**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).

**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.

**IMPORTANT SAFETY INFORMATION**

Only 1,000 mg iron/10 mL (100 mg/mL) single-dose vial of Monoferric is available in the United States.

**Revenue codes**

- **0250** General Pharmacy
- **0260** IV therapy

**National Drug Code (NDC)**

The NDC 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. As not all NDC numbers are set up the same, the table below demonstrates how to achieve the 11 digit NDC code for Monoferric.

*Sample diagnosis codes for the appropriate patient prescribed Monoferric (ferric derisomaltose) injection.*

<table>
<thead>
<tr>
<th>Primary Diagnosis Codes</th>
<th>Secondary Diagnosis Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDA secondary to blood loss (chronic)</td>
<td>Crohn's disease [regional enteritis]</td>
</tr>
<tr>
<td>Sideropenic dysphagia</td>
<td>Ulcerative colitis</td>
</tr>
<tr>
<td>Other IDAs</td>
<td>Celiac disease</td>
</tr>
<tr>
<td>Anemia in neoplastic disease</td>
<td>Malabsorption due to intolerance not elsewhere classified</td>
</tr>
<tr>
<td>• Code neoplasm first</td>
<td>Intestinal malabsorption unspecified</td>
</tr>
<tr>
<td>• Confirm iron deficiency</td>
<td></td>
</tr>
<tr>
<td>Anemia in chronic kidney disease (CKD)</td>
<td>CKD, stage 1</td>
</tr>
<tr>
<td>• Code CKD stage first</td>
<td>CKD, stage 2</td>
</tr>
<tr>
<td>• Confirm iron deficiency</td>
<td>CKD, stage 3</td>
</tr>
<tr>
<td>Anemia in other chronic diseases classified elsewhere</td>
<td>CKD, stage 4</td>
</tr>
<tr>
<td>• Code underlying disease first</td>
<td></td>
</tr>
<tr>
<td>• Confirm iron deficiency</td>
<td></td>
</tr>
<tr>
<td>Antineoplastic chemotherapy-induced anemia</td>
<td></td>
</tr>
<tr>
<td>• Confirm iron deficiency</td>
<td></td>
</tr>
</tbody>
</table>

The following tables display selected diagnosis codes that may be associated with iron deficiency anemia (IDA).

**Revenue codes**

- **0510** Clinic, general
- **0636** Pharmacy, drugs requiring detailed coding

**National Drug Code (NDC)**

- **5-4-1** Monoferric (1,000 mg iron/10 mL (100 mg/mL) single-dose vial)
- **73594-9310-1** New format
- **73594-9310-91** NDC number for payer

**Additional Information**

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**

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.

**Contact Information**

- **1-800-992-9022** Monday-Friday, 8 AM to 8 PM ET
- **monoferric-patient-solutions.com** | **monoferricpatientsolutionsportal.com**

Please see additional Important Safety Information throughout. Please click here for Full Prescribing Information.
SAMPLE UB-04 (CMS-1450) CLAIM FORM
FOR MONOFERRIC

Medicare and Medicaid
(Patient weight 50 kg or above): Administer 1,000 mg of Monoferic as an intravenous infusion

Note, only the 1,000 mg iron/10 mL (100 mg/mL) single-dose vial of Monoferic 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 Monoferic. 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 Monoferic, 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)).

Box 46: Enter the total number of units of service for Monoferic, J1437, Injection, ferric derisomaltose, 10 mg. In the example claim form, 1,000 mg dose of Monoferic 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 (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: For a 1,000 mg dose of Monoferic, 100 billable units may be appropriate (1,000 mg/10 mg per unit = 100)

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

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 Monoferic. 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 Monoferic administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Monoferic when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. Monoferic is contraindicated in patients with prior serious hypersensitivity reactions to Monoferic 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 Monoferic 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.

1-800-992-9022 Monday-Friday, 8 AM to 8 PM ET  monoferic-patient-solutions.com | monoferricpatientsolutionsportal.com

Please see additional Important Safety Information throughout. Please click here for Full Prescribing Information.
SAMPLE UB-04 (CMS-1450) CLAIM FORM
FOR MONOFERRIC

Medicare and Medicaid
(Patients weighing less than 50 kg): Administer 20 mg/kg actual body weight as an intravenous infusion

Note, only the 1,000 mg iron/10 mL (100 mg/mL) single-dose vial of Monoferic 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 Monoferic. 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 2: Enter the appropriate HCPCS code corresponding with the NDC number and the unit quantity. |
| Box 3: 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: N47594931001ME1000. |
| Box 4: Enter the appropriate HCPCS code for Monoferic, 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)). |
| Box 6: Enter the total number of units of service for Monoferic, J1437, Injection, ferric derisomaltose, 10 mg. Note, Monoferic’s dosing is weight based for patients under 50 kg and will vary by patient. Monoferic 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. |
| 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. More information on the claims process and the CMS fee schedule can be found here.

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

**IMPORTANT SAFETY INFORMATION (continued)**

**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 Monoferic to patients with iron overload.

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**Important:** Please see additional Important Safety Information throughout. Please click here for Full Prescribing Information.
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
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WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions
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Iron Overload
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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: