

# Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®)

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[Instructions for Use](#)

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Commercial Policy
<ul style="list-style-type: none"> <li><a href="#">Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, &amp; Monoferric®)</a></li> </ul>

## Application

This Medical Benefit Drug Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Florida	Refer to the state's Medicaid clinical policy
Indiana	<a href="#">Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, &amp; Monoferric®) (for Indiana Only)</a>
Kansas	None
Louisiana	<a href="#">Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, &amp; Monoferric®) (for Louisiana Only)</a>
North Carolina	None
Ohio	<a href="#">Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, &amp; Monoferric®) (for Ohio Only)</a>
Pennsylvania	Refer to the state's Medicaid clinical policy
Texas	Refer to drug-specific criteria found within the <i>Texas Medicaid Provider Procedures Manual</i>

## Coverage Rationale

This policy refers to the following intravenous iron replacements:

- Feraheme® (ferumoxytol)
- Injectafer® (ferric carboxymaltose)
- Monoferric® (ferric derisomaltose)

The following intravenous iron replacements are not subject to the coverage criteria in this section:

- Ferrlecit® (sodium ferric gluconate complex)
- Infed® (iron dextran)
- Venofer® (iron sucrose)

**Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), and Monoferric (ferric derisomaltose) are proven for the following indications:**

- [Iron Deficiency Anemia \(IDA\) Without Chronic Kidney Disease \(CKD\)](#)

**Feraheme, Injectafer, and Monoferric are medically necessary when the following criteria are met:**

- For **initial therapy**, **all** of the following:
    - Submission of medical records (e.g., lab values, chart notes, etc.) supporting the diagnosis of IDA; **and**
    - Patient does not have CKD; **and**
    - **One** of the following:
      - History of failure, contraindication, or intolerance, to **oral** iron therapy; **or**
      - **One** of the following:
        - Patient has severe iron deficiency in late stage pregnancy; **or**
        - Patient has impaired absorption due to prior gastric surgery or disorder of the gastrointestinal tract (e.g., celiac disease, inflammatory bowel disease); **or**
        - Blood loss exceeds the ability to replete iron orally
  - and**
  - **One** of the following:
    - **Both** of the following:
      - Submission of laboratory values demonstrating treatment failure to at least **two** of the following intravenous iron therapies (**Note**: Laboratory values should be obtained within 4 to 12 weeks following the last dose of intravenous iron in a treatment course.):
        - Ferrlecit® (sodium ferric gluconate complex)
        - Infed® (iron dextran)
        - Venofer® (iron sucrose)
      - and**
      - Prescriber attests that in the clinical response with Feraheme, Injectafer, or Monoferric would be expected to be superior to the clinical response experienced with the preferred intravenous iron products
    - or**
    - **Both** of the following:
      - History of intolerance, contraindication, or severe adverse event, to **all** of the following intravenous iron therapies not previously tried and experienced treatment failure:
        - Ferrlecit® (sodium ferric gluconate complex); **and**
        - Infed® (iron dextran); **and**
        - Venofer® (iron sucrose)
      - and**
      - Prescriber attests that the same intolerance, contraindication, or severe adverse event experienced with the preferred intravenous iron products would not be expected to occur with Feraheme, Injectafer, or Monoferric
  - and**
  - Feraheme, Injectafer, or Monoferric dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
  - Initial authorization will be for no longer than 12 months
- For **continuation of therapy**, **all** of the following:
  - Coverage has previously been provided by UnitedHealthcare for Feraheme, Injectafer, or Monoferric for the treatment of IDA based on documented history of **one** of the following:
    - Intolerance, contraindication, or severe adverse event to all three preferred intravenous iron products; **or**
    - Treatment failure of at least two of the three preferred intravenous iron products
  - and**
  - Submission of recent laboratory results (within the past 4 to 12 weeks) since the last Feraheme, Injectafer, or Monoferric administration to demonstrate need for additional therapy; **and**
  - Patient does not have CKD; **and**
  - Feraheme, Injectafer, or Monoferric dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
  - Continuation authorization will be for no longer than 12 months
- **Iron Deficiency Anemia (IDA) associated With Chronic Kidney Disease (CKD), without end stage renal disease (ESRD)**

**Feraheme, Injectafer, and Monoferric are medically necessary when the following criteria are met:**

- For **initial therapy**, **all** of the following:
  - Diagnosis of IDA and CKD; **and**
  - Submission of medical records (e.g., lab values, chart notes, etc.) supporting the diagnosis of IDA; **and**
  - Patient does **not** have ESRD; **and**
  - **One** of the following:

- Patient’s CKD requires hemodialysis or peritoneal dialysis treatment; **or**
- **Both** of the following:
  - Patient’s CKD does **not** require hemodialysis or peritoneal dialysis treatment; **and**
  - History of failure, contraindication, or intolerance, to **oral** iron therapy
- and**
- **One** of the following:
  - **Both** of the following:
    - Submission of laboratory values demonstrating treatment failure to at least two of the following intravenous iron therapies (**Note**: Laboratory values should be obtained within 4 to 12 weeks following the last dose of intravenous iron in a treatment course.):
      - Ferlecit® (sodium ferric gluconate complex)
      - Infed® (iron dextran)
      - Venofer® (iron sucrose)
    - and**
    - Prescriber attests that the clinical response with Feraheme, Injectafer, or Monoferric would be expected to be superior to the clinical response experienced with the preferred intravenous iron products
  - or**
  - **Both** of the following:
    - History of intolerance, contraindication, or severe adverse event, to **all** of the following intravenous iron therapies not previously tried and experienced treatment failure:
      - Ferlecit® (sodium ferric gluconate complex); **and**
      - Infed® (iron dextran); **and**
      - Venofer® (iron sucrose)
    - and**
    - Prescriber attests that the same intolerance, contraindication, or severe adverse event experience with the preferred intravenous iron products would not be expected to occur with Feraheme, Injectafer, or Monoferric
- and**
- Feraheme, Injectafer, or Monoferric dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
- Initial authorization will be for no longer than 12 months
- For **continuation of therapy**, **all** of the following:
  - Coverage has previously been provided by UnitedHealthcare for Feraheme, Injectafer, or Monoferric for the treatment of IDA with CKD based on documented history of **one** of the following:
    - Intolerance, contraindication, or severe adverse event to all three preferred intravenous iron products; **or**
    - Treatment failure of at least two of the three preferred intravenous iron products
  - and**
  - Patient does **not** have ESRD; **and**
  - Submission of recent laboratory results (within the past 4 to 12 weeks) since the last Feraheme, Injectafer, or Monoferric administration to demonstrate need for additional therapy; **and**
  - Feraheme, Injectafer, or Monoferric dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
  - Continuation authorization will be for no longer than 12 months

**Injectafer (ferric carboxymaltose) is medically necessary for the treatment of iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity in patients who meet all of the following criteria:**

- For **initial therapy**, **all** of the following:
  - Submission of medical records (e.g., lab values, chart notes, etc.) supporting the diagnosis of iron deficiency including **one** of the following:
    - Serum ferritin < 100 ng/mL; **or**
    - Both of the following:
      - Serum ferritin is 100 to 300 ng/mL; **and**
      - Transferrin saturation (TSAT) < 20%
  - and**
  - Heart failure is classified as **one** of the following:
    - New York Heart Association (NYHA) class II heart failure; **or**
    - New York Heart Association (NYHA) class III heart failure
- and**

