Iron Agents

Override(s)	Approval Duration
Prior Authorization Quantity Limit	6 months Dialysis-dependent use: 1 year

Medications	Comments	Quantity Limit
Feraheme (ferumoxytol) – brand and generic Ferrlecit (sodium ferric gluconate/sucrose complex) - brand and generic Infed (iron dextran) Venofer (iron sucrose) Injectafer (ferric carboxymaltose) Monoferric (ferric derisomaltose)	Non-Preferred	May be subject to quantity limit*
Triferic, Triferic AVNU (ferric pyrophosphate citrate)	N/A	

*Use in dialysis-dependent individuals excluded from quantity limits.

APPROVAL CRITERIA

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) or iron deficiency; **AND**

III. Individual is non-dialysis dependent; **AND**
IV. Diagnosis is confirmed by one of the following:
    A. For IDA or iron deficiency 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 or iron deficiency 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 2024, 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 2024, 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 or iron deficiency 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 individual is unable to use oral iron supplementation due to malabsorptive conditions or gastric surgery (Muñoz 2017, DeFlipp 2013); **OR**
XI. Individual is past 14 weeks of pregnancy and diagnosed with severe iron deficiency anemia, defined as Hemoglobin (HGB) less than 8 g/dL; **OR**
XII. Individual is past 34 weeks of pregnancy.

Requests for 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.

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) or iron deficiency; **AND**
III. Individual is non-dialysis dependent; **AND**
IV. Diagnosis is confirmed by one of the following:
   A. For IDA or iron deficiency 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 or iron deficiency associated with cancer/chemotherapy or non-inflammatory conditions (for example, malabsorption, malnutrition), individual meets *one* of the following within the last four (4) weeks (NCCN 2024, 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 2024, 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 or iron deficiency 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 individual is unable to use oral iron supplementation due to malabsorptive conditions or gastric surgery (Muñoz 2017, DeFlipp 2013); **OR**
XI. Individual is past 14 weeks of pregnancy and diagnosed with severe iron deficiency anemia, defined as Hemoglobin (HGB) less than 8 g/dL; **OR**

XII. Individual is past 34 weeks of pregnancy;

OR

XIII. Individual is diagnosed with iron deficiency due to blood loss; **AND**

XIV. 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.

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) or iron deficiency; **AND**
III. Individual is non-dialysis dependent; **AND**
IV. Diagnosis is confirmed by one of the following:
   A. For IDA or iron deficiency 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 or iron deficiency 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 2024, 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 2024, 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 or iron deficiency 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 individual is unable to use oral iron supplementation due to malabsorptive conditions or gastric surgery (Muñoz 2017, DeFlipp 2013); **OR**
XI. Individual is past 14 weeks of pregnancy and diagnosed with severe iron deficiency anemia, defined as Hemoglobin (HGB) less than 8 g/dL; **OR**
XII. Individual is past 34 weeks of pregnancy;

OR

XIII. Individual is diagnosed with iron deficiency in adult patients with heart failure with New York Heart Association class II/III; **AND**
XIV. Individual is using to improve exercise capacity; **AND**
XV. 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.

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) or iron deficiency; **AND**
II. Individual is non-dialysis dependent; **AND**
III. Diagnosis is confirmed by one of the following:
A. For IDA or iron deficiency 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 or iron deficiency 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 2024, 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 2024, 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.

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.

Key References:

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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.