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 health care 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 Field Reimbursement Manager (FRM) 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 diagnosis, in addition to any underlying conditions and comorbidities
- Duration of any prior IDA 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

INDICATION

Injectafer® (ferric carboxymaltose injection) is indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, or who have non-dialysis dependent chronic kidney disease.

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 page 3 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 FRM 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 requiring clinical intervention has been reported in patients at risk of low serum phosphate in the postmarketing setting. These cases have occurred mostly after repeated exposure to Injectafer in patients with no reported history of renal impairment. Possible risk factors for hypophosphatemia include a history of gastrointestinal disorders associated with malabsorption of fat-soluble vitamins or phosphate, 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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Monitor serum phosphate levels in patients at risk for low serum phosphate who require a repeat course of treatment.

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.

In clinical studies, hypertension was reported in 3.8% (67/1775) of subjects. Transient elevations in systolic blood pressure, sometimes occurring with facial flushing, dizziness, or nausea were observed in 6% (106/1775) of subjects. These elevations generally occurred immediately after dosing and resolved within 30 minutes. Monitor patients for signs and symptoms of hypertension following each Injectafer administration.

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

In two randomized clinical studies, a total of 1775 patients were exposed to Injectafer, 15 mg/kg of body weight, up to a single maximum 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 (3.8%); flushing/hot flush (3.6%); blood phosphorus decrease (2.1%); and dizziness (2.0%).

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 (rarely reported event); *nervous system disorders:* syncope; *respiratory, thoracic and mediastinal disorders*: dyspnea; *skin and subcutaneous tissue disorders*: angioedema, erythema, pruritus, urticaria.

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.

Abbreviations: AHFS DI, American Hospital Formulary Service Drug Information; ICD-10-CM, International Classification of Diseases, Tenth Revision; 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 August 17, 2020. https://www.formularywatch.com/view/gain-solid-understanding-compendia-and-its-impact-patient-access

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