- Patient has a left ventricular ejection fraction less than 45%; **and**
  - Patient has hemoglobin (Hb) < 15 g/dl; **and**
  - **One** of the following:
    - **Both** of the following:
      - Submission of laboratory values demonstrating treatment failure to at least **two** of the following intravenous iron therapies (**Note:** Laboratory values should be obtained within 4 to 12 weeks following the last dose of intravenous iron in a treatment course.):
        - Ferrlecit® (sodium ferric gluconate complex)
        - Infed® (iron dextran)
        - Venofer® (iron sucrose)
      - and**
      - Prescriber attests that the clinical response with Injectafer would be expected to be superior to the clinical response experienced with the preferred intravenous iron products
    - or**
    - **Both** of the following:
      - History of intolerance, contraindication, or severe adverse event, to **all** of the following intravenous iron therapies not previously tried and experienced treatment failure:
        - Ferrlecit® (sodium ferric gluconate complex); **and**
        - Infed® (iron dextran); **and**
        - Venofer® (iron sucrose)
      - and**
      - Prescriber attests that the same intolerance, contraindication, or severe adverse event experience with the preferred intravenous iron products would not be expected to occur with Injectafer
- and**
- Injectafer dosing is in accordance with the United States Food and Drug Administration approved labeling for iron deficiency in heart failure; **and**
  - Initial authorization will be for no longer than 12 months
- For **continuation of therapy**, **all** of the following:
    - Coverage has previously been provided by UnitedHealthcare for Injectafer for the treatment of iron deficiency based on documented history of **one** of the following:
      - Intolerance, contraindication, or severe adverse event to all three preferred intravenous iron products; **or**
      - Treatment failure of at least two of the three preferred intravenous iron products
    - and**
    - Submission of recent laboratory results (within the past 4 to 12 weeks) since the last Injectafer administration to demonstrate need for additional therapy; **and**
    - Injectafer dosing is in accordance with the United States Food and Drug Administration approved labeling for iron deficiency in heart failure; **and**
    - Continuation authorization will be for no longer than 12 months

## Definitions

For the purposes of this policy, **Iron Deficiency Anemia**: Is defined as:

- **Iron Deficiency Anemia (IDA) Without Chronic Kidney Disease (CKD) or Acute or Chronic Inflammatory Conditions:**
  - Adults and pediatric patients ≥ 12 years: Serum ferritin < 30 ng/mL or transferrin saturation (TSAT) < 20% or an absence of stainable iron in bone marrow
  - Pediatric patients < 12 years: Hemoglobin concentration below the cutoffs to define anemia in children and adolescents (Table 1) and one of the following:
    - Serum ferritin ≤ 15 ug/L
    - Reticulocyte hemoglobin content (CHr) or reticulocyte hemoglobin equivalent (RET-He) supports a diagnosis of IDA

**Table 1.** Hemoglobin Cutoffs to Define Anemia in Children and Adolescents\*\*\*

Population	Hemoglobin concentration (g/dL)
Children, 6–59 months	11.0
Children, 5–11 years	11.5

\*\*\*Hemoglobin assessments for patients less than 6 months of age are not necessary due to a lack of data to support precise cutoffs for this population.

- **Iron Deficiency Anemia (IDA) With CKD, Without End Stage Renal Disease (ESRD), or Acute or Chronic Inflammatory Conditions:** Serum ferritin < 100 ng/mL or TSAT < 20%. If serum ferritin is 100-300 ng/mL, TSAT < 20% is required to confirm iron deficiency

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J1437	Injection, ferric derisomaltose, 10 mg
J1439	Injection, ferric carboxymaltose, 1 mg
Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-ESRD use)
Q0139	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)

Diagnosis Code	Description
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.1	Sideropenic dysphagia
D50.8	Other iron deficiency anemias
D50.9	Iron deficiency anemia, unspecified
D63.1	Anemia in chronic kidney disease
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I50.1	Left ventricular failure, unspecified
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure

Diagnosis Code	Description
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified
N18.1	Chronic kidney disease, stage 1
N18.2	Chronic kidney disease, stage 2 (mild)
N18.30	Chronic kidney disease, stage 3 unspecified
N18.31	Chronic kidney disease, stage 3a
N18.32	Chronic kidney disease, stage 3b
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5

## Background

The major causes of iron deficiency are decreased dietary intake, reduced iron absorption, and blood loss. In countries with abundant resources, such as the United States, the most common cause of iron deficiency is blood loss, either overt or occult bleeding. Iron replacement, either taken orally or parenterally, provides supplemental iron and thereby increasing iron and ferritin levels, increasing iron stores, and decreasing total iron binding capacity. Iron supplementation can usually result in higher hemoglobin and hematocrit values, and often can decrease the need for epoetin in patients with anemia and chronic kidney disease.

## Clinical Evidence

### Iron Deficiency Anemia

Ferric carboxymaltose, ferric derisomaltose, and ferumoxytol are indicated for the treatment of iron deficiency anemia in patients who have intolerance to oral iron or have had unsatisfactory response to oral iron or who have chronic kidney disease (CKD).

### Technology Assessments

De Franceschi et al., published a systematic review on the advances in diagnosis and treatment in the clinical management of iron deficiency anemia in adults. The authors performed their systematic review using specific search strategy, carried out the review of PubMed database, Cochrane Database of systemic reviews and international guidelines on diagnosis and clinical management of ID from 2010 to 2016. International guidelines were limited to those with peer-review process and published in journal present in citation index database. The eligible studies show that serum ferritin and transferrin saturation are the key tests in early decision-making process to identify iron deficiency anemia (IDA). Of the over 7,000 titles screened, 195 articles were manually reviewed and 58 were selected as relevant to the analysis. For the treatment of IDA, the analysis observed the following outcomes:

- The choice on iron supplementation is based on Hgb levels, the tolerance to oral iron supplementation and the presence of concomitant disease, which might affect iron absorption.
- Intravenous iron administration is definitively more effective in correction of ID since it by-passes the iron absorption step. It offers advantages over oral iron such as:
  - Rapid repletion of iron stores
  - Single dose sufficient for most of the new IV formulation with a reduction in hospital visits
- Follow-up schedule of iron-supplementation therapy is based on the evaluation of Hgb levels at 4 weeks of treatment. Day 14 Hgb levels have been proposed in decision-making process to move patient from oral to IV administration in case of failure.
- In CKD, iron oral supplementation is recommended in patients with IDA not receiving ESAs and not on hemodialysis (HD).
- IV iron should be proposed to patients on ESAs treatment and/or on HD, based on the evidence that oral iron does not sufficiently support ESAs stimulated erythropoiesis.
- Iron supplementation should be always considered as part of clinical management of CHF patients.

- In iron-restricted iron deficiency anemia (IRIDA) patients, oral iron administration usually does not solve the problem, whereas IV iron temporarily ameliorates this condition. Ferritin levels could be reduced or normal after iron treatment.

Peyrin-Biroulet and colleagues performed a systematic review of guidelines on the diagnosis and treatment of iron deficiency across several indications. In this review 127 guidelines were identified in a search of PubMed, Cochrane, and EMBASE and in main professional society websites. Overall 29 guidelines were selected that involved multiple professional societies internationally. A total of 22 and 27 guidelines provided recommendations on diagnosis and treatment of iron deficiency (ID), respectively. To define ID, all guidelines recommended a concentration for serum ferritin. One-half of them (10 of 22) proposed transferrin saturation (TSAT) as an alternative or complementary diagnostic test. To treat ID, most of the guidelines (18 of 27) recommended preferentially the oral route if possible, particularly in children and in women in the pre- or post-pregnancy period. Iron supplementation should be administered intravenously according to 13 of 27 guidelines, particularly in patients with chronic kidney disease (CKD) (n = 7) and chemotherapy-induced anemia (n = 5). Treatment targets for ID included an increase in hemoglobin concentrations to 10-12 g/dL or normalization (n = 8) and serum ferritin > 100 µg/L (n = 7) or 200 µg/L (n = 4). For the latter, in some situations, such as CKD, ferritin concentrations should not exceed 500 µg/L (n = 5) or 800 µg/L (n = 5). Only 9 guidelines recommended TSAT as a target, proposing various thresholds ranging from 20% to 50%. The authors conclude that for the diagnosis of ID, a cutoff of 100 µg/L for serum ferritin concentration should be considered in most conditions and 20% for TSAT, except in particular situations, including young healthy women with heavy menstrual flow. New indications of intravenous iron supplementation are emerging.

## Professional Societies

In 2024, a public review draft of the Kidney Disease: Improving Global Outcomes 2025 clinical practice guideline for anemia in CKD was made available. In people with CKD, two states of iron deficiency are defined by the guideline. One form is characterized by a low TSAT and low ferritin level (e.g., TSAT < 20% and ferritin < 100 µg/l in CKD not receiving dialysis or ferritin < 200 µg/l in CKD G5HD), reflecting decreased iron levels both in the circulation and in tissue stores. Although this has historically been labeled “absolute iron deficiency”, KDIGO proposes a change in nomenclature to “systemic iron deficiency” to more accurately reflect the physiological state. The second form of iron deficiency is characterized by a low TSAT and high ferritin level (generally ferritin > 100–200 µg/l with TSAT < 20%), reflecting limited available iron for erythropoiesis despite adequate iron stores. Although this has historically been termed “functional iron deficiency”, KDIGO proposes a change in nomenclature to “iron-restricted erythropoiesis” to provide a more physiological representation for why treating people with iron may result in increased erythropoiesis and Hb concentration. Commonly used diagnostic thresholds for these parameters, such as ferritin < 100–200 µg/l or TSAT < 20% do not correlate well with bone marrow iron or Hb response to iron in people with CKD. However, because TSAT and ferritin levels are the most commonly used parameters worldwide, are readily available, and are the main parameters utilized in clinical outcome trials to date, they are still recommended to guide diagnosis and management of iron deficiency and anemia in people with CKD. The draft guidance includes various recommendations regarding iron therapy. For patients with CKD and anemia receiving hemodialysis, initiation of IV iron is suggested if transferrin saturation (TSAT) is ≤ 30% and ferritin is ≤ 500 ng/mL. For patients with CKD and anemia who are not receiving hemodialysis or treated with peritoneal dialysis, initiation of oral or IV iron is suggested if TSAT is < 40% and ferritin < 100 ng/mL or if TSAT < 25% with ferritin ≥ 100 ng/mL and < 300 ng/ml. For patients with CKD and profound iron deficiency (TSAT < 20% and ferritin < 30 ng/mL) but no anemia, consider treatment with oral or IV iron. A switch from oral to IV iron if there is an insufficient effect of an optimal oral regimen after 1 to 3 months. KDIGO recommends that in people with CKD treated with intravenous iron, the choice between different formulations is guided by cost, individual preference, and recommended dosing schedules.

In 2024, the American Gastroenterological Association (AGA) published a clinical practice update on management of iron deficiency anemia. Best Practice Advice (BPA) statements were drawn from a review of the published literature and from expert opinion. BPA statements include:

- Intravenous iron should be used if the patient does not tolerate oral iron, ferritin levels do not improve with a trial of oral iron, or the patient has a condition in which oral iron is not likely to be absorbed.
- Intravenous iron formulations that can replace iron deficits with 1 or 2 infusions are preferred over those that require more than 2 infusions.
- All intravenous iron formulations have similar risks; true anaphylaxis is very rare. The vast majority of reactions to intravenous iron are complement activation–related pseudo-allergy (infusion reactions) and should be treated as such.
- Intravenous iron therapy should be used in individuals who have undergone bariatric procedures, particularly those that are likely to disrupt normal duodenal iron absorption, and have iron-deficiency anemia with no identifiable source of chronic gastrointestinal blood loss.
- Intravenous iron therapy should be given in individuals with inflammatory bowel disease, iron-deficiency anemia, and active inflammation with compromised absorption.

- In individuals with portal hypertensive gastropathy and iron-deficiency anemia, oral iron supplements initially should be used to replenish iron stores. Intravenous iron therapy should be used in patients with ongoing bleeding who do not respond to oral iron therapy.
- In patients with iron-deficiency anemia and celiac disease, ensure adherence to a gluten-free diet to improve iron absorption. Consider oral iron supplementation based on the severity of iron deficiency and patient tolerance, followed by intravenous iron therapy if iron stores do not improve.

In 2023, the European Society of Cardiology (ESC) published a focused updated of their 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure.<sup>37</sup> Based on trials and recent meta-analysis, the following new recommendations were given in regard to iron deficiency and/or iron supplementation in patients with heart failure:

- Intravenous iron supplementation is recommended in symptomatic patients with heart failure with reduced ejection fraction (HFrEF) and heart failure with mildly reduced ejection fraction (HFmrEF), and iron deficiency, to alleviate HF symptoms and improve quality of life.
- Intravenous iron supplementation with ferric carboxymaltose or ferric derisomaltose should be considered in symptomatic patients with HFrEF and HFmrEF, and iron deficiency, to reduce the risk of HF hospitalization.

