

PEER-TO-PEER REVIEW CHECKLIST



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 a guide and is not to be taken as a specific recommendation.

If you are preparing for a peer-to-peer review, it is most likely that you are engaging in either an insurer's exception process or an appeal process. These processes are often different from a prior authorization (PA):

Prior Authorization is typically a communication intended to show that the company's policy or formulary has been followed and that, consistent with that policy, the desired treatment is appropriate and should be authorized.

Exception Request is usually a request to go outside of the insurer's policy due to medical necessity and the specific needs of a patient, which the existing policy does not adequately meet. In some cases, insurers use the same form and terminology for an exception request as for a PA.

Appeal Request is generally a request for an insurer to reconsider a decision which it has already made to not cover a therapy.

It may be helpful to know which of these processes you are in prior to a peer-to-peer discussion so that you can best prepare. A successful exception or appeal is often built on clear, documented evidence of medical necessity—this checklist may help organize your information. Specific documentation varies between payers.

NOTE: It is recommended that peer-to-peer attestation be completed by the prescribing clinician (eg, physician, PA, NP) who is treating the Injectafer patient for approved indications: iron deficiency (ID) in certain heart failure (HF) patients or iron deficiency anemia (IDA). Additionally, this prescribing clinician may request that the insurer's peer reviewer be of the same specialty (eg, hematology, oncology).



Information to gather ahead of time



Patient and insurance information

- Name and date of birth of:
 - Patient
 - Primary insurance policy holder



Previous claim information, if applicable

- Date of service for Injectafer therapy
- Explanation of why the first request was denied

Have you already initiated an appeal? If so, be prepared with the details of the appeal.

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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

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 ahead of time (cont'd)



Clinical documentation

- Summary of patient's diagnosis, which can include comorbidities, underlying condition/etiology of iron deficiency (ID) in heart failure (HF) or iron deficiency anemia (IDA), and/or medical justification for prescribing Injectafer®
- Details as to why the product you selected is medically necessary for your patient
- Any prior treatments and duration of therapy, including:
 - Adverse events
 - Outcome of therapy
- Primary (ID/IDA-related) and secondary (underlying condition) diagnoses, including ICD-10-CM codes
- Any additional patient-specific characteristics or medical records supporting the diagnosis and/or treatment

Health plans may require additional clinical documentation for the use of Injectafer. Please contact your AR Assist® Coordinator if you need support.



Drug information

- Indications statement per the Full Prescribing Information

[Click here](#) for product, billing, and administration codes associated with Injectafer use.



Additional resources to consider



Relevant publications/data

- Clinical studies, real-world evidence, and other peer-reviewed publications relevant to optimizing clinical and economic outcomes
- Data/literature supporting Injectafer efficacy and safety in a subpopulation representative of this patient (eg, characteristics of ID/deficit, etiology of IDA, comorbidities, etc.)
- Evidence-based guidelines and pathways



Supporting Letter(s) of Medical Necessity from specialists

[Click here](#) for template letters



Compendia

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 include AHFS DI, NCCN, USP DI, American Medical Association Drug Evaluations, DrugPoints, and DRUGEX.¹



For case-specific questions or additional information, call an AR Assist Coordinator at 1-877-448-4766

IMPORTANT SAFETY INFORMATION

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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.

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.

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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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