Medical Drug Clinical Criteria

Subject:	Iron Agents		
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Overview

This document addresses the use of injectable agents for the treatment of iron deficiency anemia (IDA). Agents addressed in this document include:

- Feraheme (ferumoxytol)
- Ferrlecit (sodium ferric gluconate/sucrose complex)
- Infed (iron dextran)
- Injectafer (ferric carboxymaltose)
- Monoferric (ferric derisomaltose)
- Triferic, Triferic AVNU (ferric pyrophosphate citrate)
- Venofer (iron sucrose)

Iron is a mineral in the body that is an essential component for blood production, enabling them to carry oxygen throughout the body. The majority of body iron are found in circulating red blood cells called hemoglobin, while the remaining is stored as ferritin or bound to myoglobin in muscle cells. Individuals with iron deficiency anemia may have mild to severe symptoms, ranging from fatigue, shortness of breath, and chest pain to heart failure and developmental delays in children (NHLBI 2019).

The causes of iron deficiency anemia are numerous, including gastrointestinal bleeding or other blood loss, chronic kidney disease, celiac disease, multiple blood donations, and cancer or chemotherapy-related etiologies. Diagnosis of IDA is typically confirmed by evaluating levels of serum ferritin, transferrin saturation (TSAT), absence of stainable iron in the bone marrow, or resolution of anemia upon iron administration (Auerbach 2020).

While the 2012 Kidney Disease Improving Global Outcomes (KDIGO) guidelines for anemia in chronic kidney disease do not provide any guidance on preference of available IV iron agents over another, they do suggest that a trial oral iron for 1 to 3 months can be appropriate for individuals with IDA prior to initiating IV iron. The National Comprehensive Cancer Network (NCCN) guidelines for Hematopoietic Growth Factors provides a category 2A recommendation for use of Feraheme, Ferrlecit, Infed (IV only; IM not recommended), Injectafer, Venofer, and Monoferric for the management of cancer- and chemotherapy-induced anemia. NCCN also suggests that a trial of oral iron for at least 4 weeks can be appropriate prior to initiating IV iron.

Both Feraheme and Infed have black box warnings for fatal and serious hypersensitivity reactions including anaphylaxis, and as such, the administration of which should only occur when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate/sucrose complex), Venofer (iron sucrose)

Requests for Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate/sucrose complex), Venofer (iron sucrose) may be approved if the following criteria are met:

I. Individual has a diagnosis of chronic kidney disease (CKD); **AND**
   A. Individual is dialysis dependent; **AND**
   B. Individual has iron deficiency anemia (IDA);

OR

II. Individual has a diagnosis of iron deficiency anemia (IDA); **AND**
III. Individual is non-dialysis dependent; **AND**
IV. Diagnosis is confirmed by one of the following:
   A. For IDA associated with CKD or inflammatory conditions (for example, inflammatory bowel disease [IBD], heart failure), individual meets *one* of the following within the last four (4) weeks (De Franceschi 2017):
      1. Serum ferritin levels less than 100 ng/mL; **OR**
      2. TSAT levels less than 20%; **OR**
      3. Serum ferritin is less than or equal to 500 ng/mL ***and*** TSAT is less than or equal to 30% (KDIGO 2012); **OR**
      4. Bone marrow demonstrates inadequate iron stores; **OR**
      5. Hemoglobin (HGB) less than 13 g/dl (less than 130 g/l) in males or less than 12 g/dl (less than 120 g/l) in females and TSAT 30% or less and ferritin 500ng/ml or less (500 µg/l or less) (Ko 2020); **OR**
   B. For IDA associated with cancer/chemotherapy or non-inflammatory conditions (for example, blood loss, malabsorption, malnutrition), individual meets *one* of the following within the last four (4) weeks (NCCN 2021, De Franceschi 2017):
      1. Serum ferritin levels less than 30 ng/mL; **OR**
      2. TSAT levels less than 20%; **OR**
      3. Bone marrow demonstrates inadequate iron stores; **AND**
V. Individual has had a four (4) week trial of and inadequate response, or intolerance to oral iron supplementation (NCCN 2020, KDIGO 2012); **OR**
VI. Individual is unable to use oral iron supplementation for one of the following reasons:
   A. Malabsorption conditions; **OR**
   B. Gastric Surgery (DeFlipp 2013);

OR

VII. Individual has iron deficiency anemia in pregnancy; **AND**
VIII. Diagnosis is confirmed by one of the following:
   A. Serum ferritin levels less than 30 ng/mL; **OR**
   B. TSAT levels less than 20%; **OR**
   C. Bone marrow demonstrates inadequate iron stores; **AND**
IX. Individual is past 14 weeks of pregnancy and has had a four (4) week trial of and inadequate response, or intolerance to oral iron supplementation (Muñoz 2017); **OR**
X. Individual is past 14 weeks of pregnancy and diagnosed with severe iron deficiency anemia, defined as Hemoglobin (HGB) less than 8 g/dL; **OR**
XI. Individual is past 34 weeks of pregnancy.

Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate/sucrose complex), or Venofer (iron sucrose) may not be approved when the above criteria are not met and for all other indications.

Approval Duration (dialysis-dependent use excluded)
6 months

Infed (iron dextran)

Requests for Infed (iron dextran) may be approved if the following criteria are met:

I. Individual has a diagnosis of chronic kidney disease (CKD); **AND**
   A. Individual is dialysis dependent; **AND**
   B. Individual has iron deficiency anemia (IDA);

OR

II. Individual has a diagnosis of iron deficiency anemia (IDA); **AND**

III. Individual is non-dialysis dependent; **AND**
IV. Diagnosis is confirmed by one of the following:
    A. For IDA associated with CKD or inflammatory conditions (for example, inflammatory bowel disease [IBD], heart failure), individual meets *one* of the following within the last four (4) weeks (De Franceschi 2017):
        1. Serum ferritin levels less than 100 ng/mL; **OR**
        2. TSAT levels less than 20%; **OR**
        3. Serum ferritin is less than or equal to 500 ng/mL ***and*** TSAT is less than or equal to 30% (KDIGO 2012); **OR**
        4. Bone marrow demonstrates inadequate iron stores; **OR**
        5. Hemoglobin (HGB) less than 13 g/dl (less than 130 g/l) in males or less than 12 g/dl (less than 120 g/l) in females and TSAT 30% or less and ferritin 500ng/ml or less (500 µg/l or less) (Ko 2020); **OR**
    B. For IDA associated with cancer/chemotherapy or non-inflammatory conditions (for example, blood loss, malabsorption, malnutrition), individual meets *one* of the following within the last four (4) weeks (NCCN 2021, De Franceschi 2017):
        1. Serum ferritin levels less than 30 ng/mL; **OR**
        2. TSAT levels less than 20%; **OR**
        3. Bone marrow demonstrates inadequate iron stores; **AND**
V. Individual has had a four (4) week trial of and inadequate response, or intolerance to oral iron supplementation (NCCN 2021, KDIGO 2012); **OR**
VI. Individual is unable to use oral iron supplementation for one of the following reasons:
    A. Malabsorption conditions; **OR**
    B. Gastric Surgery (DeFlipp 2013);

OR

VII. Individual has iron deficiency anemia in pregnancy; **AND**
VIII. Diagnosis is confirmed by one of the following:
    A. Serum ferritin levels less than 30 ng/mL; **OR**
    B. TSAT levels less than 20%; **OR**
    C. Bone marrow demonstrates inadequate iron stores; **AND**
IX. Individual is past 14 weeks of pregnancy and has had a four (4) week trial of and inadequate response, or intolerance to oral iron supplementation (Muñoz 2017); **OR**
X. Individual is past 14 weeks of pregnancy and diagnosed with severe iron deficiency anemia, defined as Hemoglobin (HGB) less than 8 g/dL; **OR**
XI. Individual is past 34 weeks of pregnancy;

OR

XII. Individual is diagnosed with iron deficiency due to blood loss; **AND**
XIII. Diagnosis is confirmed by one of the following:
    A. Serum ferritin levels less than 100 ng/mL; **OR**
    B. TSAT levels less than 20%; **OR**
    C. Serum ferritin is less than or equal to 500 ng/mL ***and*** TSAT is less than or equal to 30% (KDIGO 2012); **OR**
    D. Bone marrow demonstrates inadequate iron stores.

Infed (iron dextran) may not be approved when the above criteria are not met and for all other indications.

Approval Duration (dialysis-dependent use excluded)
6 months

Injectafer (ferric carboxymaltose)
Requests for Injectafer (ferric carboxymaltose) may be approved if the following criteria are met:

I. Individual has a diagnosis of chronic kidney disease (CKD); **AND**
    A. Individual is dialysis dependent; **AND**
    B. Individual has iron deficiency anemia (IDA);

OR

II. Individual has a diagnosis of iron deficiency anemia (IDA); **AND**
III. Individual is non-dialysis dependent; **AND**
IV. Diagnosis is confirmed by one of the following:

A. For IDA associated with CKD or inflammatory conditions (for example, inflammatory bowel disease [IBD], heart failure), individual meets *one* of the following within the last four (4) weeks (De Franceschi 2017):
   1. Serum ferritin levels less than 100 ng/mL; **OR**
   2. TSAT levels less than 20%; **OR**
   3. Serum ferritin is less than or equal to 500 ng/mL ***and*** TSAT is less than or equal to 30% (KDIGO 2012); **OR**
   4. Bone marrow demonstrates inadequate iron stores; **OR**
   5. Hemoglobin (HGB) less than 13 g/dl (less than 130 g/l) in males or less than 12 g/dl (less than 120 g/l) in females and TSAT 30% or less and ferritin 500ng/ml or less (500 µg/l or less) (Ko 2020); **OR**

B. For IDA associated with cancer/chemotherapy or non-inflammatory conditions (for example, blood loss, malabsorption, malnutrition), individual meets *one* of the following within the last four (4) weeks (NCCN 2021, De Franceschi 2017):
   1. Serum ferritin levels less than 30 ng/mL; **OR**
   2. TSAT levels less than 20%; **OR**
   3. Bone marrow demonstrates inadequate iron stores; **AND**

V. Individual has had a four (4) week trial of and inadequate response, or intolerance to oral iron supplementation (NCCN 2021, KDIGO 2012); **OR**

VI. Individual is unable to use oral iron supplementation for one of the following reasons:
   A. Malabsorption conditions; **OR**
   B. Gastric Surgery (DeFlipp 2013);

OR

VII. Individual has iron deficiency anemia in pregnancy; **AND**

VIII. Diagnosis is confirmed by one of the following:
   A. Serum ferritin levels less than 30 ng/mL; **OR**
   B. TSAT levels less than 20%; **OR**
   C. Bone marrow demonstrates inadequate iron stores; **AND**

IX. Individual is past 14 weeks of pregnancy and has had a four (4) week trial of and inadequate response, or intolerance to oral iron supplementation (Muñoz 2017); **OR**

X. Individual is past 14 weeks of pregnancy and diagnosed with severe iron deficiency anemia, defined as Hemoglobin (HGB) less than 8 g/dL; **OR**

XI. Individual is past 34 weeks of pregnancy;

OR

XII. Individual is diagnosed with iron deficiency in adult patients with heart failure with New York Heart Association class II/III; **AND**

XIII. Individual is using to improve exercise capacity; **AND**

XIV. Diagnosis is confirmed by one of the following (Heidenreich 2022):
   A. Serum ferritin levels less than 100 µg/L; **OR**
   B. TSAT levels less than 20% and ferritin level 100 to 300 µg/L.

Injectafer (ferric carboxymaltose) may not be approved when the above criteria are not met and for all other indications.

Approval Duration (dialysis-dependent use excluded)
6 months

Monoferric (ferric derisomaltose)

Requests for Monoferric (ferric derisomaltose) may be approved if the following criteria are met:

I. Individual has a diagnosis of iron deficiency anemia (IDA); **AND**

II. Individual is non-dialysis dependent; **AND**

III. Diagnosis is confirmed by one of the following:
   A. For IDA associated with CKD or inflammatory conditions (for example, inflammatory bowel disease [IBD], heart failure), individual meets *one* of the following within the last four (4) weeks (De Franceschi 2017):
      1. Serum ferritin levels less than 100 ng/mL; **OR**
      2. TSAT levels less than 20%; **OR**

3. Serum ferritin is less than or equal to 500 ng/mL ***and*** TSAT is less than or equal to 30% (KDIGO 2012); **OR**
4. Bone marrow demonstrates inadequate iron stores; **OR**
5. Hemoglobin (HGB) less than 13 g/dl (less than 130 g/l) in males or less than 12 g/dl (less than 120 g/l) in females and TSAT 30% or less and ferritin 500ng/ml or less (500 µg/l or less) (Ko 2020); **OR**

B. For IDA associated with cancer/chemotherapy or non-inflammatory conditions (for example, blood loss, malabsorption, malnutrition), individual meets *one* of the following within the last four (4) (NCCN 2022, De Franceschi 2017):
1. Serum ferritin levels less than 30 ng/mL; **OR**
2. TSAT levels less than 20%; **OR**
3. Bone marrow demonstrates inadequate iron stores; **AND**

IV. Individual has had a four (4) week trial of and inadequate response, or intolerance to oral iron supplementation (NCCN 2022, KDIGO 2012); **OR**

V. Individual is unable to use oral iron supplementation for one of the following reasons:
A. Malabsorption conditions; **OR**
B. Gastric Surgery (DeFlipp 2013).

