MonoFerric Patient Solutions®

MonoFerric® (ferric derisomaltose) injection

SAMPLE CMS-1500 CLAIM FORM[1] FOR MONOFERRIC | Physician office administration

(Patient Weight 50 kg or Above): Administer 1,000 mg of Monoferric as an intravenous infusion[2]

Note, only the 1,000 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 (e.g., National Drug Code (NDC), route of administration), this information may be captured in Box 19.

Box 21: Enter the appropriate ICD-10-CM diagnosis code[3] (e.g., **D50.0** for iron deficiency anemia (IDA) secondary to blood loss (chronic)). Code to the highest level of specificity.

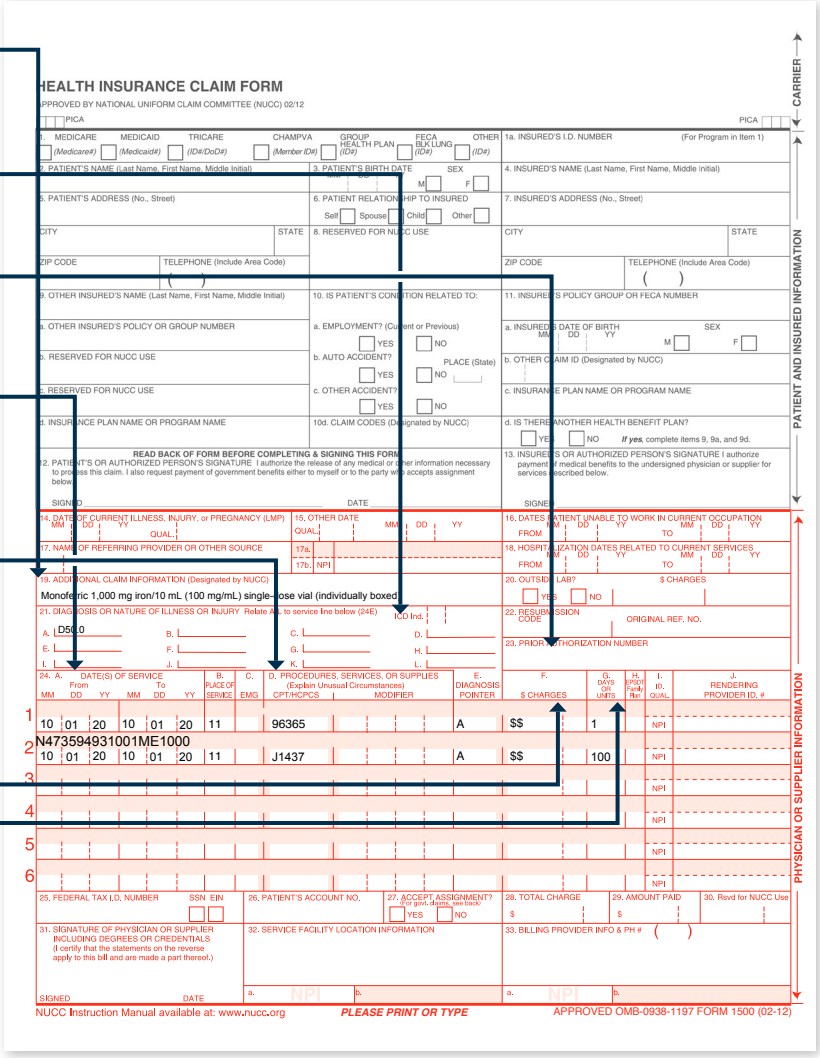
Box 23: Enter the prior authorization (PA) number.

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 (e.g., ME for milligrams), and the unit quantity. Example: N473594931001ME1000.

Box 24D: Enter the appropriate HCPCS code for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg.[4] Include the appropriate CPT code to report the administration procedure (e.g., 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)).[5]

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, 1,000 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

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

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

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY

A. D50.0

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE | 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. #

	From	To											
1	10 01 20	10 01 20	11		96365		A	$$	1		NPI		
2	N473594931001ME1000												
2	10 01 20	10 01 20	11		J1437		A	$$	100		NPI		
3											NPI		
4											NPI		
5											NPI		
6											NPI		

PHYSICIAN OR SUPPLIER INFORMATION

25. FEDERAL TAX I.D. NUMBER | SSN EIN | 26. PATIENT'S ACCOUNT NO. | 27. ACCEPT ASSIGNMENT? | 28. TOTAL CHARGE | 29. AMOUNT PAID | 30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH #

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 1,000 mg dose of Monoferric, 100 billable units may be appropriate (1,000 mg/10 mg per unit = 100)

Note: To facilitate accurate payment, report the exact dose administered.[4] More information on the claims process and the Centers for Medicare & Medicaid Services (CMS) fee schedule can be found **here**.

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.

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; or 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 signification hypotension, loss of consciousness, and/or collapse.

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SAMPLE CMS-1500 CLAIM FORM[1] FOR MONOFERRIC | Physician office administration

(Patients weighing less than 50 kg): Administer 20 mg/kg actual body weight as an intravenous infusion[2]

Note, only the 1,000 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 (e.g., NDC, route of administration), this information may be captured in Box 19.

