MonoFerric Patient Solutions®

MonoFerric® (ferric derisomaltose) injection

SAMPLE UB-04 CMS-1450 CLAIM FORM[1] FOR MONOFERRIC | Hospital outpatient 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 UB-04 claim form (also known as CMS-1450) is the standard claim form to bill Medicare Fee-For-Service (FFS). This sample is intended to educate you on completing the form when billing for Monoferric. Although this sheet provides information that may facilitate the claims process, all coding information is for reference purposes only. Use of this sample claim form or the information in this sample claim form does not guarantee reimbursement of coverage.

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: If required by the payer, enter a detailed drug description: the N4 indicator, the 11-digit National Drug Code (NDC) number, a code describing the unit of measurement qualifier (e.g., ME for milligrams), and the unit quantity. Example: N473594931001ME1000.

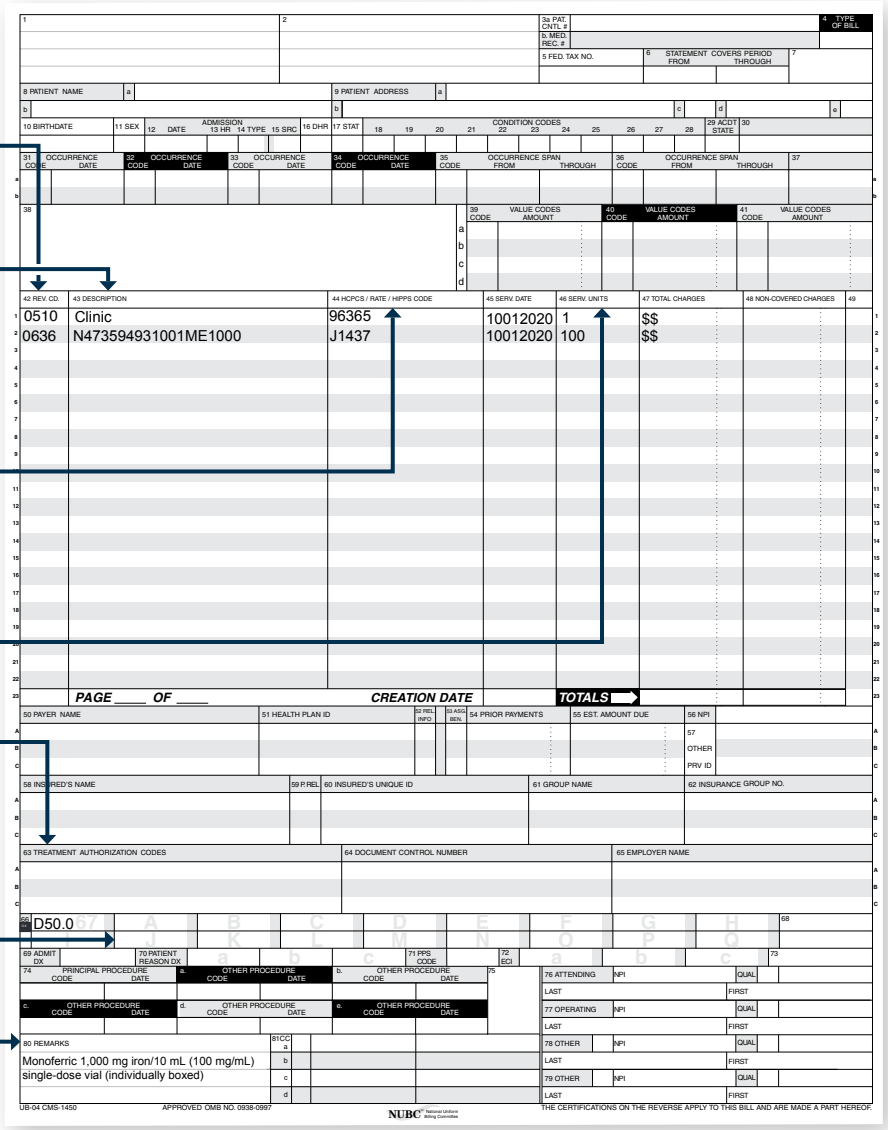
Box 44: Enter the appropriate HCPCS code for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg.[3] To report the administration procedure, enter an appropriate CPT code (e.g., 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)).[4]

Box 46: Enter the total number of units of service for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg. In the example claim form, 1,000 mg dose of Monoferric is billed in 10 mg increments for a total of 100 units billed.

Box 63: If required by payer, enter the prior authorization (PA) number.

Box 67A-67Q: Enter the appropriate ICD-10-CM diagnosis code[5] (e.g., **D50.0** for iron deficiency anemia (IDA) secondary to blood loss (chronic)). Code to the highest level of specificity.

Box 80: If required by payer, additional information remarks may be added such as NDC, route of administration, quantity, etc.



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.[3] 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 UB-04 CMS-1450 CLAIM FORM[1] FOR MONOFERRIC | Hospital outpatient 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 UB-04 claim form (also known as CMS-1450) is the standard claim form to bill Medicare FFS. This sample is intended to educate you on completing the form when billing for Monoferric. Although this sheet provides information that may facilitate the claims process, all coding information is for reference purposes only. Use of this sample claim form or the information in this sample claim form does not guarantee reimbursement of coverage.

