PRIOR AUTHORIZATION CHECKLIST

injectafer® ferric carboxymaltose injection

Insurers may require a prior authorization (PA) as part of a claim submission. The following checklist can serve as a guide to completing a PA.

IMPORTANT NOTE: Use of the 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.

PA forms may vary. As you prepare to submit the PA, your local Associate Director, Field Reimbursement (ADFR) or a Daiichi Sankyo Access Central Coordinator can provide information and considerations.

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 IDA or ID in HF diagnosis, in addition to any underlying conditions and comorbidities
- Duration of any prior treatment(s) for IDA or ID in HF 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

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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

Please see Important Safety Information on pages 3 and 4 and click here for full Prescribing Information for Injectafer.

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 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 DSIAccessCentral.com to download the Injectafer Peer-to-Peer Review Checklist.

Helping your patients access Injectafer

Daiichi Sankyo Access Central is committed to helping your patients. Your local ADFR and Daiichi Sankyo Access Central Coordinators are able to provide:

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

Visit DSIAccessCentral.com or call a Daiichi Sankyo Access Central Coordinator at 1-866-4-DSI-NOW (1-866-437-4669) to enroll eligible patients.

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, and malnutrition. In most cases, hypophosphatemia resolved within three months.

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Indications and Important Safety 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 (≥4%) were hypophosphatemia (13%), injection site reactions (8%), rash (8%), headache (5%), and vomiting (5%).

Continued on following page

Please click here for full Prescribing Information for Injectafer.

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Important Safety Information (*cont'd*)

ADVERSE REACTIONS (*cont'd*)

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.

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.

CLINICAL CONSIDERATIONS IN PREGNANCY

Untreated IDA in pregnancy is associated with adverse maternal outcomes such as postpartum anemia. Adverse pregnancy outcomes associated with IDA include increased risk for preterm delivery and low birth weight.

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.

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.

Please click here for full Prescribing Information for Injectafer.

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. Gain a solid understanding of compendia and its impact on patient access. Formulary watch. Published July 1, 2012. Accessed February 14, 2024. https://www.formularywatch.com/view/gain-solid-understanding-compendia-and-its-impact-patient-access

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