PRIOR AUTHORIZATION (PA) CHECKLIST

injectafer® ferric carboxymaltose injection

Insurers may require a PA as part of a claim submission. The following checklist can serve as a guide to help complete a PA.

IMPORTANT NOTE: Use of this resource does not guarantee that the insurance company will provide reimbursement for the medicine requested and is not intended to be a substitute for, or an influence on, the independent medical judgment of the healthcare provider. This is only a guide and is not to be taken as a specific recommendation.

PA forms may vary. As you prepare to submit the PA, your AR Assist® Coordinator can provide support.

Information to gather for PA submission

Patient information

- Name
- Demographics
- Contact information
- Insurance plan
  - Member ID
  - Policy number
  - Group number
  - Phone/fax number

Provider information

- Name
- National Provider Identifier (NPI)
- Contact information

Clinical documentation

- Summary of patient's diagnosis, in addition to any underlying conditions and comorbidities
- Duration of any prior treatment(s) and response(s)
- Demonstrated intolerance to or contraindication for possible alternatives, if applicable
- Current laboratory reports (eg, current hemoglobin level, iron deficiency over time)
- Specialist attestation or other rationale for prescribing Injectafer
- Relevant diagnosis, procedure, and place of service codes

Click here for product, billing, and administration codes associated with Injectafer use.

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INDICATIONS

Injectafer® (ferric carboxymaltose injection) is indicated for the treatment of iron deficiency anemia (IDA) in adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron, and in adult patients who have non-dialysis-dependent chronic kidney disease. Injectafer is also indicated for iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: SYMPTOMATIC HYPOPHOSPHATEMIA

- **INJECTAFER can cause severe, prolonged hypophosphatemia associated with serious outcomes, including hospitalization, osteomalacia, and fractures requiring clinical intervention.**
- **Hypophosphatemia has occurred in patients with normal baseline phosphate levels and without apparent risk factors for hypophosphatemia.**
- **Check serum phosphate levels prior to a repeat course of treatment in patients at risk for low serum phosphate and in any patient who receives a repeat course of therapy within three months. Correct pre-existing hypophosphatemia prior to administering INJECTAFER.**
- **Advise patients receiving INJECTAFER about the risk of hypophosphatemia and to report any signs and symptoms of hypophosphatemia (e.g., fatigue, muscle weakness or pain, bone and joint pain, bone fractures).**

Please see additional Important Safety Information, including BOXED WARNING, and accompanying Full Prescribing Information.

Information to gather for PA submission (cont'd)

Additional resources to consider

Peer-reviewed resources to support the medical rationale, such as:

- Clinical studies, real-world evidence, or health economics research demonstrating clinical outcomes
- Compendia, evidence-based guidelines, and pathways
  - Drug compendia are defined as summaries of drug information that are compiled by experts who have reviewed clinical data on drugs[1]
  - CMS-recognized compendia may include AHFS DI, NCCN, USP DI, American Medical Association Drug Evaluations, DrugPoints, and DrugDex[1]

A peer-to-peer medical review may be requested in the event of a claim denial or policy restrictions.

If you want to learn more, visit AR-Assist.com to download the Injectafer® (ferric carboxymaltose injection) Peer-to-Peer Review Checklist.

Helping your patients access Injectafer

AR Assist® is committed to helping your patients access Injectafer. Your AR Assist Coordinators are able to provide:

- Information about financial assistance for eligible patients
- Coding and billing support
- Benefits verification and information on navigating the PA process
- Status updates for you and your patient throughout the process

Visit AR-Assist or call an AR Assist Coordinator at 1-877-448-4766 to help enroll eligible patients.

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

INJECTAFER is contraindicated in patients with hypersensitivity to INJECTAFER or any of its inactive components.

