RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	ferric carboxymaltose
Policy Number:	RxA.394
Drug(s) Applied:	Injectafer®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Ferric carboxymaltose (Injectafer®) injection is an iron replacement product indicated for treatment of iron deficiency anemia (IDA) in adult patients who have:

- Intolerance to oral iron or have had unsatisfactory response to oral iron; or
- Non-dialysis dependent chronic kidney disease (CKD).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Ferric Carboxymaltose (Injectafer®)	IDA with or without non-dialysis dependent CKD (adults)	≥ 50kg (110lb): two 750 mg doses separated by at least 7 days for a cumulative dose of 1500 mg per course. < 50kg (110lb): two doses separated by at least 7 days as 15 mg/kg body weight. Treatment may be repeated if iron deficiency anemia reoccurs	≥ 50kg (110lb):750 mg per dose Treatment course: up to 1500 mg. < 50kg (110lb): 15 mg/kg.

Dosage Forms

- Intravenous solution: 750 mg iron/15 mL single- dose vial

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Iron Deficiency Anemia with Chronic Kidney Disease (must meet all):

1. Diagnosis of IDA and CKD;
2. IDA is confirmed by either of the following:
   a. Transferrin saturation (TSAT) ≤ 30%;
   b. Serum ferritin ≤ 500 ng/mL;

3. If CKD does not require hemodialysis or peritoneal dialysis, oral iron therapy is not optimal due to any of the following: a. TSAT < 12%;
    a. Hgb < 7 g/dL;
    b. Symptomatic anemia;
    c. Severe or ongoing blood loss;
    d. Oral iron intolerance
    e. Unable to achieve therapeutic targets with oral iron;
    f. Co-existing condition that may be refractory to oral iron therapy;
4. Dose does not exceed 750 mg elemental iron per infusion/injection.

Approval duration
Commercial: 3 months
Medicaid: 3 months

B. Iron Deficiency Anemia without Chronic Kidney Disease (must meet all):

1. Diagnosis of IDA confirmed by any of the following:
    a. Serum ferritin < 15 ng/mL or < 30 ng/mL if pregnant;
    b. Serum ferritin ≤ 41 ng/mL and Hgb < 12 g/dL (women)/< 13 g/dL (men);
    c. TSAT < 20%;
    d. Absence of stainable iron in bone marrow;
    e. Increased soluble transferring receptor (sTfR) or sTfR-ferritin index;
    f. Increased erythrocyte protoporphyrin level;
2. Oral iron therapy is not optimal due to any of the following:
    a. TSAT < 12%;
    b. Hgb < 7 g/dL;
    c. Symptomatic anemia;
    d. Severe or ongoing blood loss;
    e. Oral iron intolerance;
    f. Unable to achieve therapeutic targets with oral iron;
    g. Co-existing condition that may be refractory to oral iron therapy;
3. At the time of the request, member does not have CKD;
4. Dose does not exceed 750 mg elemental iron per infusion/injection.

Approval duration
Commercial: 3 months
Medicaid: 3 months

II. Continued Approval Criteria

A. Iron Deficiency Anemia with Chronic Kidney Disease (must meet all):

1. Currently receiving the medication that has been authorized by RxAdvance or member has previously met all initial approval criteria listed in this policy;
2. Documentation of one of the following laboratory results measured since the last IV iron administration:
    a. TSAT ≤ 30%;
    b. Serum ferritin ≤ 500 ng/mL;
3. If request is for a dose increase, new dose not exceed 750 mg elemental iron per infusion/injection.

Approval duration
Commercial: 3 months
Medicaid: 3 months

B. B. Iron Deficiency Anemia without Chronic Kidney Disease (must meet all):

2. Currently receiving the medication that has been authorized by RxAdvance or member has previously met all initial approval criteria listed in this policy;
3. Documentation of one of the following laboratory results measured since the last IV iron administration:
   a. Serum ferritin < 15 ng/mL or < 30 ng/mL if pregnant;
   b. Serum ferritin ≤ 41 ng/mL and Hb < 12 g/dL (women)/< 13 g/dL (men);
   c. TSAT < 20%;
   d. Absence of stainable iron in bone marrow;
   e. Increased sTfR or sTfR-ferritin index;
   f. Increased erythrocyte protoporphyrin level;
4. At the time of the request, member does not have CKD;
5. If request is for a dose increase, new dose does not exceed 750 mg elemental iron per infusion/injection.

Approval duration
Commercial: 3 months
Medicaid: 3 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CKD: chronic kidney disease
ESA: erythropoiesis stimulating agent
Hb: hemoglobin
IDA: iron deficiency anemia
sTfR: soluble transferring receptor
TSAT: transferrin saturation

APPENDIX B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of OTC Oral Iron Formulations*		
Ferrous fumarate (Ferretts, Ferrimin 150, Hemocyte)	Varies	
Ferrous gluconate (Ferate)		
Ferrous sulfate (BProtected Pedia Iron, Fer-In-Sol, FeroSul, FerrouSul, Iron Supplement Childrens, Slow Fe, Slow Iron)		
Polysaccharide-iron complex (EZFE 200, Ferrex 150, Ferrix x150, Myferon 150, NovaFerrum 125, NovaFerrum 50, NovaFerrum Pediatric Drops, Nu-Iron, Poly-Iron 150)		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
*Oral formulations include elixirs, liquids, solutions, syrups, capsules, and tablets - including delayed/extended-release tablets.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity to Injectafer or any of its inactive components

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information
Not Applicable

References

1. Injectafer prescribing information. Shirley, NY: American Regent, Inc.; February 2020. Available from https://injectafer.com/. Accessed July 14, 2020.
2. KDIGO 2012 clinical practice guideline for evaluation and management of chronic kidney disease. *Kidney International Supplements.* January 2013; 3(1): 1-136.
3. KDIGO 2012 clinical practice guideline for anemia in chronic kidney disease. *Kidney International Supplements.* August 2012; 2(4): 279-331.
4. Camaschella C. Iron-Deficiency Anemia. *N Engl J Med.* 2015; 372: 1832-43. DOI: 10.1056/NEJMra1401038.
5. Short MW, Domagalski JE. Iron Deficiency Anemia: Evaluation and Management. *Am Fam Physician.* 2013; 87(2): 98-104. http://www.aafp.org/afp/2013/0115/p98.pdf
6. Oral iron monographs. In: UpToDate (Lexicomp), Waltham, MA: Walters Kluwer Health; 2018. Available at www.uptodate.com. Accessed July 14, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was updated. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Commercial approval duration and Medicaid approval duration updated. 6. Updated Dosing Information to specify maximum dose and included “Treatment may be repeated if iron deficiency anemia reoccurs” 7. Updated dosage form to “Intravenous solution: 750 mg iron/15 mL single- dose vial” 8. References were updated.	07/14/2020	09/14/2020