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: If required by the payer, enter a detailed drug description: the N4 indicator, the 11-digit NDC number, a code describing the unit of measurement qualifier (e.g., ME for milligrams), and the unit quantity.
Example: N473594931001ME1000.

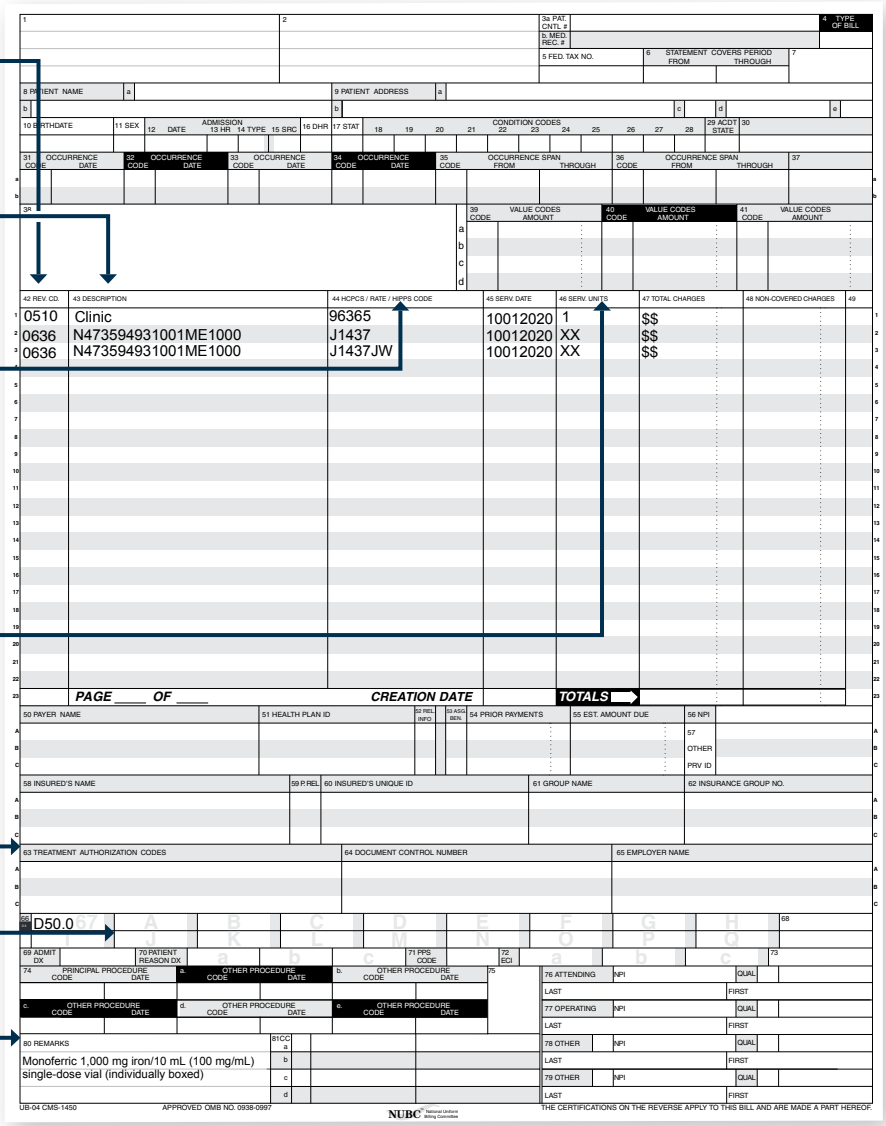
Box 44: Enter the appropriate HCPCS code for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg.[3] To report the administration procedure, enter an appropriate CPT code (e.g., 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)).[4]

Box 46: Enter the total number of units of service for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg. 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]

Box 63: Enter the PA number.

Box 67A-67Q: Enter the appropriate ICD-10-CM diagnosis code[5] (e.g., **D50.0** for IDA secondary to blood loss (chronic)). Code to the highest level of specificity.

Box 80: If required by payer, additional information remarks may be added such as NDC, route of administration, quantity, etc.



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.[3] More information on the claims process and the CMS fee schedule can be found **here**.

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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
- 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.

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 ≥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 1450 (UB-04). **https://www.cms.gov/Regulations-and-Guidance/ Guidance/Manuals/Downloads/clm104c25.pdf**. Accessed December 5, 2022. **2.** Monoferric [Prescribing Information]. Morristown, NJ: Pharmacosmos Therapeutics Inc; 2023. **3.** Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions: Secon Quarter, 2020 Coding Cycle for Drug and Biological Products. **https://www.cms.gov/files/document/2020-hcpcs-applicationsummary-quarter-2-2020-drugs-and-biologicals-updated-07312020.pdf**. Accessed December 5, 2022. **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 2020. Accessed December 5, 2022. **5.** Centers for Medicare and Medicaid Services. 2023 ICD-10-CM. **https://www.cms.gov/ medicare/icd-10/2023-icd-10-cm**. 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/JWModifier-FAQs.pdf**. Accessed December 5, 2022.

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