INJECTAFER® (ferric carboxymaltose)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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INJECTAFER (ferric carboxymaltose) (cont.)

Description:

Injectafer is a high dose iron replacement infusion indicated for the treatment of iron deficiency anemia in adults who have intolerance to oral iron or have had an unsatisfactory response to oral iron. Injectafer is also indicated for iron deficiency anemia in adults with non-dialysis dependent chronic kidney disease (NDD-CKD).

Definitions:

Adult: Age 18 years and older

Criteria:

See Resources section for FDA-approved dosage.

- FDA-approved dosage of Injectafer is considered *medically necessary* for adults with documentation of *ANY* of the following:
  1. Absence of hypersensitivity to Injectafer or any of its components
  2. Intolerance to oral iron or have had unsatisfactory response to oral iron
  3. Non–dialysis-dependent chronic kidney disease

- Injectafer for all other indications not previously listed or if above criteria not met is considered *experimental or investigational* based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.
INJECTAFER (ferric carboxymaltose) (cont.)

Resources:

Literature reviewed 10/11/16. We do not include marketing materials, poster boards and non-published literature in our review.

Injectafer Package Insert.

- FDA-approved indication and dosage:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
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<tbody>
<tr>
<td>An iron replacement product indicated for the treatment of iron deficiency anemia in adult patients who have intolerance to or an unsatisfactory response to oral iron or who have non-dialysis-dependent chronic kidney disease</td>
<td>For patients weighing 50 kg (110 lbs.) or more: Give Injectafer in two doses separated by at least 7 days. Give each dose as 750 mg for a total cumulative dose not to exceed 1500 mg of iron per course.</td>
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<tr>
<td>For patients weighing less than 50 kg (110lbs.): Give Injectafer in two doses separated by at least 7 days. Give each dose as 15 mg/kg body weight for a total cumulative dose not to exceed 1500 mg of iron per course.</td>
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<tr>
<td>The dosage of Injectafer is expressed in mg of elemental iron. Each mL of Injectafer contains 50 mg of elemental iron. Injectafer treatment may be repeated if iron deficiency anemia reoccurs.</td>
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<tr>
<td>Administer Injectafer intravenously, either as an undiluted slow intravenous push or by infusion. When administering as a slow intravenous push, give at the rate of approximately 100 mg (2mL) per minute. When administered via infusion, dilute up to 750 mg of iron in no more than 250 mL of sterile 0.9% sodium chloride injection, USP, such that the concentration of the infusion is not less than 2 mg of iron per mL and administer over at least 15 minutes.</td>
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<tr>
<td>When added to an infusion bag containing 0.9% sodium chloride injection, USP, at concentrations ranging from 2 mg to 4 mg of iron per mL, Injectafer solution is physically and chemically stable for 72 hours when stored at room temperature. To maintain stability, do not dilute to concentrations less than 2 mg iron/ml.</td>
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<td>Safety and effectiveness of Injectafer have not been established in pediatric patients.</td>
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