In 2023, recommendations from the *International Consensus Conference on Anemia Management in Surgical Patients* were published. A group of experts in patient blood management (PBM) selected a multidisciplinary panel to participate in the International Consensus Conference on Anemia Management in Surgical Patients (ICCAMs). The opinion of the panel was that the available data suggest that iron therapy as a treatment for preoperative anemia should be limited to patients with IDA. Consensus Statements were provided for Treatment of Preoperative Anemia and Preoperative Iron Therapy:

- The aim of treating preoperative anemia is to improve Hb concentration and this may decrease RBC transfusion.
- Therapy should be tailored to the etiology of anemia.
- Iron therapy should be administered as treatment for preoperative IDA, except when it is contraindicated.
- IV iron is preferable to oral iron in preoperative IDA.
- Preoperative oral iron therapy should be started as early as possible.
- Preoperative IV iron therapy should be started as early as possible.
- Administration of IV iron is generally well tolerated and does not increase the patient's risk of infection.

In 2022, the American Heart Association (AHA), American College of Cardiology (ACC), and Heart Failure Society of America (HFSA) published their clinical practice guidelines for the management of heart failure. Recommendations are provided for select patients with heart failure (HF) and iron deficiency and anemia. The guidelines state:

- Iron deficiency is usually defined as ferritin level < 100 µg/L or 100 to 300 µg/L, if the transferrin saturation is < 20%.
- Intravenous repletion of iron has been shown to improve exercise capacity and QOL.
- Oral iron is not adequate to treat iron deficiency anemia in patients with HF.

In 2021, the European Society of Cardiology (ESC) published their clinical practice guidelines for the diagnosis and treatment of acute and chronic heart failure. In regard to the treatment of iron deficiency anemia in heart failure, the guidelines state:

- Iron supplementation with i.v., ferric carboxymaltose should be considered for the improvement of symptoms, exercise capacity, and QOL in patients with HF and LVEF < 45%.
- Iron supplementation with i.v., ferric carboxymaltose should also be considered for the reduction of HF rehospitalizations in patients with LVEF < 50% recently hospitalized for worsening HF.
- Oral iron therapy is not effective in iron repletion and did not improve exercise capacity in patients with HFrEF and iron deficiency and therefore is not recommended for the treatment of iron deficiency in patients with HF.

In 2013, the American Academy of Pediatrics (AAP) published a clinical report for the diagnosis and prevention of iron deficiency and Iron-Deficiency Anemia in infants and young children (0-3 years of age). In regard to diagnosis, the AAP defines anemia as a hemoglobin (Hgb) concentration 2 standard deviations below the mean Hgb for a normal population of the same gender and age range, as defined by the World Health Organization, the United Nations Children's Fund, and the United Nations University. Additional screening tests for iron deficiency or iron deficiency anemia should include measurements of serum ferritin and C-reactive protein (CRP levels), or reticulocyte Hgb concentration (CHr).

# U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Feraheme (ferumoxytol) is 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 or who have chronic kidney disease (CKD).

Injectafer (ferric carboxymaltose) is an iron replacement product indicated for the treatment of IDA in: adult and pediatric patients 1 year of age and older who have intolerance to oral iron or have had unsatisfactory response to oral iron; and adult patients who have non-dialysis dependent CKD. Injectafer is also indicated for the treatment of iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity.

Monoferric (ferric derisomaltose) is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron or who have non-hemodialysis dependent chronic kidney disease.

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## Policy History/Revision Information

Date	Summary of Changes
02/01/2026	<p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>Updated definition of “Iron Deficiency Anemia (IDA) With CKD, Without End Stage Renal Disease (ESRD), or Acute or Chronic Inflammatory Conditions”</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> <li>Archived previous policy version CS2025D0088O</li> </ul>

## Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® clinical guidelines, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.