Medical Department Procedure Manual

Section: Chapter 7A Prescription Medications Prior Authorization   Number: 07.003

Title: ferric carboxymaltose (Injectafer®)   Page 1 of 4

Approval: Robert Bonnell, M.D., Med. Dir.   DATES - Origination: 01/29/14
Responsible Party: CPM Director   Revised: 11/18/15   Effective: 04/08/14
Distribution: Medical Department   P&T Review: 11/18/15   Annual Review: 11/18/15

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department:

   1.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, updated and/or revised, or archived.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.
Background Information, continued:

**Medication Summary**

- Iron deficiency anemia occurs when the body does not have enough iron. The body uses iron to make hemoglobin, which carries oxygen throughout the body.

- There are many causes of iron deficiency anemia including, but not limited to: heavy menstrual bleeding; lack of iron in food intake; bleeding caused by ulcers, hemorrhoids, or cancer; celiac disease or removal of part of the stomach or small intestine.

- Iron deficiency anemia can be treated by oral iron products (many products) or by intravenous infused iron products (iron sucrose [Venofer], iron dextran [dexferrum {Infed}], or ferric carboxymaltose [Injectafer]).

**Coverage Guidelines**

- Member must be eligible and have applicable benefits.

- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

**Additional Information**

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.

- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.
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Procedure:

1.0 Request for initial therapy with ferric carboxymaltose (Injectafer®) for iron deficiency anemia requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

1.1 Member has been diagnosed with iron deficiency anemia;

1.2 Member has laboratory documented iron deficiency defined as ONE of the following:
   1.2.1 Measures ferritin level is less than 15 mcg/L OR
   1.2.2 Measured serum iron level AND transferrin saturation level are below the laboratory’s lower limit of normal AND measured total iron-binding capacity is above the laboratory’s upper limit of normal

1.3 Member has had inadequate response or intolerance to oral iron products;

1.4 Member has had inadequate response or intolerance to either Venofer or dexferrum (Infed);

1.5 If criteria are met, request may be approved for two (2) doses of Injectafer 750 mg maximum at least seven (7) days apart.

2.0 Request for continuation therapy with ferric carboxymaltose (Injectafer®) for iron deficiency anemia requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

2.1 Member met initiation criteria; and

2.2 Member had positive response to previous treatment.
References:
