

## Clinical Policy: Deferoxamine (Desferal)

Reference Number: LA.PHAR.146

Effective Date:

Last Review Date: 08.22

Line of Business: Medicaid

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### 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

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

It is the policy of Louisiana Healthcare Connections 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**

1. Diagnosis of chronic iron overload due to transfusion-dependent anemia (e.g., congenital/acquired anemias including thalassemia, sickle cell anemia, aplastic anemia, myelodysplasia);
2. Transfusion history of  $\geq 100$  mL/kg of packed red blood cells (e.g.,  $\geq 20$  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 the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Acute Iron Intoxication**

1. Re-authorization is not permitted. Members must meet 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 Louisiana Healthcare Connections benefit or member has previously met all initial approval criteria;
2. Current documentation (within the last 30 days) shows a serum ferritin level  $\geq 500$  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 Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.  
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

**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 policies – LA.PMN.53 for Medicaid, 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**

<u>Indication</u>	<u>Dosing Regimen</u>	<u>Maximum Dose</u>
<u>Acute iron intoxication</u>	<u>1000 mg x 1 dose, then 500 mg Q4 hr x 2 doses PRN, then 500 mg Q4-12 hr PRN*</u>  <u>*IM route if patient not in shock; IV infusion limited to patients in cardiovascular collapse.</u>	<u>6,000 mg/24 hr</u>
<u>Chronic iron overload</u>	<u>1000-2000 mg SC QD (20-40 mg/kg/day) over 8-24 hours.</u>	<u>See dosing regimen.</u>
	<u>20-40 mg/kg IV daily (children*) and 40-50 mg/kg IV daily (adults) for 5-7 days per week</u>  <u>*Average dose should not exceed 40 mg/kg/day until growth has ceased.</u>	<u>40 mg/kg/day (children)</u> <u>60 mg/kg/day (adults)</u>
	<u>500-1,000 mg IM/day</u>	<u>1,000 mg/day</u>

**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) 4<sup>th</sup> 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.

### Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<u>HCPCS Codes</u>	<u>Description</u>
J0895	<u>Injection, deferoxamine mesylate, 500 mg</u>

<u>Reviews, Revisions, and Approvals</u>	<u>Date</u>	<u>LDH Approval Date</u>
<u>Converted corporate to local policy.</u>	<u>09.22</u>	

### 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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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