



MonoFerric
Patient Solutions®



MonoFerric®
(ferric derisomaltose)
injection

MonoFerric Patient Solutions® Program

REIMBURSEMENT GUIDE

Pharmacosmos Therapeutics Inc.

120 Headquarters Plaza East Tower, 6th Floor
Morristown, NJ 07960

Updated: June 2023

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



MonoFerric®
(ferric derisomaltose)
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Monoferric Patient Solutions® (MPS) Program Reimbursement Guide is intended to provide an overview of the program along with providing an overview of coding and coverage information related to Monoferric® (ferric derisomaltose) injection. Healthcare providers (HCP) can use this guide, in addition to other sources of information, to determine for themselves the appropriate claims to file for Monoferric-related services. Pharmacosmos Therapeutics Inc. does not guarantee payment or coverage for any product or service.

The healthcare billing environment is constantly evolving to keep pace with scientific advances and financial constraints. Information specific to billing and coding is subject to change without notice and should be verified by the provider for each patient prior to treatment. A provider should contact patients' payers directly for any revised or additional requirements, information, or guidance.

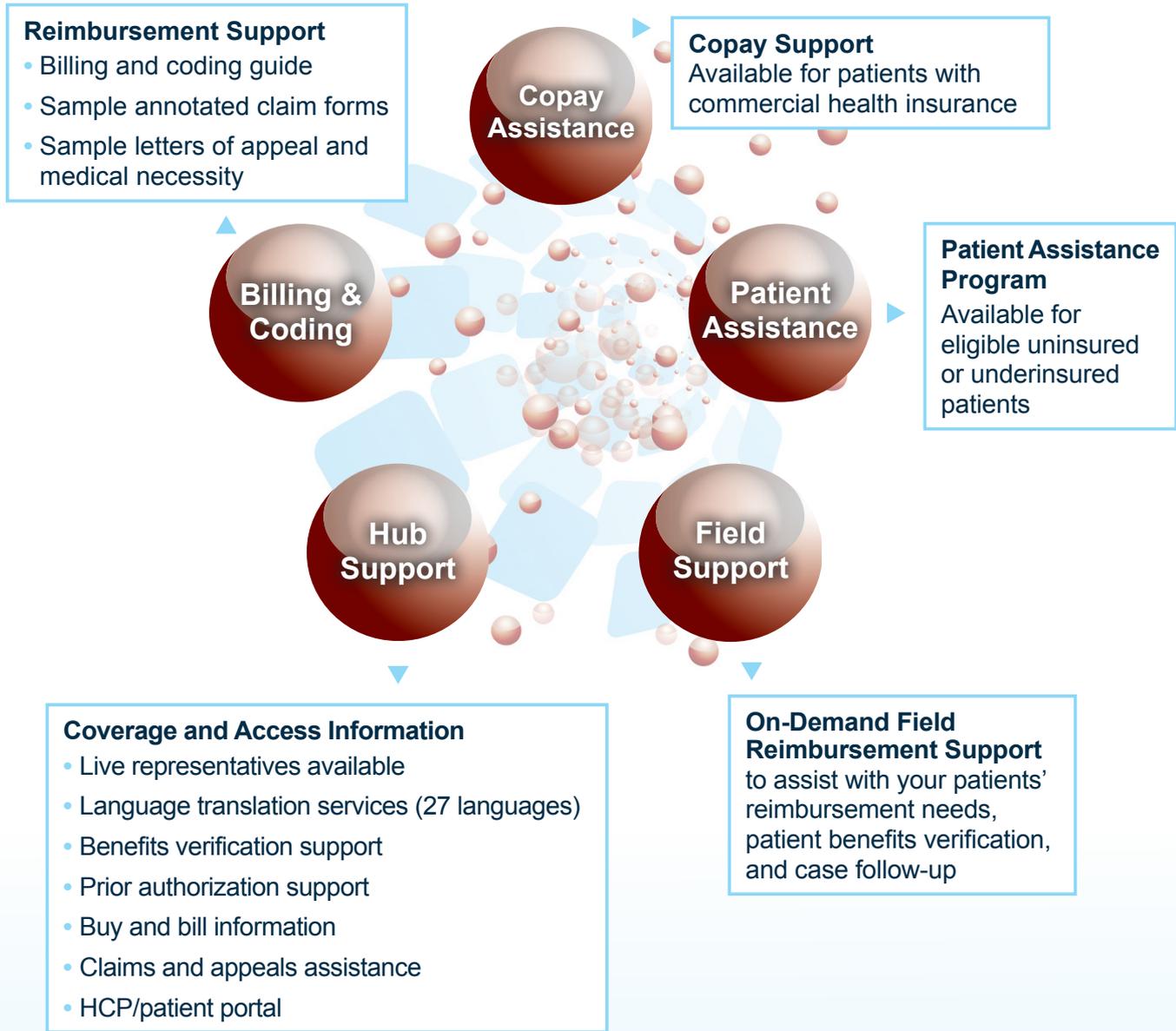
It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies.

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

Monoferric Patient Solutions® Program Overview

Rapid Response, Customized Solutions

MPS Delivers Diverse Support to Address Monoferric Treatment Needs



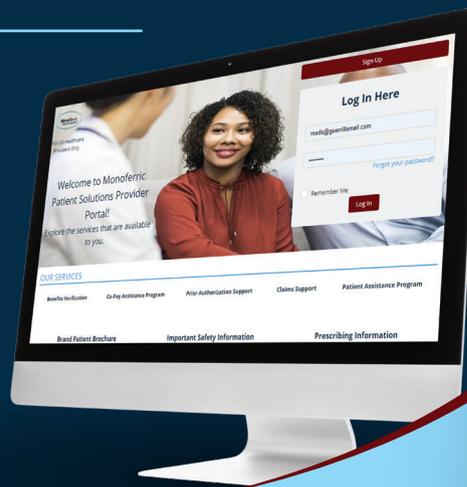
Please see Important Safety Information throughout and full [Prescribing Information](#).

How to enroll in any of the available support services (Reimbursement, Patient Assistance Program, Copay)

Enrollment options:

- You may enroll your patient online via the portal monoferricpatientsolutionsportal.com
- You may also visit monoferric-patient-solutions.com to download the editable form, complete the required fields, and fax to **1-833-888-8837**
- For copay support, you can visit monoferriccopay.com or call **1-800-475-4928**

MPS Program may contact you and/or your patient for additional information in order to initiate next steps.



Overview of the steps that may occur once you have made the decision to prescribe MonoFerric for an appropriate patient and have decided to enroll your patient with iron deficiency anemia (IDA) into the MPS Program:

Available offerings include assistance with benefit verifications, prior authorizations (PA), claim and appeal support, financial assistance, field reimbursement support, and the Patient Assistance Program. The MPS Patient Access Specialists will follow-up with your office and provide information on your patient's eligibility for the selected access offerings. Keep in mind that the access journey and timelines may vary depending on your patient's qualification for program offering(s)

TO LEARN MORE



MonoFerric Patient Solutions



1-800-992-9022
Hours of Operation:
Monday-Friday, 8 AM to 8 PM ET



HCP Portal

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.

