

PRIOR AUTHORIZATION CHECKLIST



Insurers may require a prior authorization (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
- 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.](#)

Continued on following page

HF=heart failure; ID=iron deficiency; IDA=iron deficiency anemia; NPI=National Provider Identifier.

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

CONTRAINDICATIONS

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

Please see additional Important Safety Information on pages 3 and 4 and [click here for 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 drugs¹
 - CMS-recognized compendia may include AHFS DI, NCCN, USP DI, American Medical Association Drug Evaluations, DrugPoints, and DRUGDEX¹

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](https://AR-Assist.com) or call an AR Assist Coordinator at 1-877-448-4766 to help enroll eligible patients.

SELECT IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS

Symptomatic Hypophosphatemia

Symptomatic hypophosphatemia with serious outcomes including osteomalacia and fractures requiring clinical intervention has been reported in patients treated with Injectafer in the post-marketing setting. These cases have occurred mostly after repeated exposure to Injectafer in patients with no reported history of renal impairment. However, symptomatic hypophosphatemia has been reported after one dose. Possible 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). In most cases, hypophosphatemia resolved within three months.

Please see additional Important Safety Information on pages 3 and 4 and [click here](#) for Full Prescribing Information.



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Correct pre-existing hypophosphatemia prior to initiating therapy with Injectafer. Monitor serum phosphate levels in patients at risk for chronic low serum phosphate. 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 second course of therapy within three months. Treat hypophosphatemia as medically indicated.

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) of these 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

Adults

In two randomized clinical studies [Studies 1 and 2], a total of 1775 patients were exposed to Injectafer, 15 mg/kg of body weight, up to a maximum single dose of 750 mg of iron on two occasions, separated by at least 7 days, up to a cumulative dose of 1500 mg of iron. Adverse reactions reported by >2% of Injectafer-treated patients were nausea (7.2%), hypertension (4%), flushing (4%), injection site reactions (3%), erythema (3%), hypophosphatemia (2.1%), and dizziness (2.1%).

Pediatric

The safety of Injectafer in pediatric patients was evaluated in Study 3. Study 3 was a randomized, active-controlled study in which 40 patients (1 to 12 years of age: 10 patients, 12 to 17 years of age: 30 patients) received Injectafer 15 mg/kg to a maximum single dose of 750 mg (whichever was smaller) on Days 0 and 7 for a maximum total dose of 1500 mg; 38 patients evaluable for safety in the control arm received an age-dependent formulation of oral ferrous sulfate for 28 days. The median age of patients who received Injectafer was 14.5 years (range, 1-17); 83% were female; 88% White and 13% Black. The most common adverse reactions ($\geq 4\%$) were hypophosphatemia (13%), injection site reactions (8%), rash (8%), headache (5%), and vomiting (5%).

Patients With Iron Deficiency and Heart Failure

The safety of Injectafer was evaluated in adult patients with iron deficiency and heart failure in randomized controlled trials FAIR-HF (NCT00520780), CONFIRM-HF (NCT01453608), and AFFIRM-AHF (NCT02937454) in which 1016 patients received Injectafer versus 857 received placebo. The overall safety profile of Injectafer was consistent across the studied indications.

Continued on following page

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

Post-Marketing Experience

The following 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 in the 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 [click here](#) for Full Prescribing Information.

AHFS DI=American Hospital Formulary Service Drug Information; ICD-10-CM=International Classification of Diseases, Tenth Revision; 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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