VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

INFeD® (iron dextran)

Effective Date: 10/23/12

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

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INFeD® is a Hematinic . The released iron, from the plasma, eventually replenishes the depleted iron stores in the bone marrow where it is incorporated into hemoglobin

Pre-Authorization Criteria:

Iron deficiency in adult and pediatric patients ≥4 months of age with intolerance to oral iron or unsatisfactory response to oral iron after trying at least two different forms (e.g. sulfate, gluconate, fumarate, carbonate)

NOTE: There are various forms of iron for parenteral use, each with individual dosing regimens. The VCHCP formulary is restricted to Infed, Injectafer, Ferrlecit and Ferheme.

NOTE: The Institute for Safe Medication Practices (ISMP) includes this medication among its list of drugs which have a heightened risk of causing significant patient harm when used in error.

Dosing: Adult

NOTE: Maximum cumulative dose is restricted to 1000 mg per 30 days

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

Dose (mL) = 0.0442 (desired Hgb - observed Hgb) x LBW + (0.26 x LBW) Desired

hemoglobin: Usually 14.8 g/dL

LBW = Lean body weight in kg

Iron replacement therapy for blood loss: (INFeD®), I.V. (INFeD®): Replacement iron (mg) = blood loss (mL) x Hct

Maximum daily dosage: 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 I.V.: Test dose: 25 mg slow I.V. slow push, followed 1 hour later by 100 mg over 5 minutes; larger doses 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: Dose

(mL) = 0.0442 (desired Hgb - observed Hgb) x W + (0.26 x 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]

PRECAUTIONS

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)

- **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.. 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.

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