Medical Policy

Feraheme® ((ferumoxytol))	
MEDICAL POLICY NUMBER	MED_Clin_Ops-121
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan*: ALL *Small Group:* ALL *Medicare Advantage*: ALL

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity Feraheme® (ferumoxytol) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Feraheme will be provided for 3 months and may be renewed.

- Max Units (per dose and over time):
  - Q0138 (non-ESRD): 1020 billable units per 28 days

Initial

A. Patient is 18 years of age or older; **AND**
B. Other causes of anemia (e.g., blood loss, vitamin deficiency, etc.) have been ruled out; **AND**
C. Patient does not have a history of allergic reaction to any intravenous iron product; **AND**
D. Other supplemental iron is to be discontinued prior to administration of Feraheme; **AND**
E. Laboratory values must be obtained within 28 days prior to the anticipated date of administration; **AND**

Iron Deficiency Anemia (IDA) Without Chronic Kidney Disease (CKD)

A. Diagnosis is confirmed by the following:
    a. Serum ferritin < 15 ng/mL or < 30 ng/mL if pregnant; **OR**
    b. Serum ferritin < 30 ng/mL; **AND**
        i. Hgb less than 12 g/dL for females or less than 14 g/dL for males; **OR**
    c. Transferrin saturation (TSAT) less than 20%; **AND**
B. Oral iron therapy is not optimal due to any of the following:
    a. TSAT < 12%;
    b. Hgb < 7 g/dL;
    c. Severe or ongoing blood loss exceeds the ability to replete iron orally;
    d. Oral iron intolerance (e.g., diarrhea, constipation, nausea, vomiting, etc.);
    e. Unable to achieve therapeutic targets with oral iron;
    f. Co-existing condition that may be refractory to oral iron therapy (e.g., impaired absorption due to prior gastric surgery or inflammatory bowel disease, etc.); **AND**
C. At the time of the request, patient does not have CKD.

Iron Deficiency Anemia (IDA) Associated With Chronic Kidney Disease (CKD), Without End Stage Renal Disease (ESRD)

A. Diagnosis of IDA is confirmed by the following:
    a. TSAT of equal to or less than 30%;
    b. Serum ferritin ≤ 500 ng/mL
B. Patient's CKD requires hemodialysis or peritoneal dialysis treatment; **OR**
C. Oral iron therapy is not optimal due to any of the following:
    a. TSAT < 12%;
    b. Hgb < 7 g/dL;
    c. Severe or ongoing blood loss exceeds the ability to replete iron orally;
    d. Oral iron intolerance (e.g., diarrhea, constipation, nausea, vomiting, etc.);
    e. Unable to achieve therapeutic targets with oral iron;
    f. Co-existing condition that may be refractory to oral iron therapy (e.g., impaired absorption due to prior gastric surgery or inflammatory bowel disease, etc.); AND
D. At the time of the request, patient does not have ESRD

Renewal

A. Submission of recent laboratory results (within the past 4 weeks) since the last Feraheme or Injectafer administration to demonstrate need for additional therapy

LIMITATIONS/EXCLUSIONS

1) Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

1) Feraheme® (ferumoxytol injection), for intravenous use. Initial U.S. Approval: 2009

CODING

Applicable NDC Codes	
59338-0775-xx	Feraheme 510 mg/17 mL single-use vial

Applicable Procedure Code	
Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-ESRD)

ICD-10	ICD-10 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

EVIDENCE BASED REFERENCES

1. Feraheme [package insert]. Waltham, MA; AMAG Pharmaceuticals, Inc. February 2018. Accessed July 2022.

Policy History

This policy has been approved by the approval body listed below or has received other necessary approval pursuant to Brand New Day/Central Health Medicare Plan Care's policies on clinical criteria and policy development.

Approval Body	Pharmacy and Therapeutics Committee
Original Effective Date	July 26, 2022
Version Date	V1 – July 26, 2022 V2 – March 01, 2023 – Adopted by MA UMC V3 – January 01, 2024 - Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan