

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>IRON REPLACEMENT PRODUCTS INCLUDING FERUMOXYTOL (FERAHEME®) AND FERRIC CARBOXYMALTOSE INJECTION (INJECTAFER®)</b>
<b>POLICY NUMBER</b>	<b>MP-2.146</b>

<b>Original Issue Date (Created):</b>	<b>8/1/2010</b>
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**I. POLICY**

**Ferumoxytol (Feraheme®)**

Ferumoxytol (Feraheme®) may be considered **medically necessary** for the treatment of iron deficiency anemia in adult patients:

- who have chronic kidney disease (CKD); or
- who have intolerance to oral iron or have had unsatisfactory response to oral iron.

**Ferric Carboxymaltose Injection (Injectafer®)**

Ferric carboxymaltose injection (Injectafer®) may be considered **medically necessary** 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-dialysis-dependent chronic kidney disease.

*Cross-reference:*  
**MP-2.103** Off-Label Use of Medications

**II. PRODUCT VARIATIONS**

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

**Note for Medicare Advantage:**

FDA approved drugs used for indications other than what is indicated on the FDA approved product label may be covered under Medicare if it is determined that the use is medically

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accepted, taking into consideration the Medicare recognized national drug compendia, authoritative medical literature and/or accepted standards of medical practice.” Refer to Medicare Benefit Policy Manual (100-2, Chapter 15, Section 50.4.2- Unlabeled Use of Drug). <http://www.cms.gov/manuals/Downloads/bp102c15.pdf>

**III. DESCRIPTION/BACKGROUND**

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**Ferumoxytol (Feraheme®)**

Ferumoxytol (Feraheme®) is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD) and for adult patients with anemia who have intolerance to oral iron or have had unsatisfactory response to oral iron

Anemia is highly prevalent in the CKD population and is nearly universal in patients with CKD on hemodialysis. Iron deficiency is a common cause of anemia in CKD patients and may be the result of poor iron absorption, blood loss and increased erythropoiesis after use of erythropoiesis-stimulating agents (ESAs).

Ferumoxytol is an iron oxide nanoparticle with a polyglucose sorbitol carboxymethlether coating designed to minimize immunological sensitivity. The molecular weight of ferumoxytol is above the permeability cutoff of standard hemodialysis membranes; therefore, it is not removed from plasma dialysis and can be administered any time during hemodialysis.

See prescribing information for safety precautions, dosing and administration recommendations.

**Ferric Carboxymaltose Injection (Injectafer®)**

Ferric Carboxymaltose Injection (Injectafer®) is the first non-dextran IV iron approved for the treatment of adult patients with iron deficiency anemia (IDA) of various etiologies in addition to use in non-dialysis dependent CKD patients. See prescribing information for safety precautions, dosing and administration recommendations.

**IV. RATIONALE**

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For information of clinical studies for ferumoxytol (Feraheme®) and ferric carboxymaltose injection (Injectafer®), refer to the prescribing information.

**V. DEFINITIONS**

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**IRON DEFICIENCY ANEMIA-** The most common known form of nutritional disorder in the world, iron deficiency results in anemia because iron is necessary to make hemoglobin, key molecule in red blood cells responsible for the transport of oxygen. In iron deficiency anemia, the red cells appear abnormal and are unusually small (microcytic) and pale (hypochromic). The pallor of the red cells reflects their low hemoglobin content.

**CHRONIC KIDNEY DISEASE-** Chronic kidney disease (CKD), also known as chronic renal disease, is a progressive loss of renal function over a period of months or years. The symptoms of worsening kidney function are unspecific, and might include feeling generally unwell and experiencing a reduced appetite.

### VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

### VII. DISCLAIMER

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*Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

### VIII. CODING INFORMATION

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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**Ferumoxytol (Feraheme®) is covered when medically necessary:**

<b>HCPCS Code</b>	<b>Description</b>
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)

**The following diagnosis codes are considered medically necessary for Q0138 and Q0139:**

<b>ICD-10-CM Diagnosis Code</b>	<b>Description</b>
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.8	Other iron deficiency anemias
D50.9	Iron deficiency anemia, unspecified
D63.1	Anemia in chronic kidney disease
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
N18.1	Chronic kidney disease, stage 1
N18.2	Chronic kidney disease, stage 2 (mild)
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
N18.9	Chronic kidney disease, unspecified

**Ferric Carboxymaltose Injection (Injectafer®) is covered when medically necessary:**

<b>HCPCS Code</b>	<b>Description</b>
J1439	Injection, ferric carboxymaltose, 1 mg

