

Prior Authorization DRUG Guidelines

INFeD® (iron dextran)

Effective Date: 10/23/12

Date Developed: 10/15/12 by Albert Reeves MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20

INFeD® is a Hematinic .

Pre-Authorization Criteria:

VCHCP will authorize **INFeD®** for FDA approved treatment of iron deficiency in patients in whom oral administration is infeasible or ineffective.

Use-Unlabeled Cancer-/chemotherapy-associated anemia.

Dosing: Adult

Iron-deficiency anemia: I.M. (INFeD®), I.V., INFeD®):

$$\text{Dose (mL)} = 0.0442 (\text{desired Hgb} - \text{observed Hgb}) \times \text{LBW} + (0.26 \times \text{LBW})$$

Desired hemoglobin: Usually 14.8 g/dL

LBW = Lean body weight in kg

Iron replacement therapy for blood loss: (INFeD®), I.V. (INFeD®):

$$\text{Replacement iron (mg)} = \text{blood loss (mL)} \times \text{Hct}$$

Maximum daily dosage: Manufacturer's labeling: **Note:** Replacement of larger estimated iron deficits may be achieved by serial administration of smaller incremental dosages. Daily dosages should be limited to 100 mg iron (2 mL)

Total dose infusion (unlabeled): The entire dose (estimated iron deficit) may be diluted and administered as a one-time I.V. infusion.

Cancer-/chemotherapy-associated anemia (NCCN guidelines v.2.2010)

(unlabeled use): I.V.: Test dose: 25 mg slow I.V. slow push, followed 1 hour later by 100 mg over 5 minutes; larger doses (unlabeled), up to total dose infusion (over several hours) may be administered. Low-molecular-weight iron dextran preferred.

Dosing: Pediatric

Iron-deficiency anemia: I.M. (INFeD®), I.V. INFeD®):

Children 5-15 kg: Should not normally be given in the first 4 months of life:

$$\text{Dose (mL)} = 0.0442 (\text{desired Hgb} - \text{observed Hgb}) \times W + (0.26 \times W)$$

Desired hemoglobin: Usually 12 g/dL

W = Total body weight in kg

Children >15 kg: Refer to adult dosing.

Iron replacement therapy for blood loss: Refer to adult dosing.

Maximum daily dose:

Children <5 kg: 25 mg iron (0.5 mL)

Children 5-10 kg: 50 mg iron (1 mL)

Children ≥10 kg: Refer to adult dosing.

DOSAGE FORMS AND STRENGTHS

Injection, solution:

INFeD®: Elemental iron 50 mg/mL (2 mL) [low-molecular-weight iron dextran]

ADMINISTRATION:

I.M. (INFeD®): Use Z-track technique (displacement of the skin laterally prior to injection); injection should be deep into the upper outer quadrant of buttock; alternate buttocks with subsequent injections. Administer test dose at same recommended site using the same technique.

I.V.: Test dose should be given gradually over at least 30 seconds (INFeD®). Subsequent dose(s) may be administered by I.V. bolus undiluted at a rate not to exceed 50 mg/minute or diluted in 250-1000 mL NS and infused over 1-6 hours (initial 25 mL should be given slowly and patient should be observed for allergic reactions); avoid dilutions with dextrose (increased incidence of local pain and phlebitis)

Warnings/Precautions

Concerns related to adverse effects:

- Delayed reaction: Delayed (1-2 days) infusion reaction (including arthralgia, back pain, chills, dizziness, and fever) may occur with large doses (eg, total dose infusion) of I.V. iron dextran; usually subsides within 3-4 days. May also occur (less commonly) with I.M. administration; subsiding within 3-7 days.
- Hypersensitivity/anaphylactoid reactions: **[U.S. Boxed Warning]: Deaths associated with parenteral administration following anaphylactic-type reactions have been reported (use only where resuscitation equipment and personnel are available). A test dose should be administered to all patients prior to the first therapeutic dose. Anaphylactic and other hypersensitivity reactions have occurred**

even in patients who tolerated the test dose; observe for anaphylactic reactions during any iron dextran administration. A history of drug allergy (including multiple drug allergies) and/or the concomitant use of an ACE inhibitor may increase the risk of anaphylactic-type reactions. Adverse events (including life-threatening) associated with iron dextran usually occur more with the high-molecular-weight formulation (Dexferrum®), compared to low-molecular-weight (INFeD®) (Chertow, 2006).

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Revision History:

Date Reviewed/No Updates: 1/16/13 by A. Reeves MD
 Date Approved by P&T Committee: 10/23/12; 1/29/13
 Date Reviewed/No Updates: 1/28/14 by C. Sanders MD
 Date Approved by P&T Committee: 1/28/14
 Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
 Date Approved by P&T Committee: 1/27/15
 Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD
 Date Approved by P&T Committee: 1/26/16
 Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD
 Date Approved by P&T Committee: 1/24/17
 Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD
 Date Approved by P&T Committee: 1/23/18
 Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD
 Date Approved by P&T Committee: 1/22/19
 Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD
 Date Approved by P&T Committee: 2/18/20

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
2/18/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual review