SmartHealth Ascension

Ferric carboxymaltose

(Injectafer®) J1439 (1mg)

Covered with prior authorization

Ferric carboxymaltose (Injectafer®) may be authorized when the following criteria are met:

- Individual has a diagnosis of chronic kidney disease (CKD); **AND**
    - Individual is dialysis dependent; **AND**
    - Individual has iron deficiency anemia (IDA);

OR

- Individual has a diagnosis of iron deficiency anemia (IDA); **AND**
    - Individual is non-dialysis dependent; **AND**
    - Diagnosis is confirmed by one of the following:
        - For IDA associated with CKD or inflammatory conditions (for example, inflammatory bowel disease [IBD], heart failure), individual meets one of the following within the last four (4) weeks:
            - Serum ferritin levels less than 100 ng/mL; **OR**
            - TSAT levels less than 20%; **OR**
            - Serum ferritin is less than or equal to 500 ng/mL and TSAT is less than or equal to 30%; **OR**
            - Bone marrow demonstrates inadequate iron stores; **OR**
        - For IDA associated with cancer/chemotherapy or non-inflammatory conditions (for example, blood loss, malabsorption, malnutrition), individual meets one of the following within the last four (4) weeks:
            - Serum ferritin levels less than 30 ng/mL; **OR**
            - TSAT levels less than 20%; **OR**
            - Bone marrow demonstrates inadequate iron stores;

AND

- Individual has had a four (4) week trial of and inadequate response, or intolerance to oral iron supplementation;

AND

- Requests for a non-preferred iron deficiency anemia agent Injectafer (ferric carboxymaltose) or Monoferric (ferric derisomaltose), **must also meet following criteria:**
    - Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to two (2) preferred agents; **OR**
    - The preferred agent(s) are not acceptable due to concomitant clinical conditions, including but not limited to known hypersensitivity to any active or inactive component which is not also associated with the requested non-preferred agent; **OR**
    - Individual is dialysis-dependent and using iron in conjunction with dialysis;

AND

- For patients weighing 50 kg or more, the recommended dosage is Injectafer 750 mg intravenously in two doses separated by at least 7 days for a total cumulative dose of 1,500 mg of iron per course; **OR**
- For adult patients weighing 50 kg or more, an alternative dose of Injectafer 15 mg/kg to a maximum of 1,000 mg may be administered as a single-dose treatment course; **OR**
- For patients weighing less than 50 kg, the recommended dosage is Injectafer 15 mg/kg body weight intravenously in two doses separated by at least 7 days per course.

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Step/Alternative Therapies:

Preferred Product(s) [No PA Required]	**Non-Preferred Product(s) [PA Required]**
Feraheme® (ferumoxytol) Q0138, Q0139	Injectafer®(ferric carboxymaltose) J1439
Ferrlecit® (sodium ferric gluconate/sucrose complex) J2916	Monoferric® (ferric derisomaltose) J1437
Infed®(iron dextran) J1750	
Venofer® (iron sucrose) J1756	
Triferic, Triferic AVNU® (ferric pyrophosphate citrate) J1443, J1444, J1445	

Initial authorization is up to 3 months. Dialysis dependent use authorization 12 months.
Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Clinical documentation provided must be from within the most recent 12 months.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.
Injectafer is an iron replacement product indicated for the treatment of iron deficiency anemia (IDA) in:

- Adults and pediatric patients 1 year of age and older who have either intolerance to oral iron or an unsatisfactory response to oral iron.
- Adult patients who have non-dialysis dependent chronic kidney disease.

References:

De Franceschi L, Iolascon A, Taher A, Cappellini MD. Clinical management of iron deficiency anemia in adults: Systemic review on advances in diagnosis and treatment. Eur J Intern Med. 2017;42:16–23.
Iron-Deficiency Anemia. National Heart, Lung, and Blood Institute (NHLBI). 2019. Available at https://www.nhlbi.nih.gov/healthtopics/iron-deficiency-anemia. Accessed on July 14, 2021.
Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney Inter. 2012; Suppl 2: 279–335. Available from: https://www.kidney.org/professionals/guidelines/guidelines_commentaries/anemia.
NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Hematopoietic Growth Factors. V4.2021. Revised May 20, 2021.
Peyrin-Biroulet L, Williet N, Cacoub P. Guidelines on the diagnosis and treatment of iron deficiency across indications: a systematic review. Am J Clin Nutr. 2015;102(6):1585–1594.
Injectafer (ferric carboxymaltose) label. (2021, April). Accessdata.fda.gov. Retrieved June 15, 2022 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/203565s014lbl.pdf.

Criteria History/ Revision Information:

Date	Summary of Changes
November 2021	IV Iron SBAR approved by Ascension Therapeutic Affinity Group
June 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
July 2022	Criteria for use summary approved by Ascension Ambulatory Care Expert Review Panel
July 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.