WARNINGS AND PRECAUTIONS

Symptomatic Hypophosphatemia

Symptomatic hypophosphatemia, including severe cases, with serious outcomes such as osteomalacia and fractures requiring clinical intervention have occurred in patients treated with INJECTAFER in the post-marketing setting. These cases have occurred after single and multiple doses of INJECTAFER. Risk factors for hypophosphatemia include a history of gastrointestinal disorders associated with malabsorption of fat-soluble vitamins or phosphate, inflammatory bowel disease, concurrent or prior use of medications that affect proximal renal tubular function, hyperparathyroidism, vitamin D deficiency, malnutrition, and hereditary hemorrhagic telangiectasia (HHT or Osler-Weber-Rendu syndrome). However, individuals without apparent risk factors have experienced symptomatic hypophosphatemia. In most cases, hypophosphatemia resolved within three months.

Check serum phosphate levels prior to a repeat course of treatment if the patient is at risk for low serum phosphate or if the patient will receive a repeat course of therapy within three months of the prior course. Correct pre-existing hypophosphatemia prior to administering INJECTAFER. Monitor serum phosphate levels in patients at risk for chronic low serum phosphate. Treat hypophosphatemia as medically indicated.

Consider permanent discontinuation of INJECTAFER for severe symptomatic hypophosphatemia or persistent hypophosphatemia.

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Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving INJECTAFER. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after INJECTAFER administration for at least 30 minutes and until clinically stable following completion of the infusion. Only administer INJECTAFER when personnel and therapies are immediately available for the treatment of serious hypersensitivity reactions. In clinical trials, serious anaphylactic/anaphylactoid reactions were reported in 0.1% (2/1775) of subjects receiving INJECTAFER. Other serious or severe adverse reactions potentially associated with hypersensitivity which included, but were not limited to, pruritus, rash, urticaria, wheezing, or hypotension were reported in 1.5% (26/1775) ofthese subjects.

Hypertension

In clinical studies, hypertension was reported in 4% (67/1775) of subjects in clinical trials 1 and 2. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/1775) of subjects in these two clinical trials. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each INJECTAFER administration.

Laboratory Test Alterations

In the 24 hours following administration of INJECTAFER, laboratory assays may overestimate serum iron and transferrin bound iron by also measuring the iron in INJECTAFER.

ADVERSE REACTIONS

The most common adverse reactions in adult patients (>2%) are nausea, hypertension, flushing, injection site reactions, erythema, hypophosphatemia, and dizziness.

The most common adverse reactions in pediatric patients (≥4%) are hypophosphatemia, injection site reactions, rash, headache, and vomiting.

Post-Marketing Experience

Adverse reactions have been identified during post approval use of INJECTAFER. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions have been reported from the post-marketing spontaneous reports with INJECTAFER: *cardiac disorders*: tachycardia; *general disorders and administration site conditions*: chest discomfort, chills, pyrexia; *metabolism and nutrition disorders*: hypophosphatemia; *musculoskeletal and connective tissue disorders*: arthralgia, back pain, hypophosphatemic osteomalacia; *nervous system disorders*: syncope; *respiratory, thoracic, and mediastinal disorders*: dyspnea; *skin and subcutaneous tissue disorders*: angioedema, erythema, pruritus, urticaria; *pregnancy*: fetal bradycardia.

USE IN SPECIFIC POPULATIONS

Pregnancy – *Fetal/Neonatal Adverse Reactions*

Severe adverse reactions including circulatory failure (severe hypotension, shock including inthe context of anaphylactic reaction) may occur in pregnant women with parenteral iron products (such as INJECTAFER), which may cause fetal bradycardia, especially during the second and third trimester.

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You are encouraged to report Adverse Drug Events to American Regent, Inc.® at 1-800-734-9236 or to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

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Please see Full Prescribing Information, including BOXED WARNING.

AHFS DI=American Hospital Formulary Service Drug Information; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; ID=iron deficiency; IDA=iron deficiency anemia; NCCN=National Comprehensive Cancer Network; NPI=National Provider Identifier; USP DI=United States Pharmacopeia Drug Information.

Reference: 1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394). Original Effective Date: October 1, 2015. Revision Effective Date: July 13, 2025. Accessed March 25, 2026. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33394

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