Box 21: Enter the appropriate ICD-10-CM diagnosis code[3] (e.g., **D50.0** for IDA secondary to blood loss (chronic)). Code to the highest level of specificity.

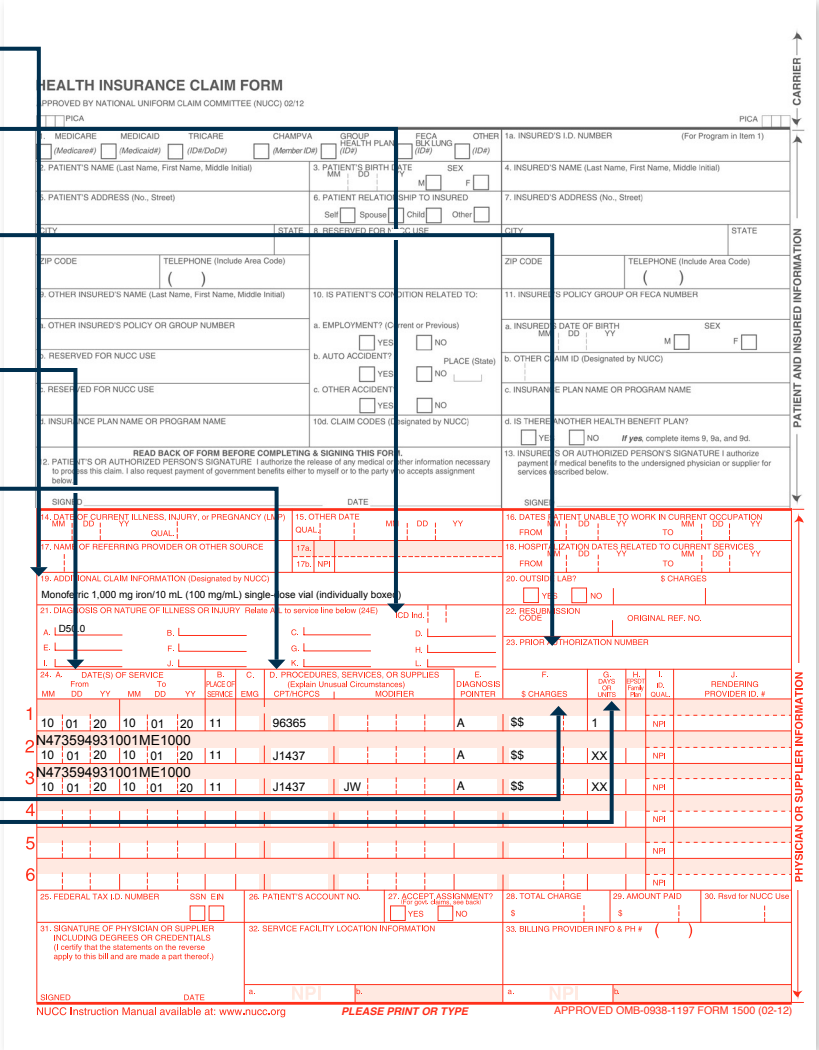
Box 23: Enter the PA number.

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 (e.g., ME for milligrams), and the unit quantity. Example: N4735949310O1ME1000.

Box 24D: Enter the appropriate HCPCS code for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg.[4] Include the appropriate CPT code to report the administration procedure (e.g., 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)).[5]

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.[6]



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21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY

A. D50.0

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 10 01 20	10 01 20	11		96365		A	$$	1		NPI	
N4735949310O1ME1000											
2 10 01 20	10 01 20	11		J1437		A	$$	XX		NPI	
3 N4735949310O1ME1000											
3 10 01 20	10 01 20	11		J1437	JW	A	$$	XX		NPI	
4										NPI	
5										NPI	
6										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: 20 mg/kg * Y kg of body weight = 20 * Y mg administered. Then [20 * Y] * 1 billing unit/10 mg = [# Billing Units]

Note: To facilitate accurate payment, report the exact dose administered.[4] More information on the claims process and the CMS fee schedule can be found **here**.

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.

IMPORTANT SAFETY INFORMATION (continued)

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.

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
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WARNINGS AND PRECAUTIONS

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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 ≥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.

References: 1. Centers for Medicare & Medicaid Services. CMS Manual System. CMS 1500. **https://www.cms.gov/Regulations-and-Guidance/Guidance/_Manuals/Downloads/clm104c26pdf.pdf**. Accessed December 5, 2022. **2.** Monoferric [Prescribing Information]. Morristown, NJ: Pharmacosmos Therapeutics Inc; 2023. **3.** Centers for Medicare & Medicaid Services. 2023 ICD-10-CM. **https://www.cms.gov/medicare/icd-10/2023-icd-10-cm**. Accessed December 5, 2022. **4.** 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-22020-drugs-and-biologicals-updated-07312020.pdf**. Accessed December 5, 2022. **5.** 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 2020. Accessed December 5, 2022. **6.** Centers for Medicare & Medicaid Services (CMS). Medicare program JW modifier: drug/biological amount discarded/ not administered to any patient frequently asked questions. **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/ Downloads/JW-Modifier-FAQs.pdf**. Accessed December 5, 2022.

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