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

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20, 2/2/21, 8/3/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

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.

IV iron replacement is preferred over oral replacement in several clinical situations (e.g., poor GI absorption, lack of response to or poor tolerability of oral iron, need for rapid repletion, chronic kidney disease, active inflammatory bowel disease, cancer, chronic or extensive blood loss).

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: Dose is expressed in mg of elemental iron.

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

> ***Fixed dose (off-label)****:* **IV:** 1 g as a single dose; dilute in 250 mL of NS and administer over 1 hour.

***Calculated dose**): IV:*
Total dose (mL) = (0.0442 × {desired hemoglobin [g/dL] − observed hemoglobin [g/dL]} × IBW [kg]) + (0.26 × IBW [kg])
IBW = Ideal body weight in kg; if actual body weight is less than IBW, use actual body weight.

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)

Cancer-/chemotherapy-associated anemia

***Weekly administration (off-label dosing; INFeD**)):*

Weeks 1 to 3: Test dose of 25 mg (over 1 to 2 minutes), followed by 75 mg (bolus) once weekly.

Weeks 4 and after: 100 mg over 5 minutes once weekly until the calculated dose is reached.

Total dose infusion (off-label dosing; INFeD): Test dose of 25 mg (over 1 to 2 minutes), followed 1 hour later by the balance of the calculated total dose mixed in 500 mL NS and infused at 175 mL/hour (Ref).

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.

- **[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.

REFERENCES

1. Auerbach M, Ballard H, Trout JR, et al, "Intravenous Iron Optimizes the Response to Recombinant Human Erythropoietin in Cancer Patients With Chemotherapy-Associated Anemia: A Multicenter, Open-Label, Randomized Trial," J Clin Oncol, 2004, 22(7):1301-7. [PubMed 15051778]

2. Auerbach M, Witt D, and Toler W, "Clinical Use of the Total Dose Intravenous Infusion of Iron Dextran," J Lab Clin Med, 1988, 111(5):566- 70. [PubMed 3361236]

3. Benito RP and Guerrero TC, "Response to a Single Intravenous Dose Versus Multiple Intramuscular Administration of Iron Dextran Complex: A Comparative Study," Curr Ther Res Clin Exp, 1973, 15(7):373-82. [PubMed 4198298]

4. Chertow GM, Mason PD, Vaage-Nilsen O, et al, "Update on Adverse Drug Events Associated With Parenteral Iron," Nephrol Dial Transplant, 2006, 21(2):378-82. [PubMed 16286429]

5. Lipschitz DA, "The Anemia of Chronic Disease," J Am Geriatr Soc, 1990, 38(11):1258-64. [PubMed 2123218]

6. National Comprehensive Cancer Network® (NCCN), "Practice Guidelines in Oncology™: Cancer- and Chemotherapy-Induced Anemia Version 2.2010." Available at http://www.nccn.org/professionals/physician_gls/PDF/anemia.pdf

7. National Kidney Foundation, "KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease," Am J Kidney Dis, 2007, 50(3):529-30. Available at http://www.kidney.org/professionals/KDOQI/guidelines_anemiaUP/index.h tm or http://www.kidney.org/professionals/KDOQI

8. Rizzo JD, Somerfield MR, Hagerty LK, et al, "American Society of Hematology/American Society of Clinical Oncology 2007 Clinical Practice Guideline Update on the Use of Epoetin and Darbepoetin," Blood, 2008, 111(1):25-41. [PubMed 17954703]

9. INFeD (iron dextran complex) [prescribing information]. Madison, NJ: Allergan USA Inc; April 2021.

10. Pavord S, Daru J, Prasannan N, Robinson S, Stanworth S, Girling J; BSH Committee. UK guidelines on the management of iron deficiency in pregnancy. Br J Haematol. 2020;188(6):819-830. doi:10.1111/bjh.16221

11. Darwish AM, Khalifa EE, Rashad E, Farghally E. Total dose iron dextran infusion versus oral iron for treating iron deficiency anemia in pregnant women: a randomized controlled trial. J Matern Fetal Neonatal Med. 2019;32(3):398-403.

12. FIGO Working Group on Good Clinical Practice in Maternal-Fetal Medicine. Good clinical practice advice: iron deficiency anemia in pregnancy. Int J Gynaecol Obstet. 2019;144(3):322-324.

13. Gutiérrez O. Treatment of iron deficiency anemia in CKD and end-stage kidney disease. Kidney Int Rep. 2021;6(9):2261-2269.

14. INFeD (iron dextran complex) [prescribing information]. Madison, NJ: Allergan USA Inc; September 2021.

15. Rogozińska E, Daru J, Nicolaides M, et al. Iron preparations for women of reproductive age with iron deficiency anaemia in pregnancy (FRIDA): a systematic review and network meta-analysis. Lancet Haematol. 2021;8(7):e503-e512.

16. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2012 clinical practice guidelines for anemia in chronic kidney disease (2012). https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2012-Anemia-Guideline-English.pdf. Accessed December 11, 2023.

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
Date Reviewed/No Updates: 2/2/21 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/2/21
Date Reviewed/Updated: 8/3/21 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 8/3/21
Date Reviewed/No Updates: 2/1/22 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/1/22
Date Reviewed/No Updates: 1/31/23 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/31/23
Date Reviewed/Updated: 2/18/25 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/18/25

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
2/2/21	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
8/3/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Additions and deletions; added references
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
1/31/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review

2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Added “IV iron replacement is preferred over oral replacement in several clinical situations (e.g., poor GI absorption, lack of response to or poor tolerability of oral iron, need for rapid repletion, chronic kidney disease, active inflammatory disease, cancer, chronic or extensive blood loss).” Dosing section updated.