



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.

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

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



Current Procedural Terminology (CPT) code

CPT* code	Description
96365²	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)

Healthcare Common Procedure Coding System (HCPSC) level II codes

HCPSC code	Descriptor	Site of care	Additional information
J1437³	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	MonoFerric⁵	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.

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

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.

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE (Medicare) ☐ MEDICAID (Medicaid) ☐ TRICARE (TRICARE) ☐ CHAMPVA (CHAMPVA) ☐ GROUP HEALTH PLAN (Group Health Plan) ☐ FECA (FECA) ☐ OTHER (Other) ☐

2. PATIENT'S NAME (Last Name, First Name, Middle Initial) 3. PATIENT'S BIRTH DATE (MM/DD/YYYY) 4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street) 6. PATIENT RELATIONSHIP TO INSURED (Self, Spouse, Child, Other) 7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE 9. RESERVED FOR NUCC USE 10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) b. AUTO ACCIDENT? c. OTHER ACCIDENT?

11. INSURED'S POLICY GROUP OR FECA NUMBER 12. INSURED'S DATE OF BIRTH (MM/DD/YYYY) 13. OTHER CLAIM ID (Designated by NUCC)

14. INSURANCE PLAN NAME OR PROGRAM NAME 15. IS THERE ANOTHER HEALTH BENEFIT PLAN? 16. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment for services described below.)

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 18. DATE 19. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (MM/DD/YYYY) 20. OTHER DATE (MM/DD/YYYY)

21. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) 22. MONOFERRIC 1,000 mg iron/10 mL (100 mg/mL) single-dose vial (individually boxed)

23. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A to service line below (24E)) 24. DATE(S) OF SERVICE (From MM/DD/YYYY To MM/DD/YYYY) 25. PLACE OF SERVICE (EMG) 26. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) 27. DIAGNOSIS PORTER 28. \$ CHARGES 29. \$ CHARGES 30. \$ CHARGES

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE(S) OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) 32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH #

34. FEDERAL TAX ID NUMBER 35. PATIENT'S ACCOUNT NO. 36. ACCEPT ASSIGNMENT? (YES/NO) 37. TOTAL CHARGE 38. AMOUNT PAID 39. REVD FOR NUCC USE

40. SIGNATURE 41. DATE 42. NPI 43. NPI 44. NPI 45. NPI 46. NPI 47. NPI 48. NPI 49. NPI 50. NPI

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 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.

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

MonoFerric[®]
(ferric derisomaltose)
injection

Note, only the 1000 mg iron/10 mL (100 mg/mL) single-dose vial of Monoferic 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 24G: Report the appropriate number of units for the procedure and the appropriate number of units 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.⁴

HEALTH INSURANCE CLAIM FORM													
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02:12													
PICA													
1. MEDICARE (Medicare) ☐ MEDICAID (Medicaid) ☐ TRICARE (DoD/DoD) ☐ CHAMPVA (Member Do) ☐ GROUP HEALTH PLAN (ID#) ☐ FECA BACKLUNG (ID#) ☐ OTHER (ID#) ☐				1a. INSURED'S I.D. NUMBER (For Program in Item 1)									
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)				3. PATIENT'S BIRTH DATE (MM/DD/YY)				SEX (M ☐ F ☐		4. INSURED'S NAME (Last Name, First Name, Middle Initial)			
5. PATIENT'S ADDRESS (No., Street)				6. PATIENT RELATIONSHIP TO INSURED (Self ☐ Spouse ☐ Child ☐ Other ☐				7. INSURED'S ADDRESS (No., Street)					
CITY				STATE				CITY		STATE			
ZIP CODE				TELEPHONE (Include Area Code)				ZIP CODE		TELEPHONE (Include Area Code)			
8. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)				10. IS PATIENT'S CONDITION RELATED TO:				1. INSURED'S POLICY GROUP OR FECA NUMBER					
9. OTHER INSURED'S POLICY OR GROUP NUMBER				a. EMPLOYMENT? (Current or Previous) ☐ YES ☐ NO				INSURED'S DATE OF BIRTH (MM/DD/YY)		SEX (M ☐ F ☐			
b. AUTO ACCIDENT? ☐ YES ☐ NO				PLACE (State)				OTHER CLAIM ID (Designated by NUC)					
c. OTHER ACCIDENT? ☐ YES ☐ NO				10g. CLAIM CODES (Designated by NUC)				INSURANCE PLAN NAME OR PROGRAM NAME					
d. INSURANCE PLAN NAME OR PROGRAM NAME				10g. CLAIM CODES (Designated by NUC)				IS THERE ANOTHER HEALTH BENEFIT PLAN? ☐ YES ☐ NO ☐ #yes, complete items 9, 9a, and 9d.					
READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM. 12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE: I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.													
14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (Last Date) (MM/DD/YY)				15. OTHER DATE (MM/DD/YY)				6. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM (MM/DD/YY) TO (MM/DD/YY)					
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE				17a. 17b. 17c. 17d. 17e. 17f. 17g. 17h. 17i. 17j. 17k. 17l. 17m. 17n. 17o. 17p. 17q. 17r. 17s. 17t. 17u. 17v. 17w. 17x. 17y. 17z.				HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM (MM/DD/YY) TO (MM/DD/YY)					
18. ADDITIONAL CLAIM INFORMATION (Designated by NUC)													
Monofonic 1,000 mg iron/100 mL (100 mg/mL) single-use vial (individualized box)													
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Indicate A-J to service line below (24E))													
23. PRIOR AUTHORIZATION NUMBER													
24. A. DATE(S) OF SERVICE TO (MM/DD/YY) B. PLACE OF SERVICE (EMG) C. D. PROCEDURE, SERVICES, OR SUPPLIES (CPT/HCPCS) E. DIAGNOSIS PORTER F. G. DATE OF LINES H. I. ID. J. RENDERING PROVIDER ID. #													
1. 10 01 20 10 01 20 11 96365 A \$S 1 NPI 2. 10 01 20 10 01 20 11 J1437 A \$S XX NPI 3. 10 01 20 10 01 20 11 J1437 JW A \$S XX NPI 4. NPI 5. NPI 6. NPI													
25. FEDERAL TAX ID. NUMBER SIN EN 26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (YES ☐ NO ☐ 28. TOTAL CHARGE \$ 29. AMOUNT PAID \$ 30. Revid for NUC Use													
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part hereof.) 32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH #													
SIGNED DATE A. NPI B. NPI													

NUCC Instruction Manual available at: www.nucc.org

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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 $[20 * Y] * 1 \text{ billing unit} / 10 \text{ mg} = [\# \text{ Billing Units}]$

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>.

Monofer[®] is available through the specialty pharmacy, Biologics by McKesson, if preferred by your office or required by your patient's health plan. Monofer[®] is also available through authorized distributors.

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

INDICATIONS AND IMPORTANT SAFETY INFORMATION

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

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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 see full [Prescribing Information](#).

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> 2. Find-A-Code. 96365 - CPT® Code in category: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug). InnoviHealth Systems, Inc. Updated 2022. Accessed January 19, 2023. <https://www.findacode.com/code.php?set=CPT&c=96365> 3. 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. Accessed January 19, 2023. <https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-2-2020-drugs-and-biologicalsupdated-07312020.pdf> 4. National Drug Code (NDC) Conversion Table. Converting NDCs from 10-digits to 11 digits. Accessed January 19, 2023. <https://phpa.health.maryland.gov/OIDEOR/IMMUN/Shared%20Documents/Handout%203%20-%20NDC%20conversion%20to%2011%20digits.pdf> 5. MonoFerric [Prescribing Information]. Morristown, NJ: Pharmacosmos Therapeutics Inc; 2023. 6. Centers for Medicare & Medicaid Services. CMS Manual System. CMS 1500. Accessed January 19, 2023. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf> 7. Centers for Medicare & Medicaid Services (CMS). Medicare program JW modifier: drug/biological amount discarded/not administered to any patient frequently asked questions. Accessed January 19, 2023. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf>



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THERAPEUTICS

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MonoFerric[®]
(ferric derisomaltose)
injection