iron replacement intravenous

Medical Benefit Drug Policy

ferric carboxymaltose (Injectafer)
ferric derisomaltose (Monoferric)
iron dextran (Infed)

Place of Service

Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: ELECTROLYTES/MINERALS/METALS/VITAMINS
Mechanism of Action: Iron replacement
HCPCS:
J1437:Injection, ferric derisomaltose, 10 mg
J1439:Injection, ferric carboxymaltose, 1 mg
J1750:Injection, iron dextran, 50 mg
How Supplied:

- Injectafer (J1439)
  - 100 mg iron/2 mL, single-dose vial
  - 750 mg iron/15 mL, single-dose vial
  - 1000 mg iron/20 mL single-dose vial
- Infed (J1750)
  - 100 mg iron/2 mL (50 mg iron/mL), single-dose vial
- Monoferric (J1437)
  - 1,000 mg iron/10 mL, single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Iron Deficiency or Iron Deficiency Anemia
- Iron Deficiency with Heart Failure [For Injectafer Only]

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

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The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Iron Deficiency or Iron Deficiency Anemia
Meets medical necessity if all the following are met:

1. Age is consistent with FDA labeled indication
2. Meets ONE of the following:
   a. Patient has non-dialysis dependent chronic kidney disease
   b. Inadequate response, intolerable side effect, or intolerance to oral iron supplementation
3. Meets ONE of the following:
   a. Inadequate response or intolerable side effect to preferred generic IV iron products [iron sucrose (generic for Venofer) and ferumoxytol (generic for Feraheme)]
   b. Contraindication to both preferred generic iron products [iron sucrose and ferumoxytol]

Covered Doses:
Injectafer

- For patients less than 50 kg: 15 mg/kg given intravenously in two doses separated by at least 7 days per course. One course is covered as often as every 28 days.
- For patients 50 kg or more:
  - 750 mg given intravenously in two doses separated by at least 7 days for a total cumulative dose of 1,500 mg of iron per course. One course is covered as often as every 28 days.
  - For adult patients 50 kg or more, an alternative dose of 15 mg/kg (up to 1,000 mg) given intravenously may be given as a single-dose per course. One course is covered as often as every 28 days.

Infed

- Dose is based lean body weight hemoglobin level. See Additional Information Section
- A dose is covered intravenously or intramuscularly as often as once daily

Monoferric:

- For patients weighing 50 kg or more: 1,000 mg given intravenously as a single dose. Repeat dose if iron deficiency anemia reoccurs. One dose is covered as often as every 28 days.
- For patients weighing less than 50 kg: 20 mg/kg actual body weight given intravenously as a single dose. Repeat dose if iron deficiency anemia reoccurs. One dose is covered as often as every 28 days.

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
D50.0, D50.1, D50.8, D50.9, D63.1, I12.9, I13.0, I13.10, I50.1, I50.20, I50.21, I50.22, I50.23, I50.30, I50.31, I50.32, I50.33, I50.40, I50.41, I50.42, I50.43, I50.810, I50.811, I50.812, I50.813, I50.814, I50.82, I50.83, I50.84, I50.89, I50.9, N18.1, N18.2, N18.30, N18.31, N18.32, N18.4, N18.5

Iron Deficiency with Heart Failure [For Injectafer Only]
Meets medical necessity if all the following are met:

1. Age is consistent with FDA labeled indication
2. Patient has NYHA class II/III heart failure
3. Inadequate response or intolerable side effect to all generic IV iron products [ferric gluconate (generic for Ferrlecit), iron sucrose (generic for Venofer), and ferumoxytol (generic for Feraheme)] or contraindication to all generic IV iron products

Covered Doses:
1000 mg given intravenously per dose

	weight less than 70 kg			weight 70 kg or more		
Hg (g/dL)	<10	10-14	>14 to <15	<10	10-14	>14 to <15
DAY 1	1000 mg	1000 mg	500 mg	1000 mg	1000 mg	500 mg
WEEK 6	500 mg	No dose	No dose	1000 mg	500 mg	No dose

Administer a maintenance dose of 500 mg at 12, 24 and 36 weeks if serum ferritin <100 ng/mL or serum ferritin 100-300 ng/mL with transferrin saturation <20%. There are no data available to guide dosing beyond 36 weeks or with Hb ≥15 g/dL.

