Clinical Policy: Ferric Carboxymaltose (Injectafer)

Reference Number: PA.CP.PHAR.234
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for ferric carboxymaltose (Injectafer®).

FDA Approved Indication(s)
Injectafer is 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
- Nondialysis-dependent chronic kidney disease (CKD).

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Injectafer is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of iron deficiency anemia (IDA) and chronic kidney disease (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%;
   b. Hemoglobin (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.
4. Dose does not exceed 750 mg elemental iron per infusion/injection.

Approval duration: 3 months

B. Iron Deficiency Anemia not associated with 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.
   a.

Approval duration 3 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval Criteria

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

1. Currently receiving the medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Either of the following measured ≥ 4 weeks after 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.
   a.

Approval duration 3 months

B. Iron Deficiency Anemia not associated with Chronic Kidney Disease (must meet all):

1. Currently receiving the medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Any of the following measured ≥ 4 weeks after last IV iron administration:
   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 sTfR or sTfR-ferritin index;
   f. Increased erythrocyte protoporphyrin level;
3. At the time of the request, member does not have CKD;
4. If request is for a dose increase, new dose does not exceed 750 mg elemental iron per infusion/injection.
   a.

Approval duration 3 months

A. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53**.**

Background

Description/Mechanism of Action:

Injectafer is a non-dextran IV iron product containing the active ingredient ferric carboxymaltose (an iron carbohydrate complex) that functions as iron replacement.

Formulations:

Intravenous solution:

Injectafer: 750 mg/15 mL (15 mL)

Appendices

Appendix A: Abbreviation Key

CKD: chronic kidney disease
ESA: erythropoiesis stimulating agent
Hgb: hemoglobin
IDA: iron deficiency anemia
TIBC: total iron-binding capacity
TSAT: transferrin saturation
sTfR: soluble transferring receptor

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1439	Injection, ferric carboxymaltose, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Dosing added. References reviewed and updated.	02/18	

References

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