**The following diagnosis codes are considered medically necessary for J1439:**

<b>ICD-10 Diagnosis Code</b>	<b>Description</b>
D50.0	Iron deficiency anemia secondary to blood loss (chronic)
D50.8	Other iron deficiency anemias

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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
N18.1	Chronic kidney disease, stage 1
N18.2	Chronic kidney disease, stage 2 (mild)
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.9	Chronic kidney disease, unspecified

**IX. REFERENCES**

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*Balakrishnan VS, Rao M, Kausz AT, et al. Physicochemical properties of ferumoxytol, a new intravenous iron preparation. Eur J Clin Invest. 2009;39(6):489-496.*

*Berns J. Treatment of iron deficiency in hemodialysis patients. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated Apr 11, 2018. Website]: [www.uptodate.com](http://www.uptodate.com). Accessed August 2, 2018.*

*Centers for Medicare and Medicaid Services (CMS) Medicare Benefit Policy Manual. Publication 100-02. Chapter 15. Section 50.4.2. Unlabeled Use of Drug. Effective 10/01/03. [Website]: <http://www.cms.gov/manuals/Downloads/bp102c15.pdf>. Accessed August 2, 2018.*

*Centers for Medicare and Medicaid Services (CMS) Medicare Benefit Policy Manual. Publication 100-02. Chapter 15. Sections 50, 50.4.1, 50.4.3. Drugs and Biologicals. Effective 10/01/03. [Website]: <http://www.cms.gov/manuals/Downloads/bp102c15.pdf>. Accessed August 2, 2018.*

*Centers for Medicare and Medicaid Services (CMS) Medicare Benefit Policy Manual. Publication 100-02. Chapter 15. Section 50.4.2. Unlabeled Use of Drug. Effective 10/01/03. [Website]: <http://www.cms.gov/manuals/Downloads/bp102c15.pdf>. Accessed August 2, 2018.*

*Ferumoxytol (Feraheme) prescribing information. Revised February 5, 2018. Feraheme [Website]: <http://www.feraheme.com/>. Accessed August 2, 2018.*

*Ferric Carboxymaltose Injection (Injectafer®) prescribing information. April 2018. [Website]: <http://www.injectafer.com/> Accessed August 2, 2018.*

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*Provenzano R, Schiller B, Rao M, Coyne D, Brenner L, Pereira BJJ. Ferumoxytol as an intravenous iron replacement therapy in hemodialysis patients. Clin J Am Soc Nephrol. 2009; 4(2):386-393.*

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**X. POLICY HISTORY**

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<b>MP 2.146</b>	<b>CAC 3-10-10</b> New policy. Medically necessary for the treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD). References added.
	<b>CAC 10-25-11</b> Consensus Review
	<b>CAC 10-30-12</b> Consensus review. References updated; no changes to policy statements. Codes reviewed 10/31/12
	<b>CAC 11/26/13</b> Consensus. No change to policy statements. References updated.
	<b>CAC 9/30/14</b> Minor revision. Policy title changed to: Iron Replacement Products Including ferumoxytol (Feraheme®) and ferric carboxymaltose injection (Injectafer®) to include new iron replacement drug Ferric carboxymaltose (Injectafer). Ferric carboxymaltose injection (Injectafer®) may be considered medically necessary 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-dialysis-dependent chronic kidney disease. Policy coding reviewed. Broke out codes.
	<b>CAC 9/29/15</b> Consensus review. No change to policy statements. References and rationale reviewed. Added Medicare variation to reference NCD 110.10 Intravenous Iron Therapy. Coding reviewed.
	<b>1/7/16 Admin correction.</b> Administrative coding correction only.
	<b>6/1/16</b> Administrative change. Removed Medicare variation referencing NCD 110.10. The NCD only addresses Venofer and Ferrlecit but not Feraheme and Injectafer.
	<b>CAC 11/29/16</b> Consensus review. No change to policy statements. References and rationale reviewed. Coding reviewed. Variation reformatting.
	<b>CAC 12/19/17</b> Consensus. No change to policy statements. References and rationale reviewed.

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	<b>6/1/18 Admin Correction.</b> Policy will apply to Commercial and Medicare Products effective 6/1/18. Corrected previous version posted 6/1/18.
	<b>8/2/18 Minor review.</b> Added a new indication for ferumoxytol (Feraheme®). For patients who have intolerance to oral iron or have had unsatisfactory response to oral iron. Coding revised.

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