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

Monoferric Patient Solutions® Program is committed to providing a seamless access journey to patients and HCPs

Live representatives are available to support patients, caregivers, and HCPs through the various MPS offerings:

- ✓ Benefits verification
- ✓ Claims and appeals assistance
- ✓ Sample letters of appeal and/or medical necessity
- ✓ Prior authorization assistance
- ✓ Financial assistance
- ✓ In-person support for providers' offices by providing access to a local field reimbursement manager

MPS Program Can Assist Your Office With Investigating and Coordinating Coverage:

- 1 After following the steps on page 2 to download and complete the editable enrollment form, fax the completed and signed enrollment form, including copies of the insurance card(s) (optional), to MPS at 1-833-888-8837
- 2 MPS will contact the patient's insurance plan to research the patient's benefits for all available access methods (provider purchase and bill, assignment of benefit (AOB), and pharmacy) and capture the following:
 - Coverage restrictions (PA requirements)
 - Patient cost share responsibility (deductible and applicable copay or coinsurance requirements)
 - Contracted Specialty Pharmacy Provider (SPP), if applicable
 - Payer-suggested coding
 - Payer-specific billing instructions
- 3 Within 1-2 business days, a Patient Access Specialist will call and provide you with the following:
 - A summary of benefits to explain each patient's benefits which will also be faxed to your office
 - PA criteria, if required, along with payer-specific forms to submit to the payer for approval
 - Further assistance with the PA process, as needed
- 4 Patient Access Specialists will also conduct an application-based eligibility determination for copay assistance, as appropriate for your patients

In order to access services available through the MPS Program, providers must certify they have received consent from the patient and have on file the patient's HIPAA consent and all other necessary permissions before signing the enrollment form. If your facility prefers to conduct your own insurance investigation for each patient prior to administering Monoferric, the coverage parameters listed above and the checklists provided later in this guide can be used as a reference for verifying coverage and understanding your patient's cost-share requirements.

HIPAA=Health Insurance Portability and Accountability Act.

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

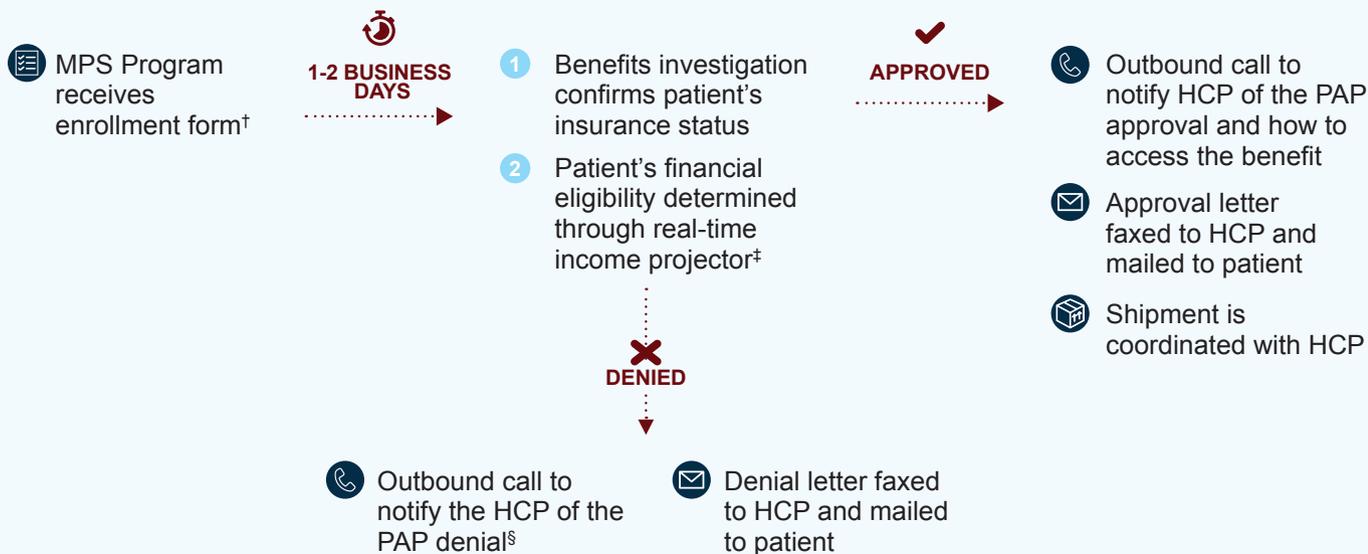
Monoferric Patient Solutions® Patient Assistance Program

Manageable Requirements to Facilitate Access

Eligibility criteria:

- ✓ Fall within the income guidelines*
- ✓ Uninsured or underinsured (patients with claims covered, paid or reimbursed, in whole or in part, by Medicaid, Medicare, or other federal or state healthcare programs are not eligible for this program)
- ✓ Must be 18 years or older
- ✓ Prescribed Monoferric for an on-label diagnosis
- ✓ Patient must be a resident of the United States (residency includes anyone who lives in one of the U.S. states, the District of Columbia, Puerto Rico, and U.S. Virgin Islands). Citizenship or legal status is not a requirement

Timeline and Process Flow for the MPS Patient Assistance Program (PAP)



*Total household income is at or below 300% of the federal poverty level (FPL). Visit <https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines>, which lists the current FPL guidelines. Pharmacosmos Therapeutics Inc. and its authorized third-party agents will use the patient's date of birth or social security number and/or additional demographic information as needed to access credit information and information derived from public and other sources to estimate income in conjunction with the eligibility determination process. As a soft credit inquiry, this option will not impact credit scores. Pharmacosmos Therapeutics Inc. and its authorized third-party agents reserve the right to ask for additional documents and information at any time. Note: Patients may retroactively qualify for assistance under the PAP if the patient's HCP submits an explanation of benefits (EOB) statement from the patient's commercial insurance provider within 120 days of the date of service.

†Review and processing time may be expedited for emergent cases.

‡MPS reserves the right to request proof of income documentation at any time from the patient.

§Patients should inform the PAP of any changes in insurance and/or financial status. If the patient's situation changes, program representatives will reassess patient's eligibility for the program.

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

MonoFerric Patient Solutions® Copay Assistance Program

Patients pay as little as \$0 per dose*

Eligibility information:

Rx To be eligible to participate in the MPS Copay Assistance Program, the patient must:

- ✓ Have commercial health insurance (ie, health insurance offered through an employer; NOT Medicare, Medicare Advantage, Medicaid, TRICARE, or Veteran Affairs healthcare)
- ✓ Reside in the United States or Puerto Rico
- ✓ Be treated by a healthcare provider in the United States or Puerto Rico
- ✓ Be 18 years of age or older
- ✓ Be prescribed MonoFerric for an on-label diagnosis

\$ If a patient is eligible to participate:

- ✓ They will receive savings on out-of-pocket (OOP) expenses (ie, deductible, copay, or coinsurance obligations) for MonoFerric of up to \$2,000 per dose*
- ✓ Copay assistance may be applied retroactively to prescription costs that occurred within 120 days prior to the date of enrollment and if the patient met all of the eligibility criteria at the time of the infusion

Copay Assistance Program Contact Information

| | | |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
|  1-800-475-4928 |  1-800-547-2117 |  monoferriccopay.com |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|

You may also check your patient's eligibility for the MPS Copay Assistance Program when enrolling your patient into MPS.

*If IDA returns within the coverage period, you would receive an annual maximum savings on OOP expenses of up to \$4,000. Additional restrictions apply. Please see full Terms and Conditions at monoferric-patient-solutions.com.

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



Monoferric Patient Solutions® Overview

Basic Coverage Information

Provider Office Setting Information

Hospital Outpatient Information

Checklists & Sample Letters

Ordering & Distribution Information

Clinical Overview

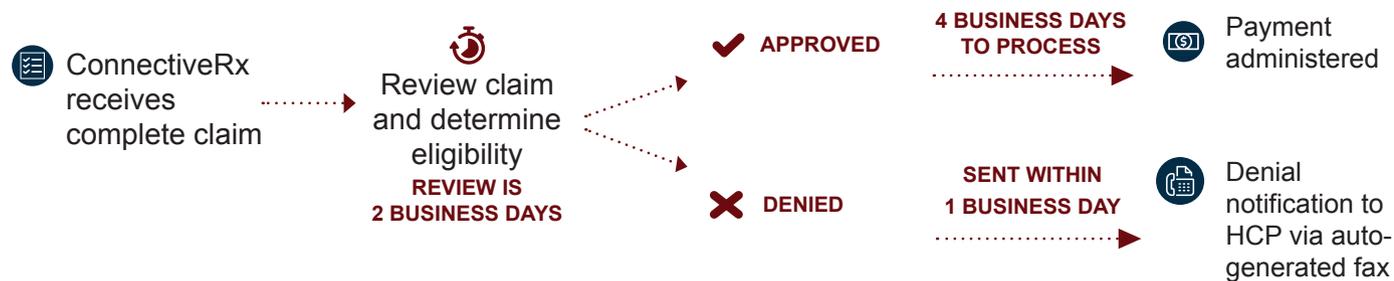
Important Safety Information

Medical Benefit Copay Claim Process Flows for Monoferric

Option 1: MPS Program



Option 2: ConnectiveRx



*Claim form and/or Explanation of Benefits (EOB).

†Review and processing time may be expedited for emergent cases.

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Basic Coverage Information

Billing and coding requirements for Monoferric will vary based on many factors, including the site of service where the drug is administered, the type of insurance the patient has, and the benefit under which Monoferric is covered.

Site of service

Monoferric may be administered in HCP offices or in hospital outpatient departments.* Note, not all payers may cover Monoferric at all sites of service, and for most payers the site of service will affect the billing and coding requirements. This guide concentrates on coverage, coding, and billing for Monoferric when administered in provider office and hospital outpatient settings.

Benefit category

Most payers cover provider-administered products, such as Monoferric, under a medical benefit rather than a pharmacy benefit. In the case of Medicare, Monoferric will typically be covered under Part B. However, private payers and Medicaid, including managed Medicaid, may require that providers obtain Monoferric through a specialty pharmacy (SP). SPs may bill the payer under the medical or pharmacy benefit, depending on what that payer requires.

Payer type

Coverage, as defined by each payer type and benefit package, may vary depending on the site of service and the patient's status and medical history.

• Private payers

Although private payers may cover Monoferric, some may restrict Monoferric's coverage by imposing special distribution requirements, require precertification, and institute management controls such as step edits. Private payers vary in the payment methods they use to reimburse medical benefit drugs. Methodologies typically include:

- Percentage of Average Wholesale Price (AWP)
- Percentage of Average Sales Price (ASP)
- Percentage of Wholesale Acquisition Price (WAC)
- Invoice cost
- Percentage of billed charges
- Hybrid or other methodologies

Your payment terms for Monoferric for a particular patient will be based on your individually negotiated contract with that patient's payer. If your site has questions about payment or details within your provider contract, you can call the payer directly or contact your payer contract representative for more details. However, in general, private payers use a variety of methods to determine payment for drug administration and provider office visits, known as Evaluation and Management (E/M), including:

- Fee schedule-based reimbursement
- Usual, customary, and reasonable charges
- Reimbursement based on a percentage of the Medicare Physician Fee Schedule (MPFS)
- Percentage of billed charges

It will be important for your site to set the appropriate charges for Monoferric when submitting your claim, accounting for your negotiated contracts across all payers.

*Not an all-inclusive list of potential settings of care.

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

Basic Coverage Information (cont'd)

- **Medicare**

Adults with IDA may qualify for Medicare. Medicare typically covers and separately reimburses drugs provided in the provider office as well as drugs provided in the hospital outpatient department that are not self-administered and are provided incidental to a provider's service. Medicare is federally funded health insurance coverage for the aged and disabled who meet 1 of the following criteria:

- Age 65 or older and self or spouse is eligible for Social Security or Railroad Retirement Benefits
- Under age 65 and getting Social Security Disability Insurance (SSDI) benefits, after 2 years
- Under age 65 with end-stage renal disease (ESRD)

Medicare is comprised of 4 different parts: A, B, Medicare Advantage (C), and D

Part A

- Basic services offered by Medicare – includes inpatient services, hospitalizations, hospice care, skilled nursing facility stays, and some home health services

Part B

- Provider-administered drugs, durable medical equipment, some home healthcare, laboratory services, physical therapy, and occupational therapy
- Medicare Part B is an optional benefit, as Medicare beneficiaries must separately enroll and may pay additional premiums/deductibles

Part C

- A type of Medicare health plan offered by a private company that contracts with Medicare to provide Part A, B, and often D benefits
- Medicare Advantage plans fully replace Medicare Parts A and B for those who enroll

Part D

- Self-administered or oral drugs
- Medicare Part D is an optional benefit, as Medicare beneficiaries must separately enroll and may pay additional premiums/deductibles

- **Medicaid**

Medicaid coverage and payment for MonoFerric will vary by state and managed Medicaid plan. Providers should check with the state program or plan for specific coverage information.

- Reimbursement methodologies will vary by state and managed care organization and may be based on ASP, AWP, WAC, and/or total invoice cost
- Beneficiary cost-sharing will also vary by state but is usually nominal, unless the beneficiary must comply with spend-down requirements
- Payment for services rendered, such as administration for MonoFerric, office visits (E/M), and related services, is also highly variable. Methodologies may include fee schedule; percentage of the MPFS; usual, reasonable, and customary, and/or a percentage of billed charges

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

Provider Billing and Coding | Office Setting

Medicare, Medicaid, and Commercial

Medicare, Medicaid, and Commercial

Monoferric received U.S. Food and Drug Administration (FDA) approval in January 2020 and is available for distribution. It is an iron replacement product indicated for the treatment of IDA in adult patients, aged 18 years and older, who have intolerance to oral iron or have had unsatisfactory response to oral iron and/or who have non-hemodialysis dependent chronic kidney disease.¹

Coverage

For patients enrolled in Medicaid, a Medicare Advantage plan, or a commercial health plan, coverage of Monoferric will vary by payer. Some payers may also apply utilization restrictions for Monoferric. For Medicare patients, Monoferric will typically be covered under Medicare Part B when used for an FDA-approved indication and when medically reasonable and necessary.

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 HCPs, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the provider.

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](#).

Provider Billing and Coding | Office Setting (cont'd)

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 IDA.*

Primary Diagnosis Codes

| ICD-10-CM ² 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 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 ² 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 (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.

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 | |
|--------------------|------------------------------------------------------------------------------------------|
| 96365 ³ | 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 ⁴ | 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 the shaded area of Box 24A above the date of service. 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 zero to be placed in a specific position to meet the 5-4-2 format requirement.⁵ 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 ¹ | 1000 mg iron/10 mL (100 mg/mL) single-dose vial ¹ | 73594-9310-1 | 5-4-2 | 73594-9310- <u>01</u> |

Additional Information

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

*CPT © 2021 American Medical Association. All rights reserved.

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](#).

Sample CMS-1500 Claim Form⁶ for Monoferric

Patient weight 50 kg or above: Administer 1000 mg of Monoferric as an intravenous infusion¹

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 code² (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 for paper claims, 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.⁴ 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]).³

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.⁴ 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>.

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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Sample CMS-1500 Claim Form⁶ for Monoferric

Patient weight less than 50 kg: Administer 20 mg/kg actual body weight as an intravenous infusion¹

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.

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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.⁴ Include the appropriate CPT code to report the administration procedure (eg, 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]).³

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.⁷

| DATE OF SERVICE | FROM | TO | QUAL | ICD-10-CM | HCPCS | MODIFIER | CHARGE | UNIT | DISC | RENDERING PROVIDER ID |
|-----------------|----------|----|------|-----------|-------|----------|--------|------|------|-----------------------|
| 10 01 20 | 10 01 20 | 11 | | D50.0 | 96365 | A | \$\$ | 1 | | NPI |
| 10 01 20 | 10 01 20 | 11 | | J1437 | | A | \$\$ | XX | | NPI |
| 10 01 20 | 10 01 20 | 11 | | J1437 | JW | A | \$\$ | XX | | NPI |

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.⁴ 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>.

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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Hospital Outpatient Information

Coverage, Billing, and Coding

Medicare, Medicaid, and Commercial

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Coverage

For patients enrolled in Medicaid, a Medicare Advantage plan, or a commercial health plan, coverage of Monoferric will vary by payer. Some payers may also apply utilization restrictions for Monoferric. For Medicare patients, Monoferric will be covered under Medicare Part B when used for an FDA-approved indication and when medically reasonable and necessary.

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 HCPs, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the provider.

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.

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

Hospital Outpatient Information (cont'd)

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 IDA.*

Primary Diagnosis Codes

| ICD-10-CM ² 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 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 ² 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 (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](#).

Hospital Outpatient Information (cont'd)

CPT code

| CPT* code | |
|--------------------|------------------------------------------------------------------------------------------|
| 96365 ³ | Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug) |

HCPCS level II codes

| HCPCS code | Descriptor | Site of care | Additional information |
|--------------------|----------------------------------------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| J1437 ⁴ | Injection, ferric derisomaltose, 10 mg | All sites of care | If required by the payer, include the N4 qualifier, NDC number, unit of measure qualifier, and amount administered to the patient in Box 43. Example: N473594931001ME1000 |

Revenue codes

| Revenue code | Description | Revenue code | Description |
|--------------|------------------|--------------|-------------------------------------------|
| 0250 | General Pharmacy | 0510 | Clinic, general |
| 0260 | IV therapy | 0636 | Pharmacy, drugs requiring detailed coding |

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.⁵ 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 ¹ | 1000 mg iron/10 mL (100 mg/mL) single-dose vial ¹ | 73594-9310-1 | 5-4-2 | 73594-9310- <u>0</u> 1 |

Additional Information

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

*CPT © 2021 American Medical Association. All rights reserved.

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.

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

Sample UB-04 CMS-1450 Claim Form⁸ | Hospital Outpatient Administration

Patient weight 50 kg or above: Administer 1000 mg of Monoferric as an intravenous infusion¹

Note, only the 1000 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 NDC number, a code describing the unit of measurement qualifier (eg, ME for milligrams), and the unit quantity. Example: N473594931001ME1000.

Box 44: Enter the appropriate HCPCS code for Monoferric, J1437, Injection, ferric derisomaltose, 10 mg.⁴ To report the administration procedure, enter an appropriate CPT code (eg, 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis [specify substance or drug]).³ Medicare and other payers require either JW modifier to report wastage or JZ modifier to indicate no wastage.⁷

Box 46: Enter the total number of units of service 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.

Box 63: If required by payer, enter the PA number.

Box 67A-67Q: Enter the appropriate ICD-10-CM diagnosis code² (eg, **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 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 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)

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 UB-04 CMS-1450 Claim Form⁸ | Hospital Outpatient Administration

Patient weight less than 50 kg: Administer 20 mg/kg actual body weight as an intravenous infusion¹

Note, only the 1000 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 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 (eg, ME for milligrams), and the unit quantity.
Example: N473594931001ME1000.

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

Box 46: 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.⁷

Box 63: Enter the PA number.

Box 67A-67Q: Enter the appropriate ICD-10-CM diagnosis code² (eg, 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 $[20 * Y] * 1 \text{ billing unit}/10 \text{ mg} = \text{[# Billing Units]}$

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>.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

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.

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

Checklists & Sample Letters

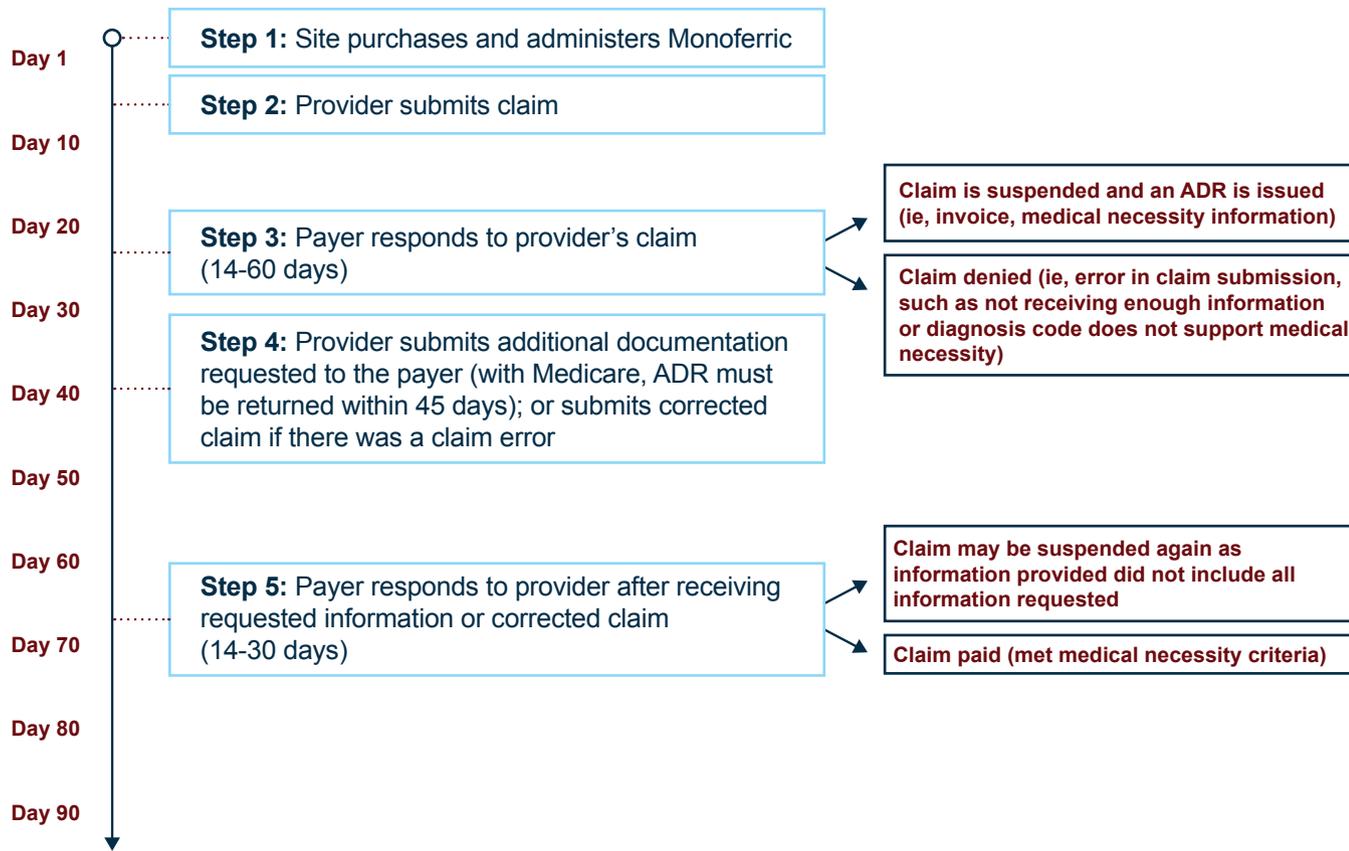
Benefits Verification and PA Checklist

When calling a payer to verify benefits and inquire about PA, the following key questions should be considered:

- What is the status of the insurance plan?**
 - Active
 - Terminated
 - Pending
- Is PA required?**
 - What is the PA process?
 - What is the telephone or fax number for the PA department?
 - What information is required?
 - How long will it take?
 - Does the PA number need to be included on the claim form?
- What is the patient's deductible?**
 - Has it been met? If not, what amount has been applied to date?
- What is the patient's co-payment or coinsurance for Monoferric?**
- Does the patient have an OOP maximum?**
 - Has it been met? If not, what amount has been applied to date?
- Does the patient have an annual or lifetime benefit maximum?**
 - Has it been met? If not, what amount has been applied to date?
- Does the patient have other insurance benefits that will need to be coordinated?**
- What acquisition options are available? (buy-and-bill or SP)**
 - If SP, does the plan require a specific SP?
- What are the coding and claims submission requirements for Monoferric?**
 - HCPCS code to report Monoferric
 - Number of units
 - Claims telephone number and address
 - Claims completion instructions
 - Required documentation (ie, prescribing information and statement of medical necessity)

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

Timeline of the Claims Submission Process



ADR=Alternative Dispute Resolution.

Complete, timely, and accurate claims submission will facilitate prompt payment.

If a claim is suspended or denied, providers should contact the payer directly for claims details, or providers may also contact MPS Program for additional support.

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

Claims Filing Checklist

The following tips may assist you with filing claims successfully for an infusion therapy:

- Verify patient eligibility and benefits with the payer before providing Monoferric.**
- Document your verification of patient's eligibility and benefits.**
- Obtain precertification, if required.**
- Use appropriate codes to report the patient's condition, the drugs the patient is on, and the services you have provided.**
 - HCPCS code
 - CPT code
 - ICD-10-CM code
- Include additional information requested by the payer on the CMS-1500 form or on the CMS-1450 (UB-04) form.**
 - Monoferric
 - Dosage
 - NDC number
 - Route of administration
 - Unit description (as required by the specific payer for a code that is not otherwise classified)
- Attach additional information to the claim if necessary.**
 - Letter of Medical Necessity
 - Full Prescribing Information
 - FDA approval letter
 - Patient notes
- Review claim for accuracy, including patient identification numbers, coding, and number of units.**
- File claim as soon as possible and within payer filing time limits.**
- Reconcile claim reports promptly and thoroughly to ensure claims have been appropriately processed and paid.**
- Verify that payment amounts correspond with your public payer allowables and your private payer contracts.**

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

Letter of Medical Necessity Information

This section provides information and examples that can help ensure your communications with health plans regarding medical exception are as complete as possible. These samples are intended to provide examples of the type of information that will usually be required. You can refer to the checklist on the first page of each section as you develop and complete your own letters.

Below is information that may be needed to support the development of your Letter of Medical Necessity:

Patient information

- Patient name
- Patient date of birth
- Insurance ID
- Insurance group number
- Case ID (if applicable)

Clinical rationale

- Patient diagnosis
- Comprehensive list of previous treatment therapies used
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting MonoFerric
- Test results and chart notes
- Hospital admission and/or emergency room notes

Additional supporting documentation may vary between health plans, but may include:

- Full Prescribing Information
- FDA approval letter
- Relevant peer-reviewed articles

Recommended use of the Sample Letter of Medical Necessity

We have provided the sample Letter of Medical Exception on the following page to assist with a coverage request for MonoFerric. Use of this document does not guarantee coverage for the medication for your patient.

To use this letter, please copy the text from pages [23-24] and paste it onto your office letterhead. Be sure to replace all bracketed text with the appropriate patient-specific information before forwarding your customized letter to your patient's insurance provider. If the provided fields do not accurately reflect your practices, please modify them to represent your particular circumstances.

When determining if treatment with MonoFerric is medically appropriate for a patient, please refer to the Full Prescribing Information.

