iron replacement intravenous

Commercial Medical Benefit Drug Policy

For oncology-related indications, medical necessity criteria can be found here: Blue Shield Oncology-Related Medication Policies.

For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's CarePro Provider Portal to submit your request.

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration
ferric carboxymaltose (Injectafer)
ferric derisomaltose (Monoferric)
iron dextran (Infed)

The following generic IV products DO NOT require prior authorization:
ferric gluconate (Ferrlecit): J2916
iron sucrose (Venofer): J1756
ferumoxytol (Feraheme): Q0138 or Q0139

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
- 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 Health and Safety Code section 1367.21 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.

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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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:
One year

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: 3Q2025
Changes from previous policy version:

- For oncology-related indications, medical necessity criteria can be found here: Blue Shield Oncology-Related Medication Policies.
- For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's CarePro Provider Portal to submit your request.

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