Coverage Period:
1 year

ICD-10:
I09.81, I11.0, I50.1, I50.20, I50.21, I50.22, I50.23, I50.30, I50.31, I50.32, I50.33, I50.40, I50.41, I50.42, I50.43, I50.810, I50.811, I50.812, I50.813, I50.814, I50.82, I50.83, I50.84, I50.89, I50.9

Additional Information

Infed Dosing

Patient Lean Body Weight	Recommended Volume (mL) of Infed Based on Observed Hemoglobin [100 mg iron/2 mL (single-dose vial)]

kg	lb	3 (g/dL)	4 (g/dL)	5 (g/dL)	6 (g/dL)	7 (g/dL)	8 (g/dL)	9 (g/dL)	10 (g/dL)
5	11	3	3	3	3	2	2	2	2
10	22	7	6	6	5	5	4	4	3
15	33	10	9	9	8	7	7	6	5
20	44	16	15	14	13	12	11	10	9
25	55	20	18	17	16	15	14	13	12
30	66	23	22	21	19	18	17	15	14
35	77	27	26	24	23	21	20	18	17
40	88	31	29	28	26	24	22	21	19
45	99	35	33	31	29	27	25	23	21
50	110	39	37	35	32	30	28	26	24
55	121	43	41	38	36	33	31	28	26
60	132	47	44	42	39	36	34	31	28
65	143	51	48	45	42	39	36	34	31
70	154	55	52	49	45	42	39	36	33
75	165	59	55	52	49	45	42	39	35
80	176	63	59	55	52	48	45	41	38
85	187	66	63	59	55	51	48	44	40
90	198	70	66	62	58	54	50	46	42
95	209	74	70	66	62	57	53	49	45
100	220	78	74	69	65	60	56	52	47
105	231	82	77	73	68	63	59	54	50
110	242	86	81	76	71	67	62	57	52
115	253	90	85	80	75	70	64	59	54
120	264	94	88	83	78	73	67	62	57

Table values were calculated based on a normal adult hemoglobin of 14.8 g/dL for patients with body weights greater than 15 kg (33 lbs) and a hemoglobin of 12 g/dL for patients with body weights less than or equal to 15 kg (33 lbs).

Alternatively, the total dose may be calculated using the formulas below:
Adults and Children over 15 kg (33 lbs): Dose (mL) = 0.0442 (Desired Hb - Observed Hb) x LBW + (0.26 x LBW)
Based on:

- Desired Hb = the target hemoglobin in g/dL [Normal hemoglobin (males and females) for body weight over 15 kg (33 lbs) is 14.8 g/dL.]
- Observed Hb = the patient's current hemoglobin in g/dL

- LBW = Lean body weight in kg [A patient's lean body weight (or actual body weight if less than lean body weight) should be utilized when determining dosage.]
  - For males: LBW = 50 kg + 2.3 kg for each inch of patient's height over 5 feet
  - For females: LBW = 45.5 kg + 2.3 kg for each inch of patient's height over 5 feet
  - To calculate a patient's weight in kg when lbs are known: weight in lbs / 2.2 = weight in kg

Children 5 to 15 kg (11 to 33 lbs)
Dose (mL) =0.0442 (Desired Hb − Observed Hb) x W + (0.26 x W)
Based on:

- Desired Hb = the target hemoglobin in g/dL [Normal hemoglobin for children with body weight of 15 kg (33 lbs) or less is 12 g/dL.]
- W = body weight in kg
- To calculate a patient's weight in kg when lbs are known: weight in lbs / 2.2 = weight in kg

NYHA Functional Classification

Class I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
Class II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath) or chest pain.
Class III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea (shortness of breath) or chest pain.
Class IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases

American Heart Association. Classes and Stages of Heart Failure. https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure.

References

1. Injectafer (ferric carboxymaltose injection) Prescribing Information. American Regent, Inc.; Shirley, NY: 1/2025.
2. Infed (iron dextran injection). Prescribing Information. AbbVie Inc.; North Chicago, IL: 8/2024.
3. Monoferric (ferric derisomaltose). Prescribing Information. Pharmacosmos Therapeutics, Inc.; Morristown, NJ: 8/2022.
4. American Heart Association. Classes and Stages of Heart Failure. https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure. Last reviewed: May 21, 2025. Accessed August 2, 2025.

Review History

Date of Last Annual Review: 3Q2026

Changes from previous policy version:

- No change to policy following routine annual review

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee