



MonoFerric[®]
(ferric derisomaltose)
injection

PROVIDER BILLING AND CODING GUIDE

Medicare, Medicaid, and Commercial

Pharmacosmos Therapeutics Inc.

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Morristown, NJ 07960

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



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

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.

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



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- <u>0</u> 1 |

Additional Information

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

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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.

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SAMPLE CMS-1500 CLAIM FORM⁶



Patient weight 50 kg or above: Administer 1000 mg of MonoFerric as an intravenous infusion⁵

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 code¹ (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: N473594931001ME1000.

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.

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.

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SAMPLE CMS-1500 CLAIM FORM⁶



Patient weight less than 50 kg: Administer 20 mg/kg actual body weight as an intravenous infusion⁵

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.

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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]

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 on <https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf>.

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.

Please see Important Safety Information throughout and full [Prescribing Information](#).

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

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IMPORTANT SAFETY INFORMATION

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WARNINGS AND PRECAUTIONS

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ADVERSE REACTIONS

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



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

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