

## SAMPLE UB-04 CMS-1450 CLAIM FORM<sup>1</sup> FOR MONOFERRIC | Hospital outpatient administration (Patient weight 50 kg or above): Administer 1,000 mg of MonoFerric as an intravenous infusion<sup>2</sup>

Note, only the 1,000 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 National Drug Code (NDC) number, a code describing the unit of measurement qualifier (e.g., ME for milligrams), and the unit quantity. Example: N473594931001ME1000.

**Box 44:** Enter the appropriate HCPCS code for MonoFerric, J1437, Injection, ferric derisomaltose, 10 mg.<sup>3</sup> To report the administration procedure, enter an appropriate CPT code (e.g., 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)).<sup>4</sup>

**Box 46:** Enter the total number of units of service for MonoFerric, J1437, Injection, ferric derisomaltose, 10 mg. In the example claim form, 1,000 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 prior authorization (PA) number.

**Box 67A-67Q:** Enter the appropriate ICD-10-CM diagnosis code<sup>5</sup> (e.g., D50.0 for iron deficiency anemia (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.

1		2		3a PAY CNTL # 3b MED REC #		4 TYPE OF BILL	
5 PATIENT NAME		6 PATIENT ADDRESS		7 STATEMENT COVERS PERIOD FROM		8 STATEMENT COVERS PERIOD THROUGH	
9 BIRTHDATE	10 SEX	11 DATE	12 ADMISSION	13 HP	14 TYPE	15 SRC	16 DHR
17 STAT	18	19	20	21	22	23	24
25	26	27	28	29 ACCT	30 STATE		
31 OCCURRENCE DATE	32 CODE	33 OCCURRENCE DATE	34 CODE	35 OCCURRENCE DATE	36 CODE	37 OCCURRENCE DATE	38 CODE
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559	560	561	562	563	564	565	566
567	568	569	570	571	572	573	574
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599	600	601	602	603	604	605	606
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679	680	681	682	683	684	685	686
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735	736	737	738	739	740	741	742
743	744	745	746	747	748	749	750
751	752	753	754	755	756	757	758
759	760	761	762	763	764	765	766
767	768	769	770	771	772	773	774
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847	848	849	850	851	852	853	854
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863	864	865	866	867	868	869	870
871	872	873	874	875	876	877	878
879	880	881	882	883	884	885	886
887	888	889	890	891	892	893	894
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903	904	905	906	907	908	909	910
911	912	913	914	915	916	917	918
919	920	921	922	923	924	925	926
927	928	929	930	931	932	933	934
935	936	937	938	939	940	941	942
943	944	945	946	947	948	949	950
951	952	953	954	955	956	957	958
959	960	961	962	963	964	965	966
967	968	969	970	971	972	973	974
975	976	977	978	979	980	981	982
983	984	985	986	987	988	989	990
991	992	993	994	995	996	997	998
999	1000	1001	1002	1003	1004	1005	1006
1007	1008	1009	1010	1011	1012	1013	1014
1015	1016	1017	1018	1019	1020	1021	1022
1023	1024	1025	1026	1027	1028	1029	1030
1031	1032	1033	1034	1035	1036	1037	1038
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1047	1048	1049	1050	1051	1052	1053	1054
1055	1056	1057	1058	1059	1060	1061	1062
1063	1064	1065	1066	1067	1068	1069	1070
1071	1072	1073	1074	1075	1076	1077	1078
1079	1080	1081	1082	1083	1084	1085	1086
1087	1088	1089	1090	1091	1092	1093	1094
1095	1096	1097	1098	1099	1100	1101	1102
1103	1104	1105	1106	1107	1108	1109	1110
1111	1112	1113	1114	1115	1116	1117	1118
1119	1120	1121	1122	1123	1124	1125	1126
1127	1128</						

**SAMPLE UB-04 CMS-1450 CLAIM FORM<sup>1</sup> FOR MONOFERRIC | Hospital outpatient administration**  
**Patients weighing less than 50 kg: Administer 20 mg/kg actual body weight as an intravenous infusion<sup>2</sup>**

Note, only the 1,000 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 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.

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Example: N473594931001ME1000.

**Box 44:** Enter the appropriate HCPCS code for Monofer<sup>®</sup>, J1437, Injection, ferric derisomaltose, 10 mg.<sup>3</sup> To report the administration procedure, enter an appropriate CPT code (e.g., 96365 Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)).<sup>4</sup>

**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.<sup>6</sup>

**Box 63:** Enter the PA number.

**Box 67A-67Q:** Enter the appropriate ICD-10-CM diagnosis code<sup>5</sup> (e.g., **D50.0** for IDA secondary to blood loss (chronic)). Code to the highest level of specificity.

**Box 80:** If required by payer, additional information remarks may be added such as NDC, route of administration, quantity, etc.

[illegible]

**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.<sup>3</sup> More information on the claims process and the CMS fee schedule can be found [here](#).

**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 health care 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 health care 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.

## IMPORTANT SAFETY INFORMATION (continued)

## WARNINGS AND PRECAUTIONS

**Hypersensitivity Reactions:** Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving Monoferic. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after Monoferic administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer Monoferic when

personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. Monoferic is contraindicated in patients with prior serious hypersensitivity reactions to Monoferic or any of its components. In clinical trials in patients with IDA and CKD, serious or severe hypersensitivity were reported in 0.3% (6/2008) of the Monoferic treated subjects. These included 3 events of hypersensitivity in 3 patients; 2 events of infusion-related reactions in 2 patients and 1 event of asthma in one patient.

# INDICATION

MonoFerric is indicated for the treatment of iron deficiency anemia (IDA) in adult patients:

- who have intolerance to oral iron or have had unsatisfactory response to oral iron
- who have non-hemodialysis dependent chronic kidney disease (NDD-CKD)

# IMPORTANT SAFETY INFORMATION

## CONTRAINDICATIONS

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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Please [click here](#) for Full Prescribing Information.

**References:** 1. Centers for Medicare & Medicaid Services. CMS Manual System. CMS 1450 (UB-04). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>. Accessed December 5, 2022. 2. MonoFerric [Prescribing Information]. Morristown, NJ: Pharmacosmos Therapeutics Inc; 2023. 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. <https://www.cms.gov/files/document/2020-hcpcs-applicationsummary-quarter-2-2020-drugs-and-biologicals-updated-07312020.pdf>. Accessed December 5, 2022. 4. Find-A-Code. 96365 - CPT® Code in category: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug). InnoviHealth Systems, Inc. <https://www.findacode.com/code.php?set=CPT&c=96365>. Updated 2020. Accessed December 5, 2022. 5. Centers for Medicare and Medicaid Services. 2023 ICD-10-CM. <https://www.cms.gov/medicare/icd-10/2023-icd-10-cm>. Accessed December 5, 2022. 6. Centers for Medicare & Medicaid Services (CMS). Medicare program JW modifier: drug/biological amount discarded/not administered to any patient frequently asked questions. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JWModifier-FAQs.pdf>. Accessed December 5, 2022.