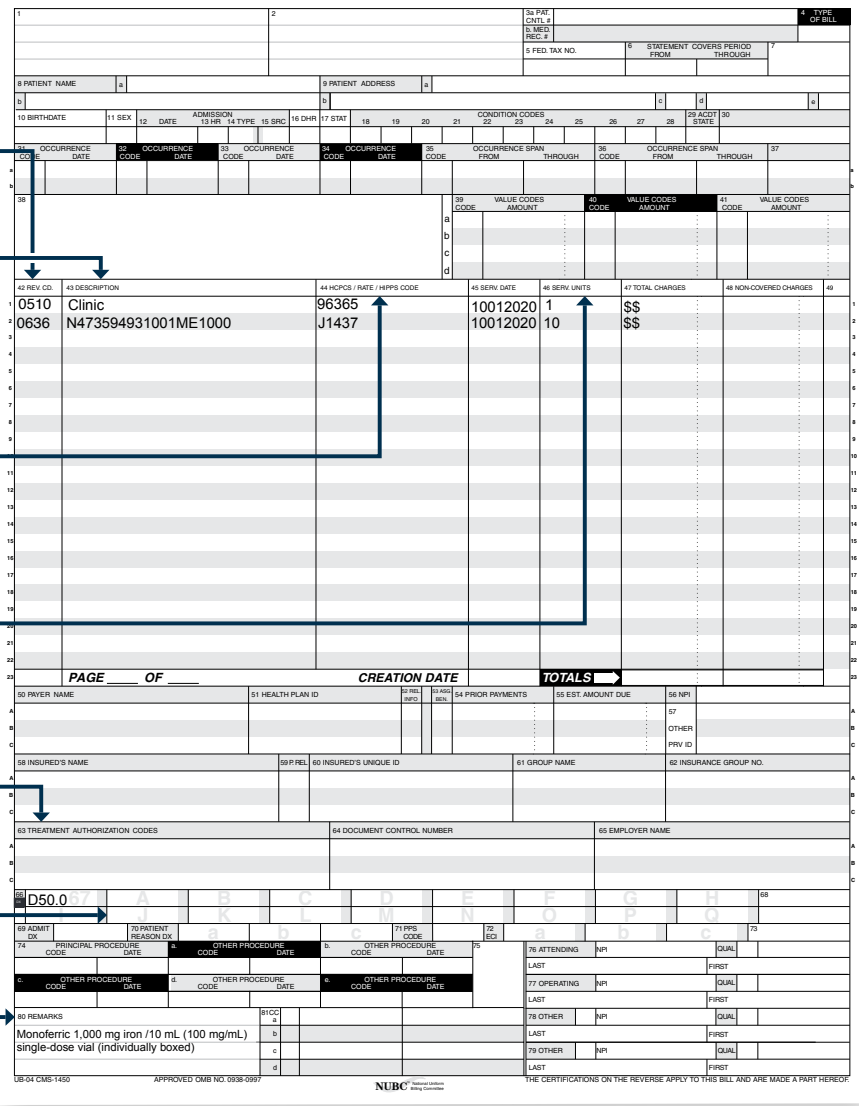
Box 44: Enter the appropriate, HCPCS code for MonoFerric, J1437, Injection, ferric derisomaltose, 10 mg. To report the administration procedure, enter an appropriate CPT code (e.g., 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)).⁴

Box 46: Enter the total number of units of service for MonoFerric, J1437, Injection, ferric derisomaltose, 10 mg. The payer may refer to the actual quantity administered via Box 43 and Box 80. Note, MonoFerric's dosing is weight based and will vary by patient. When submitting the claim form, please remember that because the billing units are 10 mg, the total amount of drug being billed must be divided by 10.

Box 63: Enter the prior authorization number.

Box 67A-67Q: Enter the appropriate ICD-10-CM diagnosis code (eg, D50.0 for iron deficiency anemia secondary to blood loss (chronic)). Code to the highest level of specificity.

Box 80: Enter additional details including the drug name, administered dose, route of administration, and NDC number.



The form is a standard UB-04 (CMS-1450) claim form. Key fields are populated with sample data:

- Box 42:** Revenue code 0510 (Clinic) and 0636 (Pharmacy drug).
- Box 43:** Description: N473594931001ME1000.
- Box 44:** HCPCS code J1437 and CPT code 96365.
- Box 46:** Serv units: 10.
- Box 63:** Prior authorization number: D50.0.
- Box 67A-67Q:** ICD-10-CM diagnosis code: D50.0.
- Box 80:** Remarks: MonoFerric 1,000 mg iron /10 mL (100 mg/mL) single-dose vial (individually boxed).

Note: To facilitate accurate payment, report the exact dose administered.² More information on the claims process and the CMS fee schedule can be found [here](#).

MonoFerric is also available through the specialty pharmacy, Biologics by McKesson, if preferred by your office or required by your patient's health plan.

References: 1. Centers for Medicare and Medicaid Services. 2020 ICD-10-CM. <https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM>. Accessed August 28, 2020. 2. Centers for Medicare & Medicaid Services. CMS Manual System. Details for title: CMS 1450 (UB-04). <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450.html>. Accessed July 17, 2020. 3. Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions: Second Quarter, 2020 Coding Cycle for Drug and Biological Products. <https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-2-2020-drugs-and-biologicals-updated-07312020.pdf>. Accessed July 17, 2020. 4. Find-A-Code. 96365 - CPT® Code in category: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug). InnoviHealth Systems, Inc. <https://www.findacode.com/code.php?set=CPT&c=96365>. Updated 2018. Accessed July 17, 2020. 5. National Drug Code (NDC) Conversion Table. Converting NDCs from 10-digits to 11 digits. <https://phpa.health.maryland.gov/OIDEOR/IMMUN/Shared%20Documents/Handout%203%20-%20NDC%20conversion%20to%2011%20digits.pdf>. Accessed August 26, 2020. 6. MonoFerric [prescribing information]. Morristown, NJ: Pharmacosmos Therapeutics, Inc; 2020.

INDICATION

Monoferric is 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
- who have non-hemodialysis dependent chronic kidney disease (NDD-CKD)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Monoferric is contraindicated in patients with a history of serious hypersensitivity to Monoferric or any of its components. Reactions have included shock, clinically significant hypotension, loss of consciousness, and/or collapse.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Monoferric. 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 Monoferric administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Monoferric when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. Monoferric is contraindicated in patients with prior serious hypersensitivity reactions to Monoferric or any of its components. In clinical trials in patients with IDA and CKD, serious or severe hypersensitivity were reported in 0.3% (6/2008) of the Monoferric treated subjects. These included 3 events of hypersensitivity in 3 patients; 2 events of infusion-related reactions in 2 patients and 1 event of asthma in one patient.

Iron Overload

Excessive therapy with parenteral iron can lead to excess iron storage and possibly iatrogenic hemosiderosis or hemochromatosis. Monitor the hematologic response (hemoglobin and hematocrit) and iron parameters (serum ferritin and transferrin saturation) during parenteral iron therapy. Do not administer Monoferric to patients with iron overload.

ADVERSE REACTIONS

Adverse reactions were reported in 8.6% (172/2008) of patients treated with Monoferric. Adverse reactions related to treatment and reported by $\geq 1\%$ of the treated patients were nausea (1.2%) and rash (1%). Adjudicated serious or severe hypersensitivity reactions were reported in 6/2008 (0.3%) patients in the Monoferric group. Hypophosphatemia (serum phosphate < 2.0 mg/dL) was reported in 3.5% of Monoferric-treated patients in Trials 1 & 2.

To report adverse events, please contact Pharmacosmos at [1-888-828-0655]. You may also contact the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

Please [click here](#) for full Prescribing Information.

Monoferric Patient Solutions



800-992-9022

| Monday-Friday, 8 AM to 8 PM ET



| monoferric-patient-solutions.com