MonoFerric®
(ferric derisomaltose)
injection

MONOFERRIC BILLING AND CODING GUIDE

Medicare, Medicaid, and Commercial

Pharmacosmos Therapeutics Inc.
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Morristown, NJ 07960

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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 payors 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.

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)

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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MONOFERRIC BILLING AND CODING

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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.[a]

Primary diagnosis codes

ICD-10-CM diagnosis code	Description
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.1	Sideropenic dysphagia
D50.8	Other iron deficiency anemias
D50.9	Iron deficiency anemia, unspecified
D63.0	Anemia in neoplastic disease
D63.1	Anemia in chronic kidney disease
D63.8	Anemia in other chronic diseases classified elsewhere
D64.81	Anemia due to antineoplastic chemotherapy

Secondary diagnosis codes

ICD-10-CM 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	Other malabsorption due to intolerance, (excludes celiac gluten-sensitive enteropathy and lactose intolerance)
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
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter

[a]Sample diagnosis codes for the appropriate patient prescribed Monoferric.

Supporting codes

Z codes are used to document patients with potential health hazards related to family and personal history and certain conditions influencing health status[2]

Z code	Description
Z90.3	Acquired absence of stomach [part of] [following subtotal gastric resection with decreased absorption of oral iron] [18 and older]
Z91.141 - Z91.148	Patient's other noncompliance with medication regimen [members who repeatedly fail to heed instructions for oral iron supplementation or are incapable of accepting or following them] [18 and older]
Z91.190 - Z91.199	Patient's noncompliance with other medical treatment and regimen [members who repeatedly fail to heed instructions for oral iron supplementation or are incapable of accepting or following them] [18 and older]
Z98.84	Bariatric surgery status [following gastric bypass surgery with decreased absorption of oral iron] [18 and older]

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MONOFERRIC BILLING AND CODING (cont'd)

Current Procedural Terminology (CPT) codes

CPT[a] code	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)

Healthcare Common Procedure Coding System (HCPCS) level II codes

HCPCS code	Descriptor	Site of care	Additional information
J1437	Injection, ferric derisomaltose, 10 mg	All sites of care	If required by the payor, include the N4 qualifier, National Drug Code (NDC), unit of measure qualifier, and amount administered to the patient in Box 43. Example: N473594931001ME1000
Modifiers			
JW[b]	Drug amount discarded/not administered to any patient		
JZ[c]	Zero drug amount discarded/not administered to any patient		

Note: *Under CMS requirements, you may be reimbursed for both administered and discarded product up to the labeled amount of the product. For more information on the JW and JZ modifiers, visit CMS.gov*

Revenue codes

Revenue codes are used by healthcare providers to document and receive reimbursement

Revenue code	Description
0250	General pharmacy
0260	IV therapy

Revenue code	Description
0510	Clinic, general
0636	Pharmacy, drugs requiring detailed coding

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 payors, 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. 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 payor
5-4-1	**Monoferric**[1]	1000 mg iron/10 mL (100 mg/mL) single-dose vial[1]	73594-9310-1	5-4-2	73594-9310-**0**1

Additional Information

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

[a]CPT codes, descriptions, and other data only are copyright 2026 American Medical Association. All Rights Reserved. Applicable FARS/HHSAR apply.

[b]Effective January 1, 2017, the JW modifier must be used to report discarded amounts of a single-dose container drug in order to obtain payment for a discarded amount of drug from single-dose or single-use packaging.

[c]Effective July 1, 2023, Medicare requires the JZ modifier on all claims for single-dose containers where there are no discarded amounts.

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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DELIVERS DIVERSE ACCESS AND REIMBURSEMENT SUPPORT FOR PATIENTS PRESCRIBED MONOFERRIC® (ferric derisomaltose)

Enrollment options are available for Monoferric Patient Solutions®[a]

Select the option you prefer:

Call us at 1-800-992-9022
Monday to Friday, 8 AM to 8 PM ET
(except holidays)

Download and fax
the enrollment form

Field Support
On-demand support for reimbursement needs, patient benefits verification, and case follow-up.

Patient Assistance
Available for eligible uninsured or underinsured patients.

Billing and Coding Guidance
Reimbursement support through the Billing and Coding Guide, sample annotated claim forms, and sample letters.

Hub Support
Coverage and access information through benefits verification support, prior authorization support, claims and appeals assistance, and language translation services.[c]

Copay Assistance
Available for eligible patients with commercial health insurance.[b]

Visit monoferriccopay.com to enroll in the Copay Assistance Program.

Eligible members can submit and track their copay claims

Step Therapy Exception Requests Support
Your FRM can provide information on access and reimbursement processes.

Learn more about state-level step therapy protections

For more information email MonoferricPatientSolutions@Pharmacosmos.us

FRM=field reimbursement manager.

[a]Monoferric Patient Solutions provides educational support only and does not submit claims or perform administrative services on behalf of providers. Program participation does not guarantee insurance coverage, product access, or reimbursement. Eligibility and restrictions apply. Final coverage decisions are made by payors.

[b]Eligibility requirements: patient must have commercial health insurance (not Medicare, Medicaid, etc), be a resident of the United States or Puerto Rico, be treated by a healthcare professional in the United States or Puerto Rico, be 18 years of age or older, and be prescribed Monoferric for an on-label diagnosis.

[c]Live representatives are available to help.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS 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.

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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Reference: 1. Monoferric [Prescribing Information]. Morristown, NJ: Pharmacosmos Therapeutics Inc; 2022.

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