

## Medical Policy

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

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at <http://www.cms.gov> for additional information.

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## 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):
  - o Q0138 (non-ESRD): 1020 billable units per 28 days

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### 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

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### 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.

<b>Approval Body</b>	Pharmacy and Therapeutics Committee
<b>Original Effective Date</b>	July 26, 2022
<b>Version Date</b>	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