MonoFerric®
(ferric derisomaltose)
injection

PROVIDER BILLING AND CODING GUIDE

Medicare, Medicaid, and Commercial

Pharmacosmos Therapeutics Inc.
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Updated: June 2023

INDICATIONS

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)

Please see Important Safety Information throughout and full Prescribing Information.

PROVIDER BILLING AND CODING: OFFICE SETTING

MonoFerric® (ferric derisomaltose) injection

Medicare, Medicaid, and Commercial

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 healthcare 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 healthcare 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.

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 (IDA).*

Primary diagnosis codes

ICD-10-CM[1] diagnosis code	Description
D50.0	IDA secondary to blood loss (chronic)
D50.1	Sideropenic dysphagia
D50.8	Other IDAs
D50.9	IDA, unspecified
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

Secondary diagnosis codes

ICD-10-CM[1] diagnosis code	Description
E83.10	Iron metabolism
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	CKD, stage 1
N18.2	CKD, stage 2 (mild)
N18.3	CKD, stage 3 (moderate)
N18.30	CKD, stage 3 unspecified
N18.31	CKD, stage 3a
N18.32	CKD, stage 3b
N18.4	CKD, stage 4 (severe)
N18.5	CKD, stage 5
N18.6	End-stage renal disease
N18.9	CKD, 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
T45.4X5D	Adverse effect of iron and its compounds, secondary encounter
T45.4X5S	Adverse effect of iron and its compounds, sequela encounter
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter

*Sample diagnosis codes for the appropriate patient prescribed Monoferric.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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PROVIDER BILLING AND CODING: OFFICE SETTING (cont'd)

MonoFerric® (ferric derisomaltose) injection

Current Procedural Terminology (CPT) code

CPT* code	Description
96365[2]	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	If required by the payer, include the N4 qualifier, National Drug Code (NDC), unit of measure qualifier, and amount administered to the patient in Box 43. Example: N473594931001ME1000

National Drug Code (NDC)

The NDC is a unique 10-digit, 3-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 0 to be placed in a specific position to meet the 5-4-2 format requirement.[4] 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	Trade name	Package strength	NDC number	New format	NDC number for payer
5-4-1	**Monoferric**[5]	1000 mg iron/10 mL (100 mg/mL) single-dose vial[5]	73594-9310-1	5-4-2	73594-9310-**0**1

Additional Information

Only the 1000 mg iron/10 mL (100 mg/mL) single-dose vial of Monoferric is available in the United States.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

SAMPLE CMS-1500 CLAIM FORM[6]

MonoFerric® (ferric derisomaltose) injection

Patient weight 50 kg or above: Administer 1000 mg of Monoferric as an intravenous infusion[5]

Note, only the 1000 mg iron/10 mL (100 mg/mL) single-dose vial of Monoferric is available in the United States. The sample form provides information for demonstration purposes only. It provides an example of the type of information that may facilitate the claims process with a patient's insurance provider. All coding information is for reference purposes only. Use of this template or the information in this sample form does not guarantee reimbursement or coverage.

Box 19: If additional information is required to describe Monoferric (eg, NDC, route of administration), this information may be captured in Box 19.

Box 21: Enter the appropriate ICD-10-CM diagnosis code[1] (eg, **D50.0** for IDA secondary to blood loss [chronic]). Code to the highest level of specificity.

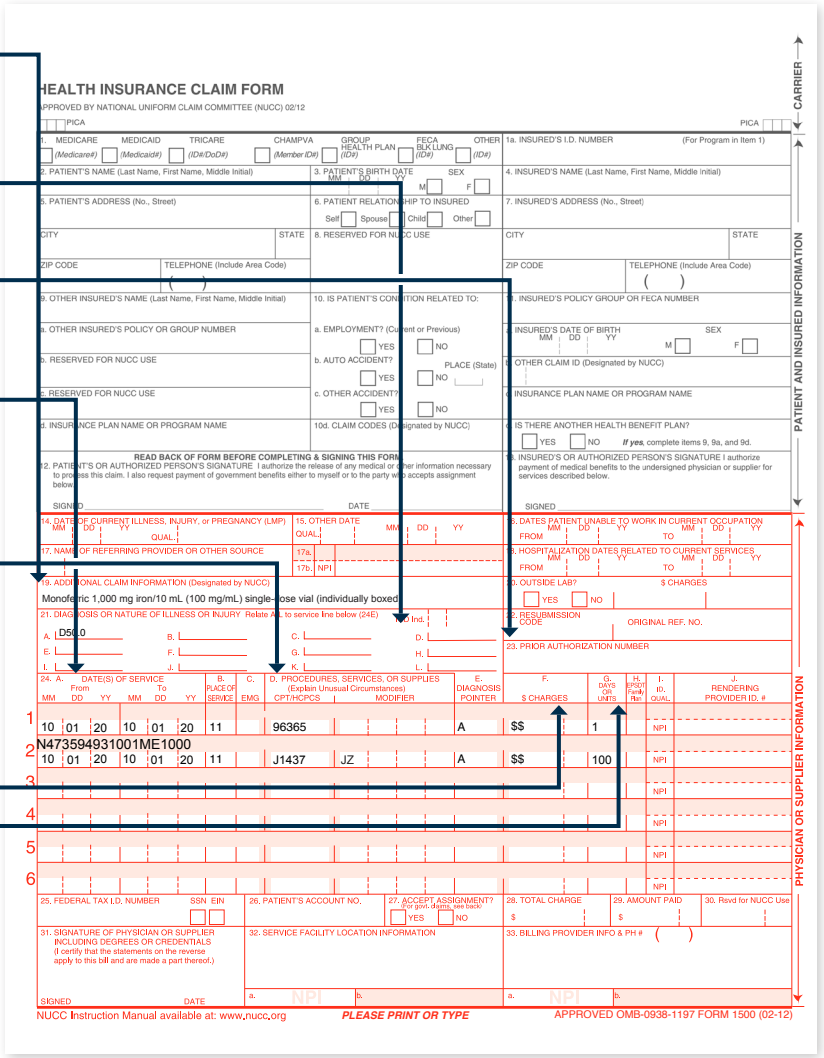
Box 23: Enter the PA number.

Box 24A: In the nonshaded area, list the date of service. If required by the payer, in the shaded area, provide a detailed drug description: the N4 indicator, the 11-digit NDC number, the unit of measurement qualifier (eg, ME for milligrams), and the unit quantity. Example: N4735949310O1ME1000.

Box 24D: Enter the appropriate HCPCS code for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg.[3] Cases with no wastage should report JZ modifier with J1437.[7] Include the appropriate CPT code to report the administration procedure (eg, 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]).[2]

Box 24F: Enter the charge for each listed service and the product.

Box 24G: Report the appropriate number of units for the procedure and the appropriate number of units for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg. In the example claim form, 1000 mg dose of Monoferric is billed in 10 mg increments for a total of 100 units billed.



HEALTH INSURANCE CLAIM FORM

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

PICA

CARRIER

PATIENT AND INSURED INFORMATION

Box 19: Monoferric 1,000 mg iron/10 mL (100 mg/mL) single-dose vial (individually boxed)

Box 21: A. D50.0

Box 24A: 1 | 10 01 20 | 10 01 20 | 11 | 96365 | | A | $$ | 1 | NPI

Box 24A: 2 | N4735949310O1ME1000

Box 24A: 2 | 10 01 20 | 10 01 20 | 11 | J1437 | JZ | A | $$ | 100 | NPI

PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: www.nucc.org | PLEASE PRINT OR TYPE | APPROVED OMB-0938-1197 FORM 1500 (02-12)

Sample billing units calculation: For a 1000 mg dose of Monoferric, 100 billable units may be appropriate (1000 mg/10 mg per unit = 100)

Note: To facilitate accurate payment, report the exact dose administered.[3] More information on the claims process and the Centers for Medicare & Medicaid Services (CMS) fee schedule can be found on https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNING AND PRECAUTIONS (cont'd)

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.

Please see Important Safety Information throughout and full Prescribing Information.

SAMPLE CMS-1500 CLAIM FORM[6]

MonoFerric® (ferric derisomaltose) injection

Patient weight less than 50 kg: Administer 20 mg/kg actual body weight as an intravenous infusion[5]

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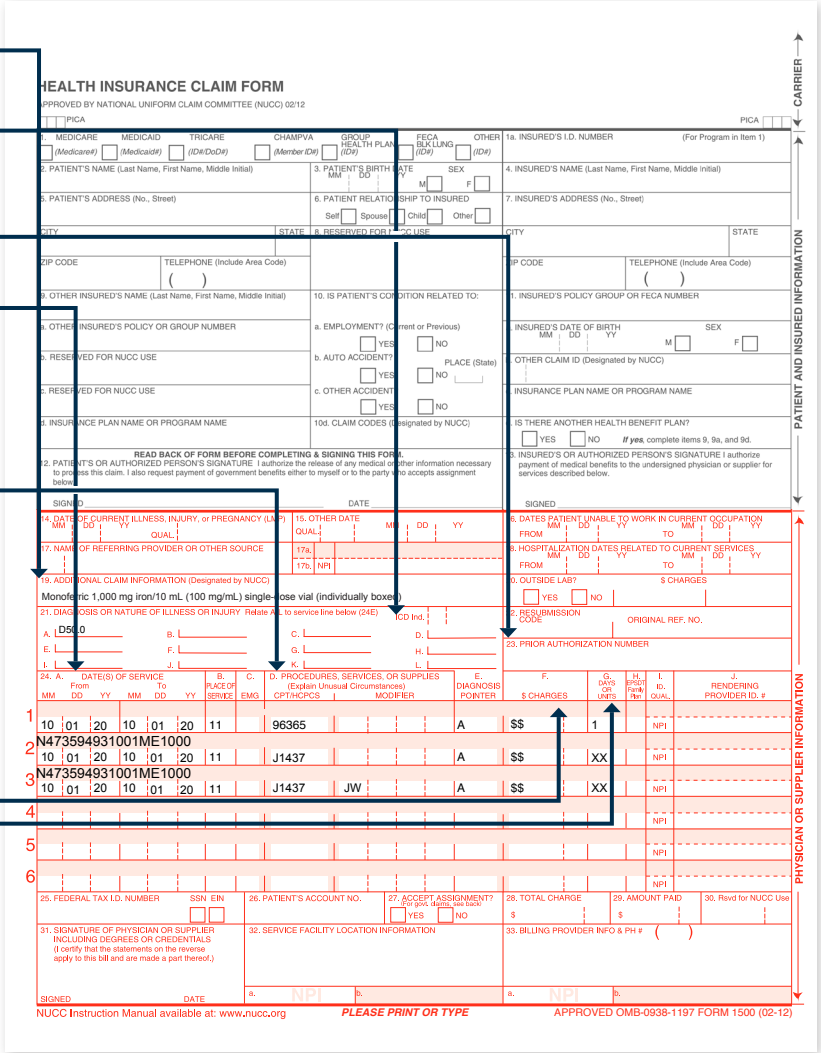
Box 24D: Enter the appropriate HCPCS code for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg.[3] Include the appropriate CPT code to report the administration procedure (eg, 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]).[2]

Box 24F: Enter the charge for each listed service and the product.

Box 24G: Report the appropriate number of units for the procedure and the appropriate number of units for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg. Note, Monoferric's dosing is weight-based for patients under 50 kg and will vary by patient. Monoferric is billed in 10 mg increments, and billing units are displayed as XX on the sample form to indicate differences in weight-based dosing. A JW modifier may be used to report the amount of the drug that is unused after administration to a patient. For Medicare and some payers, the unused amount should be reported on a separate line of the claim form, and the claim should include the drug code, modifier, and number of units discarded.[4]



Sample billing units calculation: 20 mg/kg * Y kg of body weight = 20 * Y mg administered. Then [20 * Y] * 1 billing unit / 10 mg = [# Billing Units]

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

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

Adverse reactions were reported in 8.6% (172/2008) of patients treated with Monoferric. Adverse reactions related to treatment and reported by ≥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.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION

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Please see full Prescribing Information.

References: 1. Centers for Medicare and Medicaid Services. 2023 ICD-10-CM. Accessed May 23, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm **2.** Find-A-Code. 96365 - CPT® Code in category: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug). InnoviHealth Systems, Inc. Updated 2022. Accessed January 19, 2023. https://www.findacode.com/code.php?set=CPT&c=96365 **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. Accessed January 19, 2023. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-2-2020-drugs-and-biologicalsupdated-07312020.pdf **4.** National Drug Code (NDC) Conversion Table. Converting NDCs from 10-digits to 11 digits. Accessed January 19, 2023. https://phpa.health.maryland.gov/OIDEOR/IMMUN/Shared%20Documents/Handout%203%20-%20NDC%20conversion%20to%2011%20digits.pdf **5.** Monoferric [Prescribing Information]. Morristown, NJ: Pharmacosmos Therapeutics Inc; 2023. **6.** Centers for Medicare & Medicaid Services. CMS Manual System. CMS 1500. Accessed January 19, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/ Manuals/Downloads/clm104c26pdf.pdf **7.** Centers for Medicare & Medicaid Services (CMS). Medicare program JW modifier: drug/biological amount discarded/not administered to any patient frequently asked questions. Accessed January 19, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf

MonoFerric Patient Solutions®

1-800-992-9022 | Monday-Friday, 8 AM to 8 PM ET

monoferric-patient-solutions.com | monoferricpatientsolutionsportal.com | monoferriccopay.com

PHARMACOSMOS THERAPEUTICS

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