Monoferric (ferric derisomaltose) may not be approved for the following:

I. Individual has hemodialysis dependent chronic kidney disease (CKD); **OR**
II. When the above criteria are not met and for all other indications.

Approval Duration 6 months

Triferic/Triferic AVNU (ferric pyrophosphate citrate)

Requests for Triferic/Triferic AVNU (ferric pyrophosphate citrate) may be approved if the following criteria are met:

I. Individual has a diagnosis of chronic kidney disease (CKD); **AND**
A. Individual is hemodialysis dependent; **AND**
B. Individual has iron deficiency anemia (IDA).

Triferic/Triferic AVNU (ferric pyrophosphate citrate) may not be approved for the following:

I. Peritoneal dialysis; **OR**
II. When the above criteria are not met and for all other indications.

Step Therapy

Summary of FDA-approved and NCCN 2A recommended indications for agents for Iron Deficiency Anemia (IDA):

Agent	Route	Oral iron intolerant or unresponsive IDA	CKD	Dialysis-dependent CKD only	Iron Replacement for Blood Loss	NCCN
Feraheme (ferumoxytol)	IV	x	x			x
Ferrlecit (sodium ferric gluconate/sucrose complex)	IV			x*		x
Infed (iron dextran)	IV, IM	x*				x (IV only)
Injectafer (ferric carboxymaltose)	IV	x	x			x
Monoferric (ferric derisomaltose)	IV	x	x			x
Triferic, Triferic AVNU (ferric pyrophosphate citrate)	IV			x		
Venofer (iron sucrose)	IV		x*			x

*Includes FDA-approved pediatric indication

Note: When an IDA agent is deemed approvable based on the clinical criteria above, the benefit plan may have additional criteria requiring the use of a preferred[1] agent or agents.

Non-Preferred Iron Deficiency Anemia (IDA) Step Therapy

A list of the preferred iron deficiency anemia agents is available here.

Requests for a non-preferred agent for IDA may be approved when the following criteria are met:

I. Individual has had a trial and inadequate response or intolerance to two (2) preferred agents;

OR

II. If Infed (iron dextran) is designated as non-preferred, then it may be approved for the following:
   A. Individual requires intramuscular (IM) administration due to difficult vein access that precludes use of an intravenous IDA agent; OR
   ~~A.~~B. Individual is diagnosed with iron deficiency due to blood loss;

OR

III. If Injectafer (ferric carboxymaltose) is designated as non-preferred, then it may be approved for the following:
   A. Individual is being treated for iron deficiency in heart failure;

OR

IV. The preferred agent(s) are not acceptable due to concomitant clinical conditions, including but not limited to known hypersensitivity to any active or inactive component which is not also associated with the requested non-preferred agent;

OR

V. Individual is dialysis-dependent and using iron in conjunction with dialysis.

[1]Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness.

Quantity Limits

Iron Deficiency Anemia Agents Quantity Limits

Drug	Limit
Feraheme (ferumoxytol) 510 mg/17 mL vial*	1020 mg per 6 days‡
Ferrlecit (sodium ferric gluconate/sucrose complex) 62.5 mg/5 mL vial*	1000mg per 8 weeksΔ
Injectafer (ferric carboxymaltose) 100mg/2ml vial*, 750 mg/15 mL vial*, 1000 mg/20 mL vial*	1500 mg per 7 days
Monoferric (ferric derisomaltose) 100 mg/mL vial, 500 mg/5 mL vial, 1000 mg/10 mL vial	1000 mg per day ‡
Venofer (iron sucrose) 50 mg/2.5 mL vial*, 100 mg/5 mL vial*, 200 mg/10 mL vial*	1000 mg per 14 days ‡
Override Criteria	
*Use in dialysis-dependent individuals excluded from quantity limits.	

‡Limit represents FDA-approved maximum dose recommendations per course of therapy (excluding dialysis-dependent diagnosis).
ΔLimit according to NCCN guidelines for hematopoietic growth factors (v~~4.2021~~2.2023).

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J1443	Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron [Triferic]
J1445	Injection, ferric pyrophosphate citrate solution (Triferic AVNU), 0.1 mg of iron
J1437	Injection, ferric derisomaltose, 10 mg [Monoferric]
Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for non-ESRD on dialysis) [Feraheme]
J2916	Injection, sodium ferric gluconate complex in sucrose injection, 12.5 mg [Ferrlecit]
J1750	Injection, iron dextran, 50 mg [Infed]
J1756	Injection, iron sucrose, 1 mg [Venofer]
J1439	Injection, ferric carboxymaltose, 1 mg [Injectafer]

ICD-10 Diagnosis

D50.0-D50.9	Iron deficiency anemia
D63.0-D63.8	Anemia in chronic diseases classified elsewhere
D64.81	Anemia due to antineoplastic chemotherapy
K50.00-K50.919	Crohn‘s disease [regional enteritis]
K90.0-K90.9	Celiac disease
N18.1-N18.5	Chronic kidney disease, stages I-V
O99.011	Anemia complicating pregnancy, first trimester
O99.012	Anemia complicating pregnancy, second trimester
O99.013	Anemia complicating pregnancy, third trimester
O99.019	Anemia complicating pregnancy, unspecified trimester

Document History

Revised: 09/11/2023
Document History:

- 09/11/2023 – Select Review: Add override criteria for Infed in step for iron deficiency due to blood loss, wording and formatting. Coding Reviewed: No changes. 08/18/2023 – Annual Review: Add hemoglobin in diagnosis, edit oral iron requirement, update Infed criteria to include iron deficiency from blood loss, Add Injectafer criteria related to heart failure, add override criteria for Injectafer in step, edit quantity limits, increase approval length. Step therapy table updates. Coding Reviewed: No changes.
- 05/15/2023 – Step therapy table updates.
- 05/01/2023 – Step therapy table updates.
- 03/27/2023 – Step therapy table updates.
- 01/25/2023 – Step therapy table updates.
- 01/11/2023 – Step therapy and step therapy table updates.
- 12/01/2022 – Step therapy table updates.
- 09/15/2022 – Select Review: add quantity limit for Injectafer 100mg/2ml vial. Coding Reviewed: No changes.
- 08/19/2022 – Annual Review: Add criteria for iron deficiency anemia in pregnancy, wording and formatting changes. Coding reviewed: Added ICD-10-CM 099.011, O99.012, O99.013. O99.019.
- 04/25/2022 – Step therapy table updates.
- 03/28/2022 – Step therapy table updates.
- 08/20/2021 – Annual Review: Update criteria to update approval durations to three months for all requests, and remove continuation approval duration. Add timeframe parameters for lab values for Feraheme, Infed, Venofer, Ferrlecit, Injectafer, and Monoferric. Update Monoferric non-approvable criteria to restrict use in hemodialysis patients per label. Remove QL override criteria for Monoferric. Add generically available version of Feraheme to step therapy criteria. Update Injectafer QL to include new strength. Clarify use in hemodialysis dependent CKD patients. Update references, and wording and formatting changes. Coding reviewed: Added HCPCS J1445.
- 08/23/2021 – Step therapy table updates.
- 07/26/2021 – Step therapy table updates.

- 04/26/2021 - Step therapy table updates.
- 08/21/2020 – Annual Review: Add new clinical criteria document, including PA, step therapy, and quantity limits, for Injectafer, Infed, Venofer, Triferic/Triferic AVNU, Feraheme, Monoferric, and Ferrlecit. Coding Reviewed: Added HCPCS codes- J1443, J1437, Q0138, J2916, J1750, J1439,J1756. Added ICD-10-CM codes-D50.0-D50.9, D63.0-D63.8, D64.81, K50.00-K50.919, K90.0, K90.4, K90.9, N18.1-N18.5. Effective 2/1/2021 extended ICD-10-CM K50.00-K50.919, Extended K90.0-K90.9, Removed K90.4, and K90.9.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

CC-0182 Agents for Iron Deficiency Anemia

Commercial Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
03/01/2023	Ferrlecit Feraheme Venofer	Infed Injectafer Monoferric
10/01/2023	Ferrlecit Feraheme Infed Venofer	Injectafer Monoferric

Medicaid Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
09/18/2023: AR, CA, DC, FL Healthy Kids, GA, IA, KY, LA, MD, NJ, NV, NY, OH, SC, TN, VA, WI, WNY	Ferrlecit Feraheme Infed Venofer	Injectafer Monoferric

Medicare Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
03/01/2023	Ferrlecit Feraheme Venofer	Infed Injectafer Monoferric