

Clinical Policy: Deferoxamine (Desferal)

Reference Number: ERX.SPA.91

Effective Date: 11.01.15

Last Review Date: 08.22

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Deferoxamine (Desferal[®]) is an iron-chelating agent.

FDA Approved Indication(s)

Desferal is indicated for the treatment of:

- Acute iron intoxication
 - Desferal is an adjunct to, and not a substitute for, standard measures used in treating acute iron intoxication, which may include the following: induction of emesis with syrup of ipecac; gastric lavage; suction and maintenance of a clear airway; control of shock with intravenous (IV) fluids, blood, oxygen, and vasopressors; and correction of acidosis
- Chronic iron overload due to transfusion-dependent anemias
 - Desferal can promote iron excretion in patients with secondary iron overload from multiple transfusions (as may occur in the treatment of some chronic anemias, including thalassemia). Long-term therapy with Desferal slows accumulation of hepatic iron and retards or eliminates progression of hepatic fibrosis
 - Iron mobilization with Desferal is relatively poor in patients under the age of 3 years with relatively little iron overload. The drug should ordinarily not be given to such patients unless significant iron mobilization (e.g., 1 mg or more of iron per day) can be demonstrated

Limitation(s) of use: Desferal is not indicated for the treatment of primary hemochromatosis, since phlebotomy is the method of choice for removing excess iron in this disorder.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] that Desferal is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Iron Intoxication (must meet all):

1. Diagnosis of acute iron intoxication;
2. If request is for brand Desferal, member must use generic deferoxamine, unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed 6,000 mg in 24 hours (IM or IV).

Approval duration: 1 month

B. Chronic Iron Overload due to Transfusion-Dependent Anemias (must meet all):

1. Diagnosis of chronic iron overload due to transfusion-dependent anemias (e.g., congenital/acquired anemias including thalassemia, sickle cell anemia, aplastic anemia, myelodysplasia);
2. Transfusion history of ≥ 100 mL/kg of packed red blood cells (e.g., ≥ 20 units of packed red blood cells for a 40 kg person) and a serum ferritin level $> 1,000$ mcg/L;

3. If request is for brand Desferal, member must use generic deferoxamine, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed any of the following (a, b, or c):
 - a. SC: 2,000 mg per day;
 - b. IV: 40 mg/kg per day for children; 60 mg/kg per day for adults;
 - c. IM: 1,000 mg per day.

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Acute Iron Intoxication

1. Re-authorization is not permitted. Members must meet the initial approval criteria for new cases of acute iron intoxication.

Approval duration: Not applicable

B. Chronic Iron Overload due to Transfusion-Dependent Anemias (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Current documentation (within the past 30 days) shows a serum ferritin level ≥ 500 mcg/L;
3. If request is for brand Desferal, member must use generic deferoxamine, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed any of the following (a, b, or c):
 - a. SC: 2,000 mg per day;
 - b. IV: 40 mg/kg per day for children; 60 mg/kg per day for adults;
 - c. IM: 1,000 mg per day.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;

- B.** Primary hemochromatosis.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Known hypersensitivity to the active substance
 - Severe renal disease or anuria, since the drug and the iron chelate are excreted primarily by the kidney

- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acute iron intoxication	1,000 mg x 1 dose, then 500 mg Q4 hr x 2 doses PRN, then 500 mg Q4-12 hr PRN* <i>*IM route if patient not in shock; IV infusion limited to patients in cardiovascular collapse.</i>	6,000 mg/24 hr
Chronic iron overload	1,000-2,000 mg SC QD (20-40 mg/kg/day) over 8-24 hours	See dosing regimen
	20-40 mg/kg IV daily (children*) and 40-50 mg/kg IV daily (adults) for 5-7 days per week <i>*Average dose should not exceed 40 mg/kg/day until growth has ceased.</i>	40 mg/kg/day (children) 60 mg/kg/day (adults)
	500-1,000 mg IM/day	1,000 mg/day

VI. Product Availability

Vial of lyophilized deferoxamine mesylate: 500 mg

VII. References

1. Desferal Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2021 Available at: <https://dailymed.nlm.nih.gov/dailymed/>. Accessed May 5, 2022.
2. Musallam KM, Angastiniotis M, Eleftheriou A, Porter JB. Cross-talk between available guidelines for the management of patients with beta-thalassemia major. Acta Haematol. 2013; 130: 64-73. DOI: 10.1159/000345734.
3. Hoffbrand AV, Taher A, Cappellini MD. How I treat transfusional iron overload. Blood. November 1, 2012; 120(18): 3657-3669.
4. Cappellini MD, Farmakis D, Porter J, et al. 2021 Guidelines for the management of transfusion dependent thalassemia (TDT) 4th edition. Thalassaemia International Federation. 2021. Available at: <https://thalassaemia.org.cy/publications/tif-publications/guidelines-for-the-management-of-transfusion-dependent-thalassaemia-4th-edition-2021/>. Accessed May 4, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: no significant changes; age removed from chronic iron overload criteria as can be used in patients younger than 3 in some cases; approval durations extended to 6 and 12 months for chronic iron overload; two gram vial removed; references reviewed and updated.	04.30.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.14.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	05.08.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	05.16.21	08.21
3Q 2022 annual review: no significant changes; added criterion that member must use generic deferoxamine; references reviewed and updated.	05.08.22	08.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of

physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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