Use of the letter does not guarantee that the insurance company will provide reimbursement for MonoFerric and is not intended to be a substitute for, or an influence on, the independent medical judgment of the HCP.

Be sure to include all the listed documents with the letter when you send it to your patient's insurance provider.

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

Sample Letter of Medical Necessity for MonoFerric

This sample letter is for demonstration purposes only. It provides an example of the type of information that may be required when requesting a formulary exception from a patient's insurance company. Use of this template or the information in this template does not guarantee reimbursement or coverage. It is not intended to be a substitute for, or to influence, the independent clinical decision of the prescribing healthcare professional.

[Physician or Practice Letterhead]

[Date]

[Health Plan Name]
ATTN: [Department]
[Medical Director Name]
[Health Plan Address]
[City, State ZIP]

RE: Patient Name _____
Date of Birth _____
Policy Number _____
Claim Number _____

Re: Letter of Medical Necessity for MonoFerric® (ferric derisomaltose) injection

Dear [Medical Director Name],

My name is [Physician Name] and I am a [board-certified medical specialty] [NPI]. I am writing to request a formulary exception for my patient, [Patient Name], who is currently a member of [Health Plan Name].

The prescription is for MonoFerric, which is medically appropriate and necessary for this patient who has been diagnosed with [condition], [ICD code(s)]. Therefore, I am requesting that [Health Plan Name] remove any medical policy or guideline requirements in this case so that MonoFerric can be made available to my patient as a preferred medication.

Summary of Patient's History

[Must include: Patient's clinical / medical history, diagnosis, condition, and symptoms]

[Patient Name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [condition] [ICD-10-code(s)] as of [date of diagnosis]. [He/she] has been in my care since [date].

[Include any additional considerations here:]

- [Previous treatments including drug names, duration of treatment(s), responses to those treatments (see table below)]
- [Acute and chronic complications associated with the patient's iron deficient anemia]
- [Treatment plan: expected duration of treatment or number of infusions requesting medical exception for]

My rationale for prescribing MonoFerric is based on [include a brief disease course of patient, including history of disease, laboratory results, symptoms, and previous treatments (including names, dosages, frequency, and length)]. If the patient has discontinued treatment, please include information on the reasons for such discontinuation (see table below). You may also want to include medical reasoning for choosing to bypass any alternative medications preferred by the health plan, such as COVID-19 risk exposure due to multiple infusions, patient may not be able to comply with labeled multiple dosing requirements of preferred products over an extended period of time, and treatment guidelines such as NCCN, KDIGO, and NICE.]

[Please exercise your medical judgment and discretion when providing diagnosis and characterization of the patient's medical condition].

| Past Treatment(s) | Start/Stop Dates | Reason(s) for Discontinuing |
|-------------------|-------------------|-----------------------------|
| [Drug name] | [MM/YY] – [MM/YY] | [Please list reasons] |
| [Drug name] | [MM/YY] – [MM/YY] | [Please list reasons] |

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

Sample Letter of Medical Necessity for Monoferric (cont'd)

Based on the patient's condition and my experience treating patients with **[diagnosis]** I have concluded that Monoferric is medically appropriate in this case. I further attest **[include physician expectations regarding clinical outcomes for patient]**.

I am requesting an immediate and expedited review of this request by a board certified and specialty matched physician who can render a decision based upon the standards of care outline above. If you have any questions, please contact me at **[Physician Phone Number]** for a peer-to-peer discussion. I would be pleased to speak to you in more detail about why a Monoferric formulary exception is necessary for **[Patient Name]**'s treatment of **[diagnosis]**.

If you do not feel that the information provided has established medical necessity, please provide me with your detailed rationale based upon the standards of care, the specialty of the physician who reviewed this case, and whether they are board certified in an appropriate medical specialty.

I look forward to receiving your timely response and approval of this claim.

Sincerely,
[Physician name]
[Physician signature]

[Physician address]
[Physician phone number]

Enclosures
[List enclosures, which may include medical records, clinical notes/diagnostic report, medication records, relevant laboratory reports that support the need for Monoferric, Monoferric Prescribing Information, letter of medical necessity, and other supporting documentation].

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

Letter of Appeal Information

This section provides information and examples that can help ensure your communications with health plans regarding a PA or appeal are as complete as possible. These samples are intended to provide examples of the type of information that will usually be required. You can refer to the checklist on the first page of each section as you develop and complete your own letters. Incorrect or incomplete submissions may delay the review process or result in an automatic denial of the request.

Below is information that may be needed to support the development of your Letter of Appeal:

Patient information

- Patient name
- Patient date of birth
- Insurance ID
- Insurance group number
- Case ID (if applicable)

Denial information and appeals process

- Determine the reason for the denial or underpayment
- If additional information is requested, submit the necessary documentation immediately; refer to available policies from the payer that define coverage guidelines for MonoFerric and explain how the patient in question meets those guidelines for coverage
- If the denial was due to a technical billing error (ie, missing additional information associated with a miscellaneous code, incorrect patient identification number, missing diagnosis), resubmit the corrected claim
- Verify the appeals process with the payer
- Understand the appeals submission process (form, telephone, online, etc)
- Obtain the specific appeals form (if applicable)
- Confirm the information needed to support the appeal
- Verify the appeals turnaround time and communication channel once a decision has been made

Clinical rationale

- Patient diagnosis
- Comprehensive list of previous treatment therapies used
- Confirmation that the patient has not received adequate results from previous treatments
- Rationale for selecting MonoFerric
- Test results and chart notes
- Hospital admission and/or emergency room notes

Additional supporting documentation may vary between health plans, but may include:

- Full Prescribing Information
- FDA approval letter
- Relevant peer-reviewed articles
- For 2nd-and-3rd level appeals, include a copy of the previous denial letter(s)
- Explanation of Benefits

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

Letter of Appeal Information (cont'd)

Strategies For Appeal

Strategies for appealing a denied claim if a claim for Monoferric® (ferric derisomaltose) injection is improperly reimbursed or denied, your site can appeal the denied claim or underpayment. The following provides some tips for appealing denied claims:

- Review the explanation of benefits (EOB) to determine the reason for the denial or underpayment. The MPS Program can also assist with researching the information needed for the appeals process
- If additional information is requested, submit the necessary documentation immediately; reference any available specific policies from the payer that define coverage guidelines for Monoferric (or this class of drugs) and address those guidelines specifically in your appeal and how the patient in question meets those guidelines for coverage
- Submit a corrected claim if the denial was due to a technical billing error (ie, missing additional information associated with a miscellaneous code, incorrect patient identification number, missing diagnosis)
- Verify the appeals process with the payer
 - Is there a particular form that must be completed?
 - Can the appeal be submitted over the phone or must it be in writing?
 - Where should the appeal be sent (ie, fax, mail, online)?
 - What information must be included with the appeal (ie, copy of original claim, EOB, supporting documentation)?
 - How long does the appeals process usually take?
 - How will the payer communicate the appeal decision back to your site?
- Review your appeal request for accuracy, including patient identification numbers, coding, and requested information from the payer
- Submit the claims appeal as soon as possible and within filing time limits
- Reconcile claims appeal responses promptly and thoroughly to ensure appeals have been processed appropriately
- Record appeals result (ie, payment amount or if further action is required)
- If you have already submitted a Letter of Medical Necessity, your site may want to develop a Letter of Appeal indicating why the payer should cover and reimburse Monoferric
- Include a copy of the original claim submitted to the payer, denial notification or letter, EOB, patient-specific details outlining medical necessity, the provider's plan for continuing treatment, and notes/articles supporting coverage
- If the appeal is denied, it may be necessary to contact the payer's medical director

Note: Review the appeals request for accuracy and submit as soon as possible to ensure it is within the filing time limits. It is recommended to document the appeals result for your records, and if the appeal is denied, contact the payer's medical director to request another review or peer-to-peer discussion.

Recommended use of the Sample Letter of Appeal

We have provided the sample Letter of Appeal on the following page to assist with a PA and/or claims denial for Monoferric® (ferric derisomaltose) injection. Use of this document does not guarantee coverage for the medication for your patient.

To use this letter, please copy the text from pages [27-28] and paste it onto your office letterhead. Be sure to replace all bracketed text with the appropriate patient-specific information before forwarding your customized letter to your patient's insurance provider. If the provided fields do not accurately reflect your practices, please modify them to represent your particular circumstances.

When determining if treatment with Monoferric is medically appropriate for a patient, please refer to the Full Prescribing Information.

Use of the letter does not guarantee that the insurance company will provide reimbursement for Monoferric and is not intended to be a substitute for or an influence on the independent medical judgment of the HCP.

Be sure to include all the listed documents with the letter when you send it to your patient's insurance provider.

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

Sample Letter of Appeal for Monoferric

This sample letter is for demonstration purposes only. It provides an example of the type of information that may be required when seeking an appeal of coverage denial from a patient's insurance company. Use of this template or the information in this template does not guarantee reimbursement or coverage. It is not intended to be a substitute for, or to influence, the independent clinical decision of the prescribing healthcare professional.

[Physician or Practice Letterhead]

[Date]

[Health Plan Name]

ATTN: [Department]

[Medical Director Name]

[Health Plan Address]

[City, State ZIP]

RE: Patient Name _____
Date of Birth _____
Policy Number _____
Claim Number _____

Re: Letter of Appeal for Monoferric® (ferric derisomaltose) injection

Dear [Medical Director Name],

My name is [Physician Name] and I am a [board-certified medical specialty] [NPI]. I am writing this letter to provide additional information to support my request to treat [Patient Name], who has been diagnosed with [condition], [ICD code(s)], with Monoferric, an iron replacement product 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 and/or who have non-hemodialysis dependent chronic kidney disease.

In brief, treating [Patient Name] with Monoferric is medically appropriate and necessary and should be a covered and reimbursed service. [Health Plan Name] determined Monoferric was not covered for [Patient Name] because [reason(s) for denial]. This letter provides my clinical rationale and relevant information about the patient's medical history and treatment.

Summary of Patient's History

[Must include: Patient's clinical / medical history, diagnosis, condition, and symptoms:]

[Patient Name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [condition] [ICD-10-code(s)] as of [date of diagnosis]. [He/she] has been in my care since [date].

[Include any additional considerations here:]

My rationale for prescribing Monoferric is based on [include a brief disease course of patient, including history of disease, laboratory results, symptoms, and previous treatments (including names, dosages, frequency, and length)]. If the patient has discontinued treatment, please include information on the reasons for such discontinuation, such as inability to tolerate a previous treatment, lack of response and or side effects, e.g., You may also want to include medical reasoning for choosing to bypass any alternative medications preferred by the health plan, such as COVID-19 risk exposure due to multiple infusions, patient may not be able to comply with labeled multiple dosing requirements of preferred products over an extended period of time, and treatment guidelines such as NCCN, KDIGO, and NICE.]

[Please exercise your medical judgment and discretion when providing diagnosis and characterization of the patient's medical condition].

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.

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

Sample Letter of Appeal for Monoferric (cont'd)

Based on the patient's condition and medical history, as well as my experience treating patients with IDA, I believe treatment with Monoferric is warranted, appropriate, and medically necessary in this case. The accompanying package insert provides the approved clinical information for Monoferric. I have attached relevant lab test analyses and medical records to support my decision.

I am requesting an immediate and expedited review of this appeal by a board certified and specialty matched physician who can render a decision based upon the standards of care outline above. If you have any further questions about this matter, please contact me at **[Physician Phone Number]** or via e-mail at **[Physician Email]**. I look forward to receiving your timely response and approval of this claim.

If you do not feel that the information provided has established medical necessity, please provide me with your detailed rationale based upon the standards of care, the specialty of the physician who reviewed this case, and whether they are board certified in an applicable medical specialty.

Sincerely,

[Physician name]

[Physician signature]

[Physician address]

[Physician phone number]

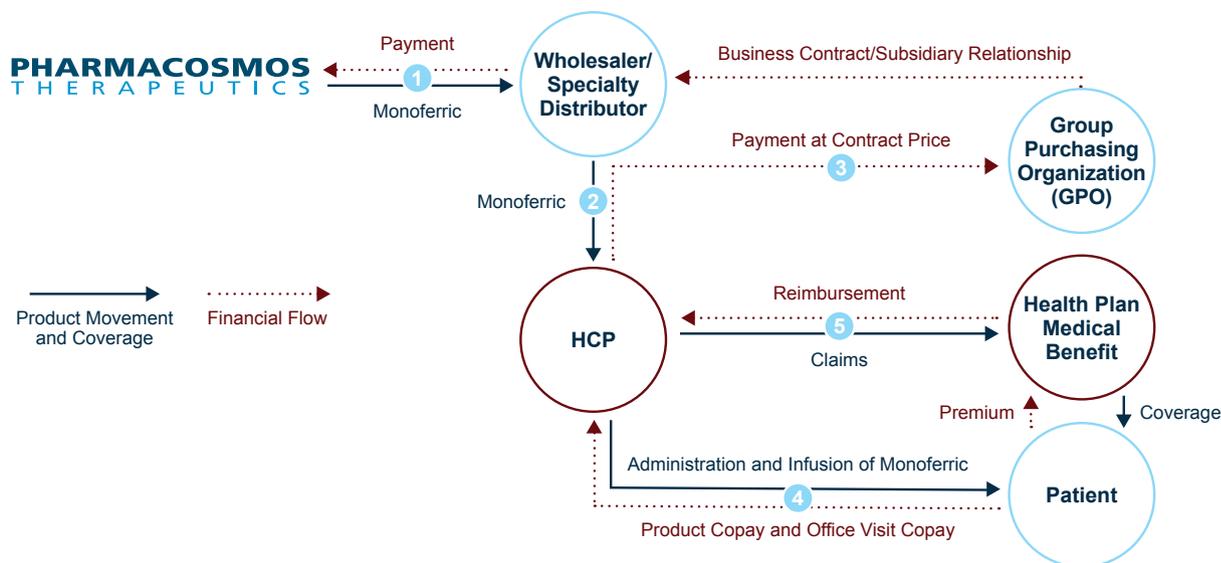
Enclosures

[List enclosures, which may include the explanation of benefits/denial letter, copies of original claim form, clinical notes/diagnostic report, medication records, relevant laboratory reports that support the need for Monoferric, Monoferric Prescribing Information, and other supporting documentation].

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

Ordering & Distribution Information

Medical Benefit (Buy-and-Bill)



| NDC Number | Supplied |
|--------------|------------------------------------------------------------------------------------------------------------------------------------|
| 73594-9310-1 | Monoferric injection is a sterile, dark brown, non-transparent aqueous solution supplied in a carton as a single-dose vial (10 mL) |

Specialty Distributors

| | | | |
|------------------------------------------|------------------------------------------------------|--------------------------------|------------------------------------------|
| McKesson Specialty Health (800) 482-6700 | AmerisourceBergen SD (ASD Healthcare) (800) 746-6273 | Oncology Supply (800) 633-7555 | Cardinal Health Specialty (800) 326-6457 |
|------------------------------------------|------------------------------------------------------|--------------------------------|------------------------------------------|

Full Line Distributors

| | | |
|-------------------------------------|----------------------------------|--------------------------------|
| McKesson Full Line (855) 625-4677 | AmerisourceBergen (610) 727-7000 | Cardinal Health (800) 926-3161 |
| Morris & Dickson Co. (800) 388-3833 | CuraScript SD (877) 599-7748 | |

Monoferric ordering options under the medical benefit

Buy-and-Bill*

- Monoferric may be ordered and purchased through a specialty distributor or wholesaler by provider
- Product shipped to provider via distributor
- After the product is received and administered, the provider will collect the patient's cost share and submit a claim form to the patient's insurer for reimbursement of the medication

AOB/SP†

- The preferred SP receives the triaged prescription for Monoferric
- The product is shipped from SP to the provider
- The patient's drug cost share is collected by SP after drug has been billed to the insurer for reimbursement of medication
- Patient's medical cost share is collected by provider after drug has been billed to the insurer for reimbursement of medication

*For certain patients, such as those with traditional Medicare (Part B benefit) only or those who reside in a Medicaid buy-and-bill state, ordering Monoferric through the buy-and-bill process may be the only option.

†Shipment under AOB may be limited if the SP is not contracted with the patient's insurance plan.

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

Clinical Overview

In this section, you will find prescribing information details that can help ensure your communications with health plans regarding medical necessity and appeals are complete and supported by the FDA-approved label.

Indication, usage, dosage, and administration¹

| Item | Details |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Indications and usage | <p>MonoFerric is indicated for the treatment of IDA in adult patients:</p> <ul style="list-style-type: none"> • who have intolerance to oral iron or have had unsatisfactory response to oral iron • who have non-hemodialysis dependent chronic kidney disease (NDD-CKD) |
| Dosage and administration | <p>For patients weighing 50 kg or more: Administer 1000 mg of MonoFerric as an intravenous infusion over at least 20 minutes as a single dose</p> <ul style="list-style-type: none"> • For patients weighing less than 50 kg: Administer MonoFerric as 20 mg/kg actual body weight as an intravenous infusion over at least 20 minutes as a single dose • Repeat MonoFerric treatment if IDA reoccurs • 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 |

Clinical trials experience¹

| Item | Details |
|----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Trial information | <p>Trial 1 included patients with IDA who had intolerance to oral iron or who had unsatisfactory response to oral iron or for whom there was a clinical need for rapid repletion of iron stores. Trial 2 included patients with IDA who had NDD-CKD. In these two 8-week trials, patients were randomized 2:1 to treatment with MonoFerric or iron sucrose. MonoFerric was intravenously administered as a single dose of 1000 mg</p> |
| Trial 1 co-primary efficacy endpoint outcome | <p>Mean change in hemoglobin (Hb) from Baseline to Week 8 Mean (95% confidence interval [CI]), g/dL was 2.49 (2.41;2.56) in the MonoFerric arm (N=1009) vs 2.49 (2.38;2.59) in the iron sucrose arm (N=503) (MonoFerric was non-inferior to iron sucrose)</p> |
| Trial 2 co-primary efficacy endpoint outcome | <p>Mean change in Hb from Baseline to Week 8 Mean (95% CI), g/dL was 1.22 (1.14;1.31) in the MonoFerric arm (N=1027) vs 1.14 (1.03;1.26) in the iron sucrose arm (N=511) (MonoFerric was non-inferior to iron sucrose)</p> |

Safety data from the clinical trials¹

- In clinical trials in patients with IDA and CKD, serious or severe hypersensitivity reactions were reported in 0.3% (6/2008) of 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 1 patient
- 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 in the combined analysis of Trials 1 and 2 were nausea (1.2%) and rash (1%) in the MonoFerric group
- Hypophosphatemia (serum phosphate <2.0 mg/dL) was reported in 3.5% of MonoFerric-treated patients in Trials 1 and 2

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](#).

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

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.

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 $\geq 1\%$ 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](#).

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

References

1. Monoferric [Prescribing Information]. Morristown, NJ: Pharmacosmos Therapeutics Inc; 2023.
2. Centers for Medicare & Medicaid Services. 2023 ICD-10-CM. Accessed May 4, 2023. <https://www.cms.gov/medicare/icd-10/2023-icd-10-cm>
3. Find-A-Code. 96365 – CPT® Code in category: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug). InnoviHealthSystems, Inc. <https://www.findacode.com/code.php?set=CPT&c=96365>
4. 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 16, 2023. <https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-2-2020-drugs-and-biologicals-updated-07312020.pdf>
5. National Drug Code (NDC) Conversion Table. Converting NDCS from 10 digits to 11 digits. <https://health.maryland.gov/phpa/OIDEOR/IMMUN/Shared%20Documents/Handout%203%20-%20NDC%20conversion%20to%2011%20digits.pdf>
6. Centers for Medicare & Medicaid Services. CMS Manual System. CMS 1500. Accessed January 16, 2023. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf>
7. Centers for Medicare & Medicaid Services (CMS). Medicare Program. Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy. Frequently Asked Questions. Accessed January 16, 2023. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>
8. Centers for Medicare & Medicaid Services. CMS Manual System. CMS 1450 (UB-04). Accessed January 16, 2023. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>

Questions? Please contact:
MonoferricPatientSolutions@Pharmacosmos.us | 1-800-992-9022

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 **MonoFerric**[®]
(ferric